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Introduction to Quality 4.0

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Quality 4.0

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Introduction

Quality 4.0 involves leveraging Industry 4.0 advancements like the Internet of Things, artificial intelligence, and big data to enhance the quality of products and services. This encompasses employing sensors and data analysis to oversee production processes in real time, detect flaws, and enhance effectiveness. The objective of Quality 4.0 is to attain elevated standards of product excellence, customer contentment, and operational efficiency by harnessing sophisticated technologies.

Quality 4.0 can be applied across diverse sectors such as manufacturing, public administration, healthcare, and service industries. In manufacturing, for instance, Quality 4.0 solutions enable real-time monitoring of production processes, defect detection, and efficiency enhancement. This entails utilising sensors, IoT devices, and data analytics to monitor production data and pinpoint areas ripe for improvement. In service sectors, Quality 4.0 technologies are instrumental in monitoring and augmenting customer satisfaction. This involves utilising data analytics to track customer feedback and ascertain areas in need of improvement.

There are several compelling reasons why teaching Quality 4.0 is crucial: burgeoning demand in industries, competitive advantage on the market, implementation of continuous improvement culture, and preparation for the changes caused by advanced technologies. Educators who impart knowledge on Quality 4.0 equip students with the requisite skills for careers in these sectors, aligning them with industry demands. By instilling an understanding of Quality 4.0, teachers can empower students to contribute towards their future employers' competitive advantage through adept utilisation of these technologies and practices. Quality 4.0 fosters a culture of perpetual enhancement, elevating product quality and customer satisfaction while streamlining operations. Higher education institutions play a pivotal role in motivating students to catalyse change and facilitate organisational improvement through adept utilisation of Quality 4.0 methodologies. Proficiency in Quality 4.0 augments career progression prospects for students. It enhances their productivity, efficiency, and value to prospective employers, thus positioning them for career advancement in their respective fields. Learning Quality 4.0 prepares students for the evolving work landscape characterised by advanced technologies. Equipping them with these skills ensures they are adept at navigating the dynamic job market, thereby enhancing their employability and prospects for success in an ever-evolving professional sphere.

Therefore, the aim of this book is to introduce the issues of Quality 4.0 to both academic teachers and students. The book was designed to complement the rich literature in the field of quality management. It can be used as an additional guide or textbook for students. The book consists of four chapters.

The first chapter, *Introduction to quality management*, discusses the essence of the fourth industrial revolution, which has become an important turning point for modern enterprises and, consequently, also for quality management. Against this background, the development, evolution of approaches to quality, as well as contemporary expectations towards this field of management are presented.

The second chapter, the *Quality 4.0 concept*, delved into the concept of Quality 4.0. The main concepts, principles and dimensions of this modern approach to quality management are presented. The role of humans in relation to cyber-physical systems are discussed. There is also

Quality 4.0 put into context with the well-known and popular quality management system standards of the ISO 9000 series.

The third chapter, *Implementation of quality management 4.0 in the organisation*, is devoted to the problems of implementing complex changes in modern enterprises. Implementing Quality 4.0 is part of a broader strategy for the digital transformation of enterprises. This is a long-term and complex project that must be properly planned and implemented. Therefore, the chapter discusses the economic profitability of implementing Quality 4.0, the importance of organisational culture and selected aspects of organisational change management.

The fourth chapter, *Quality 4.0 methods and tools*, presents an overview of the methods, techniques and tools that are used in Quality 4.0. Both well-known quality management methods and tools that find their application in new conditions, as well as new tools and techniques were presented.

The authors hope that the book will find application both in the academic community and among practitioners. In this way, it will contribute to increasing the level of competences in the field of quality management.

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- Technical University of Kosice, Slovakia,
- Tomas Bata University in Zlín, Czechia,
- Technical University of Ostrava, Czechia,
- Wroclaw University of Economics and Business, Poland.

More information about the project is available on the project website: https://quality40.uek.krakow.pl.

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Chapter 1. Introduction to quality management

1.1. Fourth industrial revolution

(1) The industrial revolutions

Technological advances have a significant impact on the approaches used to produce products and provide services. Radical advances have been made in the last few centuries. A significant milestone in the development of industrial technology was the discovery of the steam engine, which subsequently led to the mass use of new energy sources, particularly coal. This is why steam and the steam engine are traditional symbols of the so-called 1st industrial revolution. In the following years up to the present day, the whole world then went through three more major industrial revolutions (Figure 1.1).

1st industrial revolution. The first industrial revolution began in the 18th century through the use of steam power and the mechanisation of production. This has led to a fundamental transformation of agriculture, industrial production, raw material extraction, and transport. The key term of this period is industrialisation. The use of steam enabled the transition from manual to machine production. As a result, work productivity and efficiency increased, which contributed to a reduction in product prices, mainly due to lower labour costs. For example, rather than employing people to power weaving looms, steam engines were used to provide power for the machines. Other machines invented during this period include the water wheel and more complex spinning wheels (Shutt, 2021).

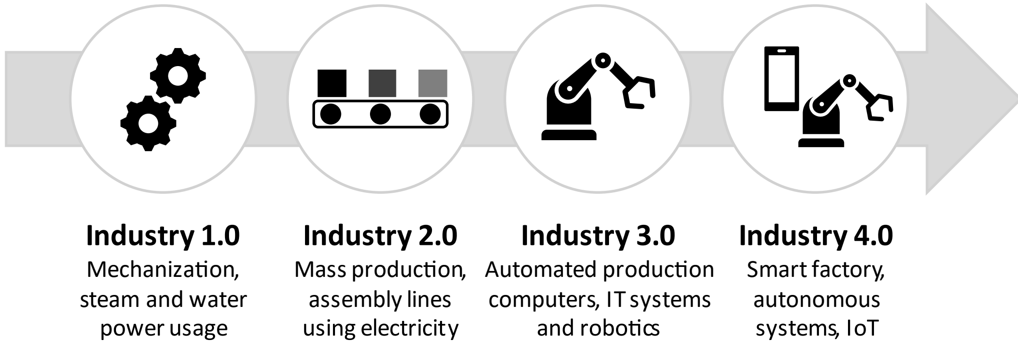

Figure 1.1. Four industrial revolutions

Source: based on (Meloeny, 2022).

2nd industrial revolution. The second industrial revolution began in the 19th century with the discovery of electricity and assembly-line manufacturing. The use of electricity enabled many industries to introduce modern production lines and to implement mass production. One of the earliest examples of the principle of mass production was the slaughterhouse. Pigs were hung on conveyor belts, and butchers performed only part of the work. Inspired by this principle, H. Ford started the first assembly line in 1913 in Detroit's car factory. The vehicles were then produced one step at a time on a conveyor belt. Until then, one car was assembled completely at one station.

3rd industrial revolution. The third industrial revolution began in the 20th century and is most often associated with automation, electronics and the rise of information technology. It began around 1970 when computers and memory-programmable controls began to be used for automation. It is the transition from mechanical and analogue electronic technology to digital electronics. Thanks to these technologies, an entire production process can be automated without human assistance. Examples are robots that perform programmed sequences without human intervention (Soldatov et al., 2022).

4th industrial revolution. Currently, we are on the threshold of the 4th industrial revolution, which is often called Industry 4.0. It builds on the developments of the 3rd industrial revolution as the next step to production automation and is characterised by the application of advanced information and communication technologies in the industrial environment. Production systems with computer technology are expanded by a network connection and have a digital twin on the Internet. The networking of the systems leads to cyber-physical production systems that allow building smart factories where production systems, components, products, and people communicate via a network and production is nearly autonomous. It increases production efficiency, reduces costs and saves resources (Castagnoli et al., 2022).

(2) Industry 4.0

The term Industry 4.0 (I4.0) was used for the first time in 2011 at the Hannover Fair in Germany in relation to the initiative to enhance German competitiveness in the manufacturing industry. It has ignited a vision of a new industrial revolution. Since then, it has spread and many similar initiatives in other countries have been developed and several definitions of Industry 4.0 have been presented in academic and non-academic sources.

The Final report of the Industrie 4.0 Working Group, *Recommendations for implementing the strategic initiative Industrie 4.0*, defines the essence of Industry 4.0 as: "technical integration of cyber-physical systems (CPS) into manufacturing and logistics and the use of the Internet of things and services (IoT) in industrial processes" (Kagermann et al., 2013).

Some other definitions explain CPS in more detail at three levels as: physical objects, data models of physical objects in a network infrastructure, and services based on available data (Drath & Horch, 2014). According to Javaid et al. (2021), I4.0 is the integration of complex physical devices and machines with networked sensors and software that aims to predict, control, and plan for better business. CPS and the IoT most often appear in definitions as the key elements that enable the creation of interconnected, intelligent production systems, enabling self-regulation and self-optimization. They contribute to the transition from centralised production towards flexible and self-controlled. A smart factory is a concept defining the future state of a fully connected manufacturing system, mainly operating without human force using a constant stream of data from connected operations and production systems to learn and adapt to new demands. Other related technological enablers of Industry 4.0 and smart factories are big data (BD), cloud computing (CC), artificial intelligence (AI), virtual and augmented reality (VR, AR), advanced robotics, additive manufacturing, cybersecurity (Benotsmane et al., 2019). The above-mentioned technologies are interdependent; for example, many of the analytical capabilities implied by CPS and the IoT are provided by data processing technologies, often offered as service applications delivered through cloud computing, advanced robotics leveraging artificial intelligence, and others.

Besides the technological elements of Industry 4.0, there are definitions highlighting the influence of technologies on the structure of the organisation, cooperation with partners and managing the entire value chain, e.g., I4.0 is the new model of value chain management throughout the product lifecycle, and a collective term for technologies and concepts of value chain organisation (Saucedo-Martínez et al., 2018). The definitions usually outline some or all the three features of Industry 4.0 (Kagermann et al., 2013; Stock & Seliger, 2016):

- horizontal integration across the entire value creation network,
- vertical integration and networked manufacturing systems,
- end-to-end engineering across the entire product life cycle.

Horizontal integration refers to the integration of IT systems, processes, resources, and information flows between the organisation and interested parties (e.g., suppliers, business partners, customers), while vertical integration concerns the integration of these elements through the departments and hierarchical levels of an organisation. These two types of integration aim to deliver an end-to-end solution across the entire value chain.

Industry 4.0 represents the further developmental stage in the management of the entire value chain in the manufacturing industry (Deloitte, 2015). The above-mentioned features enable flexible and dynamic management of complex systems and enable all players in the value chain to be digitally connected, achieving mass customisation and demand-driven supply chain services. Industry 4.0 represents a fundamental paradigm shift towards individualised production that will enable new business models and online services. The development of new business models is driven by customer needs and mass customisation requirements and enabled by innovative technologies.

According to Nosalska et al. (2019), the most frequent terms accompanying Industry 4.0 are value chain, CPS, IoT, smart factory, intelligent technologies including AI, BD and CC, business models, customisation, and smart product.

Among the main principles for the development and deployment of Industry 4.0, the following appear the most frequently (Pereira & Romero, 2017):

- interoperability – communication and data exchange between objects, machines, people,
- virtualisation – a digital reflection of the physical environment,
- decentralisation – CPS with decision-making capabilities,

- real-time capability – real-time data allowing immediate decisions,
- service orientation – product extension with services,
- modularity – dynamic configuration of the various elements of business processes.

Industry 4.0 involves a broad set of technological and business aspects. These are interdependent, and their impact on organisations should be regarded as the influence of a set of intertwined factors. Creating a concise definition that includes all of the Industry 4.0 organisational capabilities and relevant aspects remains difficult as the concept includes a wide range of issues.

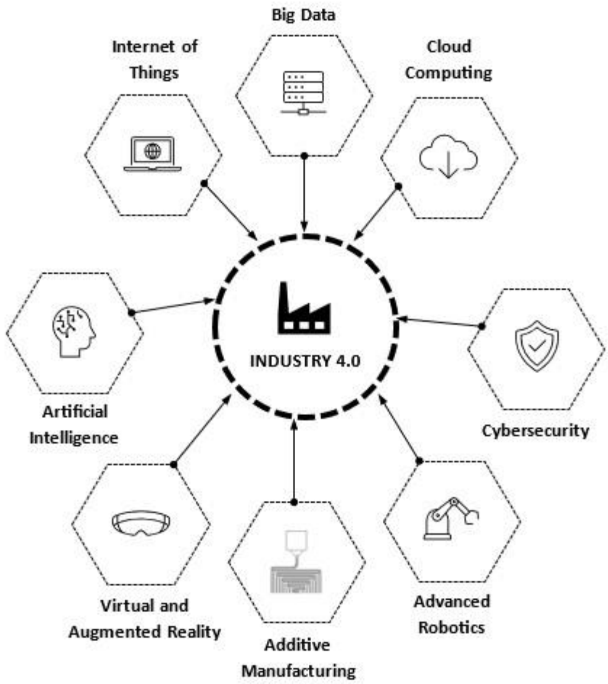

Figure 1.2. Industry 4.0 technologies

Source: own elaboration.

(3) Key elements of Industry 4.0

Based on the given definitions, it can be stated that Industry 4.0 is based on the use of modern, disruptive technologies. These technologies enable the interconnection of the physical and digital worlds, thus enabling the emergence of intelligent autonomous systems. These systems can be covered by another concept that is linked to Industry 4.0, the smart factory. The most important technologies used in Industry 4.0 and smart factories in general include

(Figure 1.2) the Internet of Things, big data, cloud computing, artificial intelligence, virtual and augmented reality, advanced robotics, additive manufacturing, and cybersecurity.

Internet of Things (IoT). The idea of this technology is the ability of electronic devices (computers and smart devices) to communicate with each other and exchange data without human assistance. A prerequisite is that these devices are connected to the Internet. Internet-connected production equipment, machines and products are equipped with sensors that provide relevant data in real-time. This makes it possible, for example, to monitor performance, track energy consumption, identify potential problems, regulate production processes, carry out preventive maintenance and more.

Big Data (BD). An essential prerequisite for implementing fast and correct autonomous decisions in smart factories is the acquisition of relevant data and its analysis in real-time. For this purpose, a large volume of data, denoted by the term big data, is required. The essence of big data is associated with three factors referred to as the “3Vs”: volume, variety and velocity.

Volume. The quantity of data matters. For big data, you need to process large volumes of unstructured, low-density data. Sources from which big data can be obtained include sensor-equipped devices, the Internet, and mobile applications. Advanced tools such as distributed databases, machine learning techniques, big data analysis or artificial intelligence are often used to process and analyse big data.

Variety. Big data consists of different types of data. This data can be unstructured, semi-structured or structured. Unstructured and semi-structured data types such as text, audio and video require additional preprocessing to derive meaning.

Velocity. Big data is generated and changes very quickly. Data can come into the system in real-time, which requires fast processing and analysis of the data in order to react quickly.

Cloud Computing (CC) is the sharing of hardware and software resources over an Internet network. Cloud computing converts all resources into a service, not only infrastructure (servers, storage, backup, firewalls), development and application platform (operating system, database server).

Artificial Intelligence (AI) is critical to digital transformation, which is one of the fundamental aspects of Industry 4.0. Artificial intelligence is the ability of machines to simulate human capabilities such as thinking, creativity and planning. Major advances in computing and new algorithms make it possible to process large amounts of data in a short time. Artificial intelligence is able to work autonomously and can adapt its actions based on previous actions. As a result, technical systems are able to perceive impulses from their environment, react appropriately, solve problems and achieve specific goals.

Virtual and Augmented Reality (VR, AR). Virtual reality is a technology that creates a completely new virtual world in which users can completely immerse themselves using special devices such as VR goggles or helmets. Augmented reality is a technology that combines the real world with digital content so that digital elements are added to the real world. Augmented reality has a wide range of uses, including mobile apps, goggles, and heads-up displays. The main difference between VR and AR is whether the user remains immersed in the virtual world or whether they still perceive the real world and digital elements are added to it. Virtual reality and augmented reality have great potential in smart factories to improve the efficiency, safety, and productivity of manufacturing processes. For example, virtual reality can be used in product and process design and development. In the virtual reality space, we can create and test prototypes during product design. Augmented reality can be used in logistics and warehousing to track and optimise the movement of goods or in quality control to visualise detailed inspection instructions in the workplace. Both technologies can be used for training and education. Employees can receive training in a virtual environment, which is cost-free and efficient.

Advanced Robotics uses advanced robotic systems that are capable of performing complex tasks, collaborating with humans and achieving a high degree of autonomy. In this context, two terms are worth mentioning: autonomous robots and collaborative robots. Autonomous robots are able to perform tasks and make decisions without human supervision. Collaborative robots are designed to work safely with humans in a work environment.

Additive Manufacturing is associated with industrial 3D printing, where three-dimensional objects are created based on digital data. It is an advanced manufacturing process that allows products to be created by sequentially adding thin layers of materials. This type of manufacturing is an alternative to traditional manufacturing methods that operate on material removal processes, e.g., turning, machining, and drilling.

Cybersecurity is key to the functioning of Industry 4.0. Cybersecurity encompasses the activities necessary to protect networks and information systems, users of these systems and others affected by cyberattacks and threats.

Information security must be maintained when using technologies related to Industry 4.0. Unauthorised access to data, misuse of data and information, disruption of IT systems or damage to information must be prevented.

The above-mentioned technologies are interrelated and represent a complex ecosystem whose elements (sub-technologies) work closely together.

(4) Challenges and barriers of the fourth industrial revolution

Industry 4.0 creates a whole range of opportunities for organisations. However, there are also some barriers associated with the gradual digital transformation, which need to be understood as challenges. Hecklau et al. (2016) and Ling et al. (2020) divided these challenges into several areas: economic, social, technical, environmental, political and legislative challenges. The most significant challenges and associated barriers include:

- a lack of will to break down existing stereotypes,
- high investment costs and uncertainties of return,
- the time required to adapt to Industry 4.0,
- a lack of standards, guidelines and procedures for digital transformation,
- shortage of skilled workers, especially in IT technologies,
- ensuring cyber security,
- outdated equipment and infrastructure.

Already in the initial stages of considering joining the Industry 4.0 concept, the organisation will have to deal with people's deep-rooted resistance to change. Top management must understand and accept the necessity of change and prepare for digital transformation processes.

Another challenge is related to the economic side of the adoption of Industry 4.0. Uncertainty about the costs and benefits leads to the fact that management hesitates to take a step towards Industry 4.0. Digital transformation is associated with relatively high investment costs (investment in machine components, IT infrastructure, IT personnel and technical training), and it may seem that these costs may be higher than the expected growth of the organisation. This can lead to financial problems. There is a need to evaluate all financial models and aspects of the investment from start to finish to ensure a return on investment. It is also necessary to understand that the investments made will not provide an immediate benefit, and the return on investment may be of a longer-term nature.

The time factor is another consideration. The transition to Industry 4.0 is a demanding project with regard to time. It is expected that the time required for the complete transformation could be up to 20 years. Building, implementing and optimising the operation of systems related to Industry 4.0 can take ten years. Subsequently, it is also necessary to count on a relatively long period for the development of the benefits of the implementation of Industry 4.0.

Currently, it is not easy to adapt to Industry 4.0 because there is a lack of clear standards, guidelines and procedures for the digital transformation related to Industry 4.0. Therefore, one of the tasks is to define the exact concepts, standards and requirements of Industry 4.0.

Another challenge is the development of human resources. The implementation of Industry 4.0 in organisations will require qualified workers at various organisational levels. In the future, low-skilled jobs will be taken over by autonomous machines, and the workers will have to acquire new skills related to the operation of smart machines. The role of the worker will change; therefore, management should emphasise interdisciplinary education in the fields of economics, engineering, informatics and mathematics. Organisations will need highly skilled workers to operate advanced production tools and systems and to be able to analyse data from machines, consumers, and global sources. There will be a special demand for workers in the field of software development and IT technologies.

Another problem may arise in connection with the need for qualified labour. This is due to the lack of training providers who would be able to provide training programs in the field of Industry 4.0.

Due to the expected use of large volumes of data, its location on clouds and sharing via the Internet, data security and privacy are two main concerns for most manufacturers. There is a need to ensure cyber security. In order to protect data, Industry 4.0 will place high demands on security architecture and security by design. An intelligent manufacturing system should have the following features: automatic detection of malware, threats and zero-installation attacks.

Many companies still have traditional processes and systems that are difficult to digitise. Outdated equipment and infrastructure are used to implement these traditional processes. This may hamper the transition to Industry 4.0. The required transformation and modernisation can be financially demanding.

The challenge for many companies and industries is to find ways to overcome barriers and gradually implement Industry 4.0 technologies. Indeed, Industry 4.0 brings a number of benefits, including increased efficiency, competitiveness and innovation, and this can ensure that organisations apply themselves in today's challenging market environment and achieve lasting success.

(5) Industry 5.0?

The term Industry 5.0 was defined by the European Commission: "Industry 5.0 complements the existing Industry 4.0 paradigm by highlighting research and innovation as drivers for a transition to a sustainable, human-centric and resilient European industry. It moves focus from shareholder to stakeholder value, with benefits for all concerned. Industry 5.0 attempts to capture the value of new technologies, providing prosperity beyond jobs and growth, while respecting planetary boundaries, and placing the wellbeing of the industry worker at the centre of the production process" (Ivanov, 2023).

Industry 5.0 is not the next industrial revolution. It is an extension of Industry 4.0, emphasising the role of humans and their ability to interact with Industry 4.0-related technologies. The concept aims to achieve greater efficiency and flexibility and focuses on sustainability. It seeks to place human creativity and well-being at the heart of industry – combining the speed and efficiency of machine technologies with the ingenuity and talent of their human counterparts. All the pillars of Industry 4.0 are linked to Industry 5.0. The key elements of Industry 5.0 include:

- humans and robots cooperation,
- personalisation,
- sustainability,
- digitalisation and decentralisation,
- advanced cybersecurity.

Industry 5.0 emphasises the collaboration of humans and robots to achieve optimal results. Robots and machines are designed to be able to interact with humans in real-time. Another key element is personalisation. This is particularly represented by custom manufacturing, which is becoming increasingly common. Thanks to technologies such as 3D printing, products can be made to individual requirements. As in other areas of human activity, Industry 5.0 emphasises sustainability and reducing environmental impact. An important part of this concept is more efficient production and the use of renewable resources. Similar to Industry 4.0, Industry 5.0 is inherently linked to digital technologies while at the same time reducing centralised production processes in favour of distributed production. Cybersecurity is related to digitalisation. As industrial systems become more interconnected, cybersecurity is an increasingly important area to address.

1.2. Selected trends of changes in organisation management

Management approaches constantly evolve in line with the dynamic and turbulent environment of business and new technologies. Organisations that are able to respond quickly and flexibly to new trends have a better chance of remaining competitive in an ever-changing business environment. Organisations are required to make their processes more efficient and competitive, with an emphasis on greater speed. This is why many organisations are adopting an agile approach to managing their operations and processes. That approach focuses specifically on flexibility, collaboration and the ability to respond quickly to change. The agile approach emphasises communication and collaboration within the team and between stakeholders, e.g., customers and developers. Frequent contact and good communication are the key elements. This approach also places great emphasis on customer satisfaction. Development is quality-oriented or focused on user needs and on delivering functional parts of the product in short time intervals (Holbeche, 2018). This cannot be achieved without human potential. Companies become increasingly aware of the importance of investing in the development of their employees. Providing training and skill improvement opportunities can lead to higher employee satisfaction and better performance. This, in turn, leads to greater flexibility and better fulfilment of all stakeholders' requirements and, consequently, the success of the company.

Traditional hierarchies can be replaced by more flexible organisational structures that allow for a faster response to change and encourage innovation. Innovation is the ability to bring new ideas, processes, products or services, which can provide a competitive advantage and enable sustainable growth. Innovation can be a driving force for organisational growth and development. New products or services can expand market share and bring new opportunities. Innovation does not have to be about new products but also about improvements in processes and ways of working. Innovations in efficiency and productivity can bring significant cost savings and improve the overall performance of an organisation. At the same time, an organisation needs to pay attention to its environmental performance. There is a growing emphasis on sustainability and corporate social responsibility. Organisations are striving to reduce their environmental footprint and engage in initiatives to promote sustainable development.

It is clear that changing trends in the management of organisations are inherently linked to technology and its development. Technological advances affect the way organisations communicate, automate processes, collect and analyse data, and, ultimately, how they operate efficiently and agilely. Currently, in the context of Industry 4.0, we can talk about technologies related to digital transformation. Digitalisation and technological innovation have a huge impact on the management of organisations and the quality of work. These technologies are discussed in later chapters of this publication. Based on the study of a number of literature sources, technological trends that are repeatedly mentioned in the literature and significantly influence quality management were identified and selected. These trends, which are briefly described below, include:

- growing storage capacity,
- quick access to data,
- faster calculations,
- fast data transmission,
- compression of transfer data,
- network access everywhere,
- quantum computers.

Growing storage capacity is a pivotal asset for companies navigating the complexities of the Industry 4.0 era. With an expansive storage infrastructure, organisations can effectively capture, retain, and analyse vast volumes of data generated from diverse sources such as IoT devices, sensors, and customer interactions. This wealth of data serves as a treasure trove of insights, enabling businesses to derive actionable intelligence and make informed decisions. For instance, in the realm of big data analytics, companies can delve deep into their data reservoirs to uncover trends, patterns, and correlations that drive operational efficiency and strategic planning. Moreover, the ability to store extensive customer data empowers businesses to personalise marketing efforts, tailor product offerings, and enhance customer satisfaction. Additionally, the availability of historical data facilitates predictive maintenance models, enabling companies to predict equipment failures, optimise maintenance schedules, and minimise downtime. Ultimately, growing storage capacity not only enhances data-driven decision-making but also fuels innovation, fosters agility, and strengthens competitiveness.

Fast access to relevant data is a key factor for organisations and their ability to meet customer requirements or achieve the required quality. Quick access to data can significantly impact an organisation's ability to respond flexibly to change, make effective decisions and maintain high levels of quality. Data is a prerequisite for continuous monitoring of the quality of products and services achieved. With quick access to relevant data, organisations can respond immediately to deviations from requirements and take corrective action. It is essential to monitor and evaluate the progress of processes to deliver quality products and services in real-time. This enables process improvement through immediate intervention in processes and also a rapid response to risk factors that could affect quality. The need for fast access to data also raises the need for faster, computation-based processing. Fast calculations can enable rapid data analysis, which is key to identifying patterns, trends and outliers. This can support better monitoring and subsequent quality improvement decisions based on detected undesirable situations. Speed in providing processed data can be key for predictive analysis that can anticipate future events or behaviours. In the context of quality, predictive analytics can prevent potential problems or improve processes. It is also important that information is exchanged quickly and instantaneously between relevant people inside the organisation (departments and staff) and outside the organisation (the customer and possibly other stakeholders), which requires fast transmission of the data obtained, supported by the use of modern technology. The speed of data transfer is influenced by its quantity. Logically, more time is needed to transfer larger amounts of data. Data compression (reduction of the volume of data transmitted) is then important and can have a significant impact on the speed, cost-effectiveness and overall efficiency of communication networks. Compression allows a reduced volume of data to be transmitted while the same amount of information is transmitted.

Access to networks everywhere, which includes wide availability and reliability of network connectivity in different locations, is an important factor for quality in many areas of life and business. There is a need for access to information at any time and from anywhere. Lack of network access can limit options, reduce efficiency and affect overall quality. This affects the quality of decision-making and the ability to respond quickly to current events. Let's give one example related to the growing trend of teleworking. Reliable network access is key to effective collaboration and communication between teams, regardless of where individual team members are located. Lack of network access can limit options, reduce efficiency and impact overall quality.

The use of quantum computing can potentially affect the quality of products achieved in various industries and fields. Quantum computers have unique properties that can offer advantages in certain situations. These computers are capable of performing optimisations and simulations more efficiently. This can bring improvements in product design and development by enabling faster and more efficient solutions to complex optimisation problems that occur in industrial design, materials research, and the development of new chemical compounds. Quantum computers have the potential to process and analyse vast amounts of data much faster than traditional computers. This can contribute to better data analysis and the generation of deeper insights, which is important for innovation and improving product quality.

1.3. Evolution of approaches to quality management

(1) Historical context

The quality of products was important for manufacturers and customers long before the industrial revolutions. The presented evolution of approaches to quality is a valuable insight into understanding modern quality management solutions.

The term *quality* resonates in all areas of our lives today. However, it is not a new term; on the contrary, it has been with mankind for millennia. People have always wondered whether the products they buy will satisfy their requirements. One of the first or even the very first, uses of the term quality is attributed to the Greek philosopher Aristotle (322 BC). Aristotle discussed various categories of things in his writings, and quality was one of these categories. According to this Greek philosopher, quality answers the question of how one thing differs from another. This philosophical perspective had limited practical usability. Over the years, efforts have been made to systematically examine the properties of things and to accurately describe their quality.

The first documented historical context relating to quality assurance or quality control is even older than the first mention of the term "quality". From the surviving historical sources, we can see that the first approaches to quality can be traced back to antiquity. Already in ancient Babylonia, around 1686BC, legal requirements with regard to quality control appeared in the code of the Babylonian king Hammurabi (Hellman & Liu, 2013). In this code, approximately the following is stipulated: “If a builder built a house for someone and did not do his work solidly and the wall falls down, that builder shall build the wall solidly with his own resources. If the building falls to pieces and the owner is killed because of it, the builder must be killed, and if one of the owner’s children is killed, one of the builder’s children will be killed.” Here, we can see the first efforts to create legislation on quality assurance and product liability. Other early approaches to quality control can be identified in ancient Egyptian culture. Scholars argue that the building of the pyramids could not have been done without a system for quality assurance and control that used professionally made instruments and measurements. The development of quality control at this time was made possible by the invention of measurements such as time, length and degree. The accuracy of measuring length and degree angle was very high in ancient Egypt. Standardisation was also widely used in the Roman Empire. For example, there were nearly 100 standards for road construction, and state quality controllers were used to take over the work using specific methods and tools (Karlovitz, 2020).

In the Middle Ages, the quality of products was monitored by various regulations of the craftsmen’s guilds. Guilds were craft associations that defended the rights and interests of their members, supervised the quality and prices of products, the education of apprentices and the passing of master examinations. For example, the guilds of shoemakers, millers, bakers and gingerbread makers, masons and stonemasons, tailors and weavers, wheelwrights and coopers, brickmakers, stonemasons and potters, and lacquerers and ranchers. In addition to the rules enforced by the individual craft guilds and, later, by the manufactories, the state began to intervene in the field of quality. The main reason for this was initially to promote the development of production and trade, but later on, the protectionist reasons became more pronounced.

The further development of approaches to quality management is related to the industrial revolutions and, in particular to the beginnings of the assembly line at the turn of the 19th and 20th centuries. During the 20th century, quality management underwent its most intensive development and resulted in the modern form we know today.

(2) The evolution of modern approaches to quality

The most prominent examples of modern approaches to quality management began to appear, especially at the beginning of the 20th century. Manufacturing companies began to focus not only on productivity but also on related production costs. In general, quality management approaches have gone through several developmental phases, from quality inspection (QI), statistical quality control (SQC), quality assurance (QA) and Total Quality Management (TQM) (Figure 1.3). The different phases have been influenced by technological developments and the advent of Industry 4.0. The use of smart technologies, together with advanced quality management practices, has given rise to the new concept of Quality 4.0. This represents a new developmental stage of quality management.

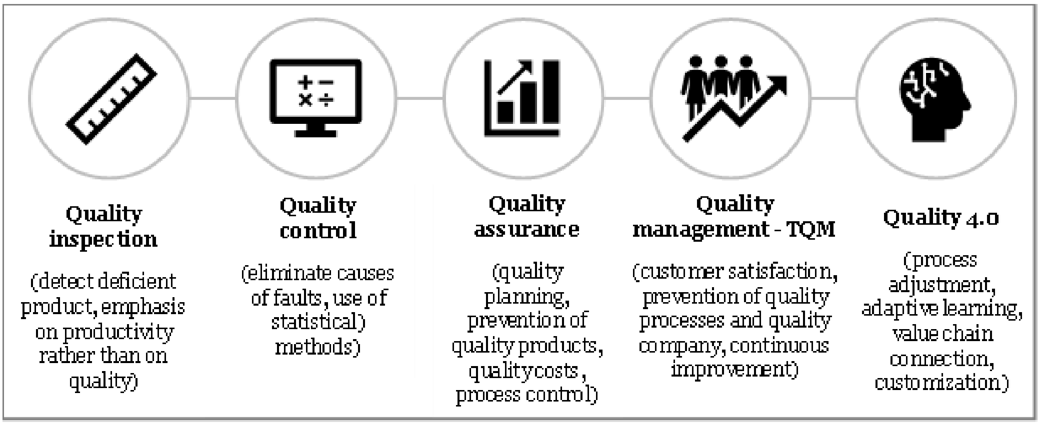

Figure 1.3. Evaluation of approaches to quality

Source: own elaboration.

The older, artisanal quality assurance model was characterised by the manufacturer (e.g., the shoemaker) being in direct contact with the customers, listening to their requirements and then trying to meet them. The advantage was immediate feedback from both the production process and the customer. The disadvantage of this model was low labour productivity. Efforts to increase labour productivity brought about many changes in the industry. One of these was a deeper division of labour and the introduction of the first production lines. The worker was no longer in direct contact with the customer. He performed only certain operations on the product and then passed it on to the next worker. It was necessary to introduce output control, providing evidence that product requirements were achieved. At this stage, referred to as **quality**

inspection, the priority was to detect products that did not conform to customer requirements, and the organisation focused on productivity at the expense of quality (Nenadál et al., 2018).

Over time, the special functions of inspectors were separated from the working professions. These were usually the most experienced (and therefore well-paid) workers, on whose shoulders rested the responsibility for quality. A significant disadvantage of this approach with technical **quality control** was that production and other groups of workers began to feel that quality assurance was not part of their job responsibilities. Gradually, organisations came to realise that they needed to focus not only on detecting defective products during and after production but that it was important to eliminate the causes of these defects and prevent their recurrence. The quantity of products being produced was becoming a problem, and it was not efficient, given the time and cost involved in inspecting every piece produced. In the 1930s, the first statistical methods of quality control were developed by the American statisticians Romig and Shewhart, and the model of production processes with sampling control was created. It was first applied in armaments production. In the civilian sphere, the model became more prominent after the Second World War, particularly in Japan, where, thanks to the work of the American W. Edwards Deming, statistical control methods were used in production processes (Nenadál et al., 2018).

Already in the 1950s, it became increasingly clear that a mere defect-free product was not necessarily a success on the market. Customers also took into account other requirements such as good looks, reliability, good handling, economy, etc. These changes in product requirements were bound to be reflected in manufacturers and suppliers. Gradually, it became established that a quality product or service is a matter for all company departments that quality is decided at the research, development, design or engineering stage. In addition, the Japanese were the first to understand the benefits of quality as an important competitive advantage and to introduce all the useful knowledge concerning **quality assurance** into everyday practice. In addition, the costs associated with providing the required quality became integral at this time, and the purpose of quality management systems was to provide products that met customer requirements while optimising the associated costs. This is then positively reflected in the price of the product (Nenadál et al., 2018).

Japanese companies have thus evolved from regulating production to preventing the possibility of defects by applying statistical methods to the complete management of all activities that affect the ability of products to meet requirements, that is, from identifying customer requirements through design, development, purchasing, production, storage, sales, transportation, installation, and technical assistance and disposal, to feedback by measuring customer satisfaction. This approach has come to be referred to as the **Total Quality Management** (TQM) model. The TQM approach was conceived during the second half of the 20^{th} century, mainly in Japan, then in the USA and Europe. The requirements for systemic quality management were first set out in the AQAP (Allied Quality Assurance Publication) standards used by NATO suppliers. Then NASA joined in, and eventually, these rules proved to be successful in civilian areas as well. In 1980, the ISO Technical Commission ISO/TC 176 was established in the International Organisation for Standardization, and its activities resulted in the drafting of the first standards and, in 1987, the adoption of the ISO 9000 series of standards for quality management defining binding criteria for its evaluation (Nenadál et al., 2018).

Around the turn of the 20^{th} and 21^{st} centuries, it appears that the further development of management led to the fusion of quality management, environmental and health and safety management, energy management, human resource management, etc., into an integrated management model. This ultimately creates a single integrated management system in organisations. It moves from product and service quality to quality and excellence in the whole organisation. In the context of the emerging Industry 4.0 concept, the shift of quality management towards the **Quality 4.0** concept is based on the widespread digitalisation and automation of quality management processes, also using the principle of feedback from customers and other stakeholders.

(3) Modern quality management – definition and meaning

The concept of quality had gradually taken shape during the second half of the 20^{th} century when a number of different definitions were gradually established. The most important modern definitions of quality were proposed by the most prominent researchers and practitioners in this field (Nenadál et al., 2018):

- J.M. Juran – “quality is fitness for use”,
- P.B. Crosby – “quality is conformity to requirements”,
- A.V. Feibenbaum – “quality is what the customer demands in return”.

However, the diversity of opinions on the concept and nature of quality has forced the world to search for a universally acceptable definition of this concept. This can be considered to be the definition from ISO 9000 (ISO 9001, 2015), stating that “quality is the degree of fulfilment of requirements by a set of inherent characteristics of an object.” This definition is somewhat difficult to understand for the vast majority of people. We will therefore try to explain it (Nenadál et al., 2018):

- requirements – all requirements can be related to customers, other stakeholders and various regulations,
- an object is a specific product, material, service, information, process, organisational system, but also a person,
- customer and other stakeholder requirements can always be understood as a realistic combination of needs and expectations,
- the ability to meet the requirements is influenced by certain characteristics (quality characteristics) typical (inherent) to the object or naturally embedded within it.

While high (good) quality is taken for granted today. However, for manufacturers and service providers, poor quality is still a problem. The consequences of poor quality, i.e. the inability to meet requirements, usually are related to (Nenadál et al., 2018):

- deepening dissatisfaction and loss of customers,
- low productivity of individuals and teams,
- decreasing employee morale,
- high costs of various compliance verification activities and necessary corrective actions,
- non-compliance with business commitments, thereby eroding the trust of business partners,
- considerable waste of all kinds,
- high inventory costs,
- unsatisfactory quality of life for everyone.

From a purely economic point of view, these can be literally fatal financial losses, which, according to many experiences from around the world, can lead to the collapse or even bankruptcy of organisations. No wonder then that quality is now considered one of the key factors for the long-term success of all types of organisations, regardless of their type and size. It is, therefore, striking that even today, in the practice of industrial as well as other organisations, we encounter some of the false beliefs attached to the term quality. Here are at least some of them (Nenadál et al., 2018):

- quality and its assurance are very costly – the opposite is true: failure to meet requirements is expensive, and in the chapter on economic analysis in quality management, we will present the necessary arguments,
- quality is what we (i.e. manufacturers and suppliers) consider it to be, not what customers consider it to be – in today's competitive environment, it is the end customers who are the critical arbiters of the existence of all organisations,
- quality can be "checked" by simply separating products that conform to the requirements from those that do not – on the contrary, experience shows that the impact of conformity verification or technical inspection on the ability to meet requirements is very small.

Based on these facts, and especially in view of the negative effects of poor quality, the goal of every organisation should be to achieve good quality. This results in the ability of the organisation to meet customer requirements and influence customer satisfaction. To this end, a systematic and coordinated implementation of all processes and activities that can influence the ability to meet customer requirements is needed. In this context, we are talking about so-called quality management, which according to the ISO 9000 standard is "coordinated activities to direct and control an organisation with regard to quality" (ISO 9001, 2015). The main functions of quality management are, in particular: maximising customer satisfaction and loyalty and supporting continuous improvement activities combined with the pursuit of minimum resource consumption.

(4) Basic principles of modern quality management

Every individual and entire community exists on the basis of certain principles. This is also the case with organisations. Most dictionaries describe the term *principle* as a generally accepted basis for action or management. K. Forsberg states that a principle is "an overarching and fundamental rule or creed for the leadership and management of an organisation, aimed at continuous and long-term performance improvement, taking into account the needs of all stakeholders" (2017). In application to quality management, the principles are the connective tissue of everything that an organisation does in order to reliably meet and exceed the requirements of all stakeholders. Some of these principles are used by ISO concepts, and others are the basis of excellence models. The following list should, therefore, be seen as a kind of intersection of these concepts. The basic principles of advanced quality management include (Nenadál et al., 2018):

1. Delivering value to customers.
2. Leadership.
3. Engaging people.
4. Agility.
5. Process approach.
6. Problem prevention.
7. Continuous improvement and innovation.
8. Evidence-based decision-making.
9. Partnership development.
10. Responsibility for a sustainable future.
11. Learning.

Each of the principles will be briefly characterised for ease of understanding. The description will also include the basic areas of processes and activities that prove necessary for their effective application in the practice of different organisations.

Delivering value to customers. Without customers, organisations cannot exist in the long term. By purchasing products and services, they essentially vote for the existence or non-existence of supplier organisations. Therefore, organisations should consistently deliver maximum value to their customers by anticipating, understanding and meeting their requirements. Experience confirms that long-term successful organisations (Nenadál et al., 2021):

- differentiate between different customer groups,
- systematically study the future needs and expectations of each customer group,
- adapt their strategic and operational objectives to the requirements of their customers,
- systematically communicate the scope and importance of customer requirements to their employees,
- strive to design and innovate their products in such a way as to guarantee the delivery of maximum value to customers,
- flexibly offer and deliver that value to customers,
- continuously and objectively examine customer perception levels through feedback and respond flexibly to the results of this examination,
- develop other forms of dialogue with their customers,
- carry out similar activities with other stakeholders.

Leadership. Sustainable improvement of the performance of organisations is unthinkable without leaders who guarantee the long-term direction of organisations and the best possible results through their behaviour, attitudes and actions. Practice shows that not every manager is also a leader. True leaders in organisations are characterised by (Nenadál et al., 2021):

- articulation, communication and promotion of the organisation's mission, vision and values,
- setting a positive example of integrity, social behaviour and ethics,
- setting the overall strategy and related sub-policies and objectives,
- communication these intentions appropriately to employees and external partners,
- supporting and rewarding employees' activities in achieving their objectives,
- creation of an environment for the generation and exercise of employee creativity,
- active engagement in the processes of improvement, innovation and change,
- continuous development of their own knowledge,
- adaptation of organisational structures to support the achievement of strategic objectives.

Engaging people. Employee engagement and creativity are key to the continued success of organisations. Only competent and well-managed employees are able to fulfil even the most demanding goals and visions. Experience confirms that long-term successful organisations are particularly successful in this respect (Nenadál et al., 2021):

- communicate the role of each employee in achieving strategic objectives,
- define sub-goals for individual employees and teams based on the strategic objectives,
- reallocate authority to their staff primarily based on their skills,
- encourage teamwork, especially in problem-solving, improvement and innovation,
- develop effective motivation programmes,
- measure and monitor the performance of individual employees and teams,
- recognise effort and performance in achieving the organisation's objectives,
- use dialogue as much as possible in communicating with each other,

- ensure employees' right to personal development and rest, even in the era of online connectivity,
- fulfil the principle of equal opportunities,
- systematically survey the opinions and satisfaction levels of their employees,
- support employees in identifying weaknesses in the organisation's activities.

Agility. The current and future success of organisations in challenging markets requires that their management is able to respond flexibly and also effectively to all external and internal opportunities, threats and other stimuli. The following contribute to this principle in practice (Nenadál et al., 2021):

- systematic use of methods and tools to identify external and internal opportunities and threats,
- developing and assessing scenarios of possible future developments in the organisation's environment,
- preparing the organisation's staff and infrastructure for the rapid implementation of change,
- widespread application of approaches to reduce the design and development time of new products, services and technologies,
- systematic reduction of production and service lead times,
- applying the principles of just-in-time strategy for both products and information transfer,
- linking information systems with suppliers and customers,
- change management based on project management and the work of interdisciplinary teams.

Process approach. It is proven that organisations work much more efficiently if they understand and manage what they do as processes. Successful organisations in the long term have at least implemented the following activities in this regard (Nenadál et al., 2021):

- definition of the scope and nature of processes with regard to the fulfilment of their strategic objectives,
- identification and management of the interrelationships and interfaces between the individual processes so that they all eventually form the process framework of the management systems,
- appointing the owners of each process and assign them the necessary responsibilities and authorities,
- identification and management of key processes,

- systematic measurement and monitoring of the performance of individual processes and management systems,
- implementation of process-oriented benchmarking,
- continuous improvement of the performance of their processes based on performance trends and benchmarking results,
- provision of all necessary resources and inputs for the implementation of processes,
- identification of constraints and risks to effective process implementation in a timely manner,
- application of effective feedback from users of the outputs of individual processes.

Problem prevention. In any human activity, as well as in the activities of organisations, it is always much more effective to prevent potential problems than to deal with their consequences. Fulfilling this principle should promote (Nenadál et al., 2021):

- systematic identification of potential external and internal threats, both to the strategic direction of organisations and to the achievement of short-term goals and objectives,
- implementation and application of risk management in all relevant areas of the organisation's activities,
- systematic identification of the organisation's weaknesses and understanding of them as opportunities for improvement and positive change,
- application of methods and tools that can effectively prevent future problems, defects, accidents, and complaints, especially in the design and development stages of products and processes,
- provision of a comprehensive set of information to end-users on the safe and correct use of the products supplied,
- timely preparation of crisis scenarios and plans, as well as the systematic review of their currency.

Continuous improvement and innovation are essential to maintaining and improving the performance of organisations, responding to threats and risks in a timely manner and eliminating existing weaknesses. Evidence shows that truly successful organisations minimally develop these activities (Nenadál et al., 2021):

- identify threats, risks and opportunities for improvement in all appropriate ways,

- decide on priorities for improvement, innovation and change based on the indicators identified,
- pay particular attention to process improvement and innovation because process outputs, i.e. products and services provided, are improved as a consequence,
- support the rapid translation of staff ideas into implemented improvement, innovation and change projects,
- apply appropriate improvement and change methodologies,
- systematically develop their employees' knowledge of these methodologies and of appropriate improvement methods and tools,
- allocate adequate financial, material, informational and human resources to improvement, innovation and change activities,
- monitor and evaluate the effects and impacts of improvements and changes on individual stakeholders, including customers,
- apply innovation not only to their final products but also to their technologies, organisational structures and management methods,
- involve members of senior management in improvement and change processes,
- develop and implement appropriate forms of employee motivation and reward.

Decision-making based on facts. All staff with decision-making powers should require and apply analysed data to the maximum extent possible to make objective decisions. Experience confirms that long-term successful organisations which are particularly successful in this regard (Nenadál et al., 2021):

- determine the appropriate range and structure of indicators, which are then monitored and used for decision-making,
- set target values for these indicators derived from strategic objectives,
- ensure systematic and fair collection of data and evidence from all relevant points through appropriate measurement and monitoring,
- verify the reliability and validity of the data and guarantee its security,
- make the widest possible use of statistical methods to analyse and process data,
- monitor trends in individual indicators and analyse the causes and impacts of these trends,
- ensure staff knowledge of data collection and analysis methods and tools,

- record, communicate and report the results of data analysis in an appropriate manner,
- take into account the competencies relating to decision-making areas when allocating responsibilities,
- require that relevant decisions are justified, explained and recorded,
- support decision-making on further improvement, development, innovation and change.

Partnership development. In order to achieve the best possible performance, organisations should carefully identify their partners and develop mutually beneficial relationships with them. In this regard, organisations with an advanced quality management system are expected to (Nenadál et al., 2021):

- identify current and potential partners, given the strategic direction,
- develop partnership programmes with these partners (especially suppliers), including mutual assistance, sharing of information on experience and good practice,
- explore the needs and expectations of each partner, as well as their views on how they perceive the organisation and its results,
- invite partners to participate in the joint improvement and change projects,
- willing to share not only the potential risks but also the benefits of the relationship,
- evaluate the effectiveness and efficiency of partnership development and, on that basis, eliminate those that are no longer working and, on the contrary, initiate new partnerships.

Responsibility for a sustainable future. Every organisation bears its share of responsibility for the quality of life of the whole society and the development of its environment in the near and distant future. It is, therefore, rightly expected that organisations will (Nenadál et al., 2021):

- articulate the basis for fulfilling this principle in its mission, vision and values,
- develop systems of social responsibility, guaranteeing a mutual balance between economic, environmental and social aspects,
- move from a policy of maximising profits to one of optimising the redistribution of profits for the benefit of society as a whole,
- systematically implement projects to improve the state of the environment and the working environment,

- actively participate in development programmes in the region, the country and abroad,
- focus on corporate philanthropy on supporting projects in the fields of education, healthcare and social services,
- encourage the participation of its employees in these projects,
- monitor the perception of company representatives regarding the organisation's activities and their impact on its surroundings, including the environment,
- rationalise the consumption of natural resources, especially non-renewable ones,
- guarantee the employability of those groups of employees whose potential the organisation will no longer be able to exploit in the future,
- see its participation in various competitions, such as national and international quality awards, social responsibility awards, not as a one-off campaign but as a chance for sustainable development.

Learning. People's knowledge is considered the most valuable asset available to organisations. Therefore, advanced organisations are expected to apply knowledge management and development practices, including, for example (Nenadál et al., 2021):

- defining the level of knowledge as a mix of theoretical knowledge and practical skills for all levels of management, including top management,
- planning and implementing appropriate approaches and methods for developing employee knowledge,
- releasing the necessary resources for the development of individual and team knowledge,
- motivating employees to acquire new knowledge,
- enabling employees to put their knowledge into practice on an ongoing basis,
- developing approaches to identify and then share good and best practices,
- transferring the experience and skills of older employees to new employees,
- supporting staff to identify and become aware of their own mistakes,
- systematic measurement of the effectiveness and efficiency of knowledge development.

Advanced quality management systems require that all of these principles be applied simultaneously and with an awareness of their very close links. These are, for example, quite evident in the principles of people involvement and learning, evidence-based decision-making, and continuous improvement. The synergistic effects of the application of the principles of advanced quality management cannot be expected to appear after only a few months. The efforts made are usually worthwhile only after a few years.

(5) The importance of human factors in quality management

For any organisation that wants to compete in today's turbulent market, it is important to use the latest scientific knowledge, invest in quality and modern technologies, develop and maintain infrastructure. However, the decisive factor has always been, is and will be human resources. In any enterprise, people are often the most important prerequisite for success or, on the contrary, the cause of failure. Their knowledge and commitment often determine the quality of products, customer satisfaction, profit or loss, market position and image of the organisation. High-quality, knowledgeable, and well-motivated people are traditionally considered to be the most important source of wealth for an organisation, and it is only right that company owners or management are able to adequately reward their committed employees.

The importance of human resources is evidenced, among other things, by the fact that human resources are included as one of the sources of organisational performance in the requirements for the quality management system in ISO 9001 and other system standards. In essence, the standards require that the organisation identify and have available the people who are necessary to effectively establish, implement, maintain and continuously improve the quality management system (ISO 9001, 2015). It should be emphasised here that these are the people at all levels of the management of the business, from the rank and file who carry out the work affecting compliance with product requirements to the management of the organisation and the executives who are responsible for establishing and effectively maintaining the quality management system. Furthermore, ISO 9004 states that competent, engaged and motivated people are a key resource for an organisation. There is a need to create an environment that enables the acquisition and retention of people who are competent and able to contribute fully to the organisation (ISO 9004, 2018).

The HR function is not only the head of the human resources system in the organisation. It is also a conceptual, methodological, advisory and control centre for the management and development of human resources. Human resources management should be clearly focused on the continuous improvement of the use and continuous development of the working abilities of human resources. In view of the above, HRM must focus in particular on (Nenadál et al., 2018):

- efforts to put the right person in the right job, i.e. to ensure that each employee is constantly prepared to adapt to the changing demands of the job,
- optimal use of the enterprise's workforce, i.e., in particular, optimal use of the pool of working time, as well as optimal use of the skills and qualifications of the workforce,
- the formation of teams, effective people management style and healthy interpersonal relationships within the enterprise, leading to the achievement of the corporate culture of the organisation,
- the personal and social development of the enterprise's workers, the development of their working abilities and social qualities, the development of their working career with the aim not only of their own internal satisfaction from the work done but even with the aim of identifying individual and corporate interests.

In order to carry out these tasks in the field of human resources, HR management must carry out the following activities:

- conduct a job analysis to determine the organisation's labour needs,
- anticipate and plan the manpower requirements necessary for the quality operation of the organisation,
- acquire the workforce needed to perform the organisation's tasks,
- to deploy workers in such a way as to make optimum use of their job skills and abilities,
- to educate and train workers so that they are prepared not only to handle all the demands of their current job but also to be prepared for any changes within the enterprise,
- establish and enforce appropriate systems of employee evaluation,
- motivate workers, develop and implement reward systems for workers,
- establish and enforce programs related to worker occupational safety and health,
- develop and implement corporate social work systems,
- develop, ensure and improve the functioning of the employee communication system.

Managers should pay more attention to the development of specific knowledge and skills of employees in the current era, characterised by rapid developments in technology. There are several reasons for this. First of all, rapidly evolving technologies are putting great pressure on shortening the innovation cycle of products and services. If an organisation fails to innovate, it loses competitiveness and can disappear or be on the fringes of the market. Therefore, highly qualified professionals are necessary in all corporate departments, including the quality department. Another reason for the need for change in organisations is the increasing share of automated work in production. This concept of increasing the share of machine work in total production is gaining in popularity and is referred to globally as part of Industry 4.0. In this context, new demands will be placed on the knowledge and skills of the quality assurance workforce. Intelligent equipment will take over some of the activities previously carried out by humans. This will be mainly heavy, dangerous, routine work, work that machines can handle and work for which there will not be enough human resources to meet the demands of production. At the same time, the labour market will be restructured to meet higher requirements for skills and expertise. People will be left to do creative, managerial, interdisciplinary or craft work (Nenadál et al., 2018).

Industry 4.0 brings new challenges and demands on employees as it is driven by digital technologies and automation. Some key aspects include digital skills, flexibility and adaptability, communication skills, cyber security, data analysis and decision-making, working with robots and automation. Overall, employees in Industry 4.0 need a combination of technical skills, adaptability, as well as intermediate skills that support effective collaboration and communication in a digital environment.

1.4. Contemporary expectations towards quality management

(1) Modern quality management problems

Quality is still a common key factor in different industries and organisations, although the specific issues and expectations related to quality may vary depending on the specific industries and take depending on the current situation the organisation is in. Many of the current quality management issues are related to the transformation of organisations to Industry 4.0 conditions or related to digital transformation and the use of new technologies, including (Ibidapo, 2022):

- integration of digital technologies with quality management,

- modernisation of outdated infrastructure that does not allow full use of modern technologies,
- training employees to use modern (digital) technologies.

There is a number of still unsolved problems or challenges of quality management. These problems are repeatedly addressed by organisations and ideal ways to optimise their solutions are sought. On the other hand, there are a number of challenges that are related to the changes in society in general and the technical progress in the last few years. Some of these challenges and problems include (Ibidapo, 2022):

- the continuous search for opportunities to improve products,
- strict compliance with regulatory requirements,
- identifying and minimising quality risks,
- developing staff competencies and strengthening their commitment to quality,
- dealing with increasing pressure on sustainability,
- increasing product complexity,
- customisation the products and services provided,
- dealing flexibly with technological change,
- integrating quality and reliability,
- changing approaches to quality management and a focus on agility.

In today's globalised world and in a time when markets and customer demands are changing rapidly, quality management in organisations has to cope with different regulations, standards and increasing requirements in different countries. Organisations need to be agile and flexible, constantly looking for ways to improve their products and services. This is achieved through continuous improvement of the entire quality management system and all its processes. This results in increased process efficiency, minimising costs associated with poor quality, better meeting customer and regulatory requirements, enhancing the ability to be innovative, increasing employee satisfaction. All this translates into strengthening the competitiveness of the organisation and its position in the global market.

Identifying and minimising quality risks such as product defects, product recalls, increased quality spending, or compliance issues is critical to maintaining reputation and trust with customers. The quality of products or services has a direct impact on customer satisfaction. By eliminating or reducing risks, an organisation can improve the quality of its outputs and thereby increase customer satisfaction and loyalty. Proper risk assessment can help to increase efficiency and reduce costs. Quality-related risks often mean errors that can lead to the need for repairs, repeat work or even product returns. By minimising these risks, organisations can reduce associated costs and improve their financial performance. Identifying and treating risks allows organisations to redirect resources to the highest-risk areas, which increases the efficiency of operations. Preventive measures and process improvements can facilitate smoother operations.

Employees and the development of their competencies in quality management are key for organisations. Employees with appropriate competencies in quality management are better able to identify and solve quality problems, which directly contributes to improving the quality of the organisation's products or services. Leading to better customer satisfaction and greater customer loyalty. By training employees in quality management, the key skills are improved. This leads to lower number of errors and, therefore, lower quality costs. Developing competencies in quality management can also promote innovation by providing employees with the tools and methodologies to think systematically about improvements, which can lead to new ideas and improvements in products and services. The combination of the above can lead to increased employee engagement and better communication between employees.

Quality and sustainability are closely linked concepts that influence and support each other. The commonalities and benefits of their interconnection are key to achieving long-term success and a positive impact on society and the environment. Quality focuses on creating products and processes that meet or exceed customer expectations and are durable and reliable. Sustainability emphasises the need for a long-term view where the decisions of today do not compromise the ability of future generations to meet their needs. By integrating these two approaches, organisations create products and services that are not only of high quality and in demand but also produced and delivered in a way that minimises environmental impact and promotes economic and social sustainability.

Product complexity refers to the complexity of product design, manufacturing, management, and use, which results from the multitude of components, processes, interactions, and functionalities associated with a given product. This complexity can affect various aspects of the product life cycle, including product development, manufacturing, marketing, distribution and service. Focusing on product complexity is particularly important for cost optimisation, better meeting customer requirements in today's global world, product sustainability and usage.

Product customisation is the process of adapting products or services to better suit the specific needs, requirements or ideas of individual customers or markets. This approach differs from traditional mass production, which focuses on creating homogeneous products in large quantities. Customisation can range from simple changes, such as the choice of product colour, to complex adjustments in product design or functionality. Focusing on product customisation brings several important benefits: increased customer satisfaction and loyalty, improved competitiveness of the organisation.

Many of the methods and tools used in planning, managing and improving quality have their origins in the pre-digital era. This is not necessarily a problem, but it can have limitations if the organisation cannot effectively adapt its processes to new trends and technologies. It is important to distinguish between tools that are still effective or the application of modern technologies that will contribute to their more effective use, and those whose use may represent a problem in today's digital age. It is possible that some traditional quality tools will reappear, but they will need to be adapted to modern requirements and technologies. Some classic approaches and methods can still provide value, especially when updated and integrated with modern digital tools. For example, classic statistical methods such as the control chart method, analysis of variance (ANOVA) or regression analysis remain useful for process evaluation and optimisation. Modern digital tools can facilitate data collection and analysis, allowing statisticians to better understand processes and identify potential improvements. Digital tools can also support collecting improvement ideas from employees and tracking progress in real-time, which can support the use of the Kaizen method. It will be no different in the case of Failure Mode and Effect Analysis (FMEA), a method designed to identify and evaluate possible failures in processes or production procedures. Modern digital tools can facilitate the automated process of information gathering and risk analysis. Modern communication tools that support virtual collaboration and the collection of ideas can support the use of classic team methods, such as brainstorming and 5W1H. In a related context, we could also mention some other tools: process capability assessment, statistical control, measurement system analysis, experiment planning, and QFD method.

The need for radical changes in approaches to quality management, motivated by the need to adapt to rapidly changing conditions, innovative trends and customer demands, may also appear to be a problem. These changes also present challenges and expectations related to the future of modern approaches to quality management. The following are some key elements of a modern approach to quality management. Modern organisations often move towards agile methodologies that emphasise rapid responses to change, flexibility and teamwork. Digital transformation means using digital technologies to improve processes, collect and analyse data, automate and optimise organisational performance. A modern approach to quality management involves the integration of digital tools and technologies to improve efficiency and performance. Even today, we must not forget to place a strong emphasis on customer experience and needs. Collecting feedback from customers and adapting flexibly to their requirements are key elements. Therefore, it is important to monitor processes from end to end and identify areas of potential improvement. This includes a holistic view of processes, from the supply chain to the customer. Without the support of active employee involvement at all levels of the organisation, the desired successes will not be achieved. Employees are encouraged to bring ideas for improvement and to participate in the continuous improvement process. Going hand in hand with quality assurance today is a concern for sustainability and environmental responsibility. This element must be integrated into a modern approach to quality management.

(2) Industry 4.0 readiness and maturity assessment models

In the previous subchapters, it was stated that some of the problems and challenges of the current quality management are related to the adaptation to the conditions of the Industry 4.0 concept or to the integration of modern (digital) technologies with traditional approaches and methods of quality management. The challenge for many organisations may be to assess the state of readiness of their quality management system for this concept or to assess the maturity of the organisation to use digital technologies and to identify opportunities to improve the conditions facilitating the transition to Industry 4.0 or the related Quality 4.0 concept. The so-called Industry 4.0 or Quality 4.0 maturity models can be used for this purpose.

When embarking on a performance improvement journey, organisations typically examine their current position. The term “maturity assessment” is used for these activities. In general, the term “maturity” refers to the state where an organisation is complete, comprehensive, ready or perfect. In the following, we will give some examples of models that allow for the aforementioned "performance assessment". Many organisations are still struggling with the concept of Industry 4.0 or Quality 4.0 because there are many ambiguities, misunderstandings and wrong approaches. These models should support internal or external assessments to review the extent to which the manufacturing organisation has adopted the concept of Industry 4.0 or Quality 4.0 into its processes and infrastructures and to identify priorities for better adaptation of the concept.

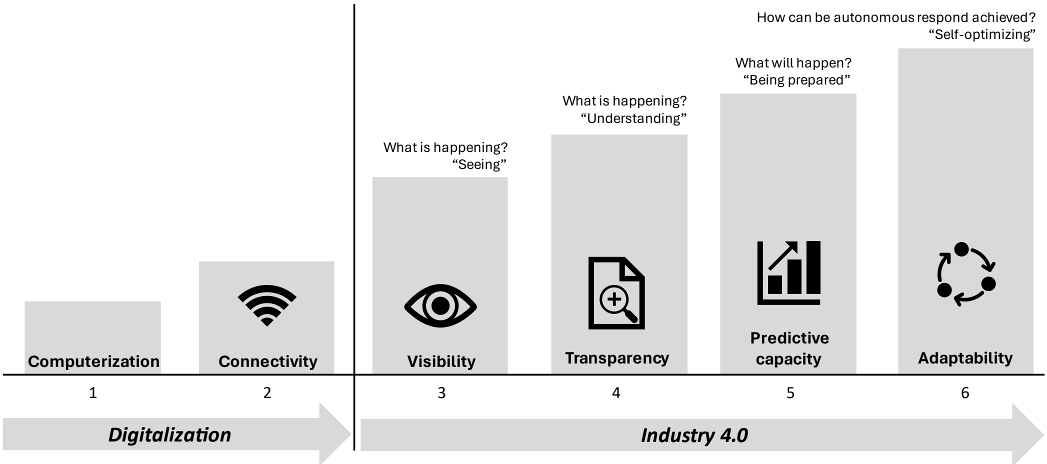

Figure 1.4. Industry 4.0 maturity stages

Source: based on (Schuh et al., 2017).

Several Industry 4.0 Maturity Models have been published by academics and consulting companies (e.g., BCG, PWC, McKinsey & Company) with varying scopes or dimensions and metrics for measuring success. Among the first models that were developed belongs to the Industry 4.0 Maturity Model published by the National Academy of Science and Engineering (acatech). The model's approach is based on a succession of maturity stages that help companies navigate their way through every stage in the transformation, from the basic requirements for Industry 4.0 to full implementation. The six maturity stages, from computerisation and connectivity up to adaptability, allowing a company to delegate certain decisions to IT systems are shown in (Figure 1.4). Four organisational structural areas of resources, information systems, culture and organisational structure are assessed. Necessary capabilities are defined for each structural area. The identification of the current I4.0 maturity stage is based on the I4.0 capabilities. The capabilities are determined on the basis of the processes in the functional areas – development, production, logistics, services and marketing & sales that are assessed. The model helps to develop a digital roadmap tailored to the needs of the organisation (Schuh et al., 2017).

The examples of other selected I 4.0 maturity or readiness models are:

- Digital compass developed by McKinsey & Company consists of eight basic value drivers (dimension) and 26 practical Industry 4.0 elements. Quality is one of the direct drivers represented by the elements like digital quality management, advanced process control and statistical process control. Other drivers in the model are supply/demand match, time to market, service/after-sale, resources/processes, asset utilisation, and labour (McKinsey & Company, 2015).
- Industry 4.0 readiness model developed by Impuls Foundation of the German Engineering Federation measures Industry 4.0 on the 7 levels of readiness. The model consists of 6 main dimensions and related 18 elements. The main dimensions are strategy and organisation, smart factory, smart operations, smart products, data-driven services, employees. It allows self-assessment and calculation of the I4.0 scorecard. It helps to identify areas that need improvement (Impuls, 2015).
- Industry 4.0 Maturity Model developed by (Schumacher et al., 2016). The model is formed by 9 dimensions and 62 elements. The main dimensions are strategy, leadership, customers, products, operations, culture, people, governance, technology (Schumacher et al., 2016). The evolution path of each element undergoes five maturity levels.
- The digital readiness assessment maturity model (DREAMY) developed by De Carolis et al. (2017) defines 5 main functional areas: design and engineering, production management, quality management, maintenance management, logistics management. quality management is represented by two elements – product testing and quality management in production. The readiness is assessed by the measurement instrument defining 5 levels of readiness. The above-mentioned areas are assessed in the context of 4 dimensions, which are part of the model: process, monitoring and controlling, technology, organisation (De Carolis et al., 2017).
- Industry 4.0 maturity model developed by (Santos & Martinho, 2019) consists of five main dimensions – organisational strategy, structure and culture, workforce, smart factories, smart processes, smart products and services. Every dimension is characterized by capabilities that are assessed by using 6 maturity levels.

There are also other I4.0 maturity models developed by academics or consulting organisations (Deloitte, 2018; Klötzer & Pflaum, 2017; PwC, 2019). These holistic models enable the assessment and utilisation of elements of I4.0 from all perspectives and hence derive encompassing success factors. There are also models that focus on the specific areas of I4.0 application or a limited number of aspects related to I4.0, such as logistics, supply chain, information technologies (Sütőová et al., 2020).

A Quality 4.0 maturity assessment model has also been proposed in academia (Nenadál et al., 2022). This model is based on the use of the Quality 4.0 conceptual assessment framework. The comprehensive assessment framework consists from 4 fundamental dimensions titled as:

- strategic direction,
- people and culture,
- processes,
- methods and tools.

These dimensions include 22 partial items. Each item must be assessed against seven maturity levels. Table 1.1 gives a generic guidance for setting out how items can be related to the levels of Quality 4.0 maturity in a tabular format.

Table 1.1. Quality 4.0 maturity levels

Maturity level	Evaluation	Description of the maturity level
Level 1 Not applied	0 – 10 %	Knowledge about modern quality management is poor. Quality control practices are based on conformity verification. Quality 4.0 concept and items are not in place.
Level 2 Beginner	11 – 25 %	Some processes of quality management are in place. The company is at the beginning phase of the Quality 4.0 road but knowledge related to advanced methods and tools absents.
Level 3 Partially applied	26 – 40 %	Some advanced methods, tools and technologies of quality management are systematically used. The company is in the process of developing a structured approach to Quality 4.0 implementation.
Level 4 Partially established	41 – 55 %	The company has some knowledge about Quality 4.0. Some prevention approaches are implemented within quality planning. Minimally, 40% of Quality 4.0 items are practically implemented in the company.
Level 5 Mostly established	56 – 70 %	Company successfully implements investments plans for Quality 4.0. The majority of all Quality 4.0 items are efficiently implemented in company.

Level 6 Advanced	71 – 85 %	Knowledge about Quality 4.0 is upper-average. Company widely uses quality management methods and tools and most of processes are digitalised. There are only few items of Quality 4.0 model which are not in company's place.
Level 7 Leader	86 – 100 %	Company systematically uses advanced knowledge and technologies in area of Quality 4.0. The company is a role model in area of Quality 4.0 concept and it is recognized as a benchmark for others.

Source: (Nenadál et al., 2022).

The team of assessors, as well as the organisation's top managers, should review the current state against a set of 22 criteria, which are contained in the special assessment matrix. Descriptors in the assessment matrix clearly provide the intent of inherent level and a brief description of each item's typical features. Such a description should not be considered a binding set of demands; on the contrary, it should be only perceived as an inspiring expression of possible view. The assessment team (or the project manager) is expected to work out a final report in which all findings (especially real strengths and weaknesses) related to the current level of the organisation's Quality 4.0 maturity assessment should be presented. This report should be submitted to the top management team for review. The management review process should provide objective decision-making focused on the next Quality 4.0 development projects. Repeated Quality 4.0 maturity assessment should evaluate the effectiveness and efficiency of these projects.

Chapter 2. Quality 4.0 concept

2.1. Definition, principles, dimensions

(1) Definition and principles

Quality is a fundamental business imperative. Nowadays, organisations must face various challenges like mass customisation, increasing product and production system complexity, complex supply chains and shortened time to market. As the production processes become increasingly complex and interconnected, the challenge of maintaining high-quality standards throughout the entire value chain intensifies. The traditional principles, practices, and tools of QM that have proven to be of value for hundreds of years are undergoing huge transformations. Quality 4.0 is a relatively new concept that is concerned with QM in the Industry 4.0 era and helps to handle the challenges mentioned above. It represents the next development stage in QM when Industry 4.0 features are integrated with traditional QM practices.

Quality 4.0 (Q4.0) can be defined as the integration of advanced technologies within all quality management phases (quality planning, assurance, control, and improvement) to achieve new optimums in performance, operational excellence, and innovation.

Q4.0 should be considered as a development of traditional approaches, with more emphasis on connectivity between machines and people, with the deployment of artificial intelligence and automation for improving performance and making timely, data-driven decisions in an end-to-end scenario, involving all stakeholders and providing visibility and transparency. Besides technological aspects, Q4.0 brings differences in leadership and organisation culture and required competencies. The main principles of Q4.0 can be summarised as follows:

- data value and data-based decision-making,
- connectivity and transparency,
- rapid adaptive learning and combined intelligence,
- cross-functional collaboration,
- value co-creation – customers, suppliers and partners are fully integrated into creating value of products and services.

Data is increasingly a contextually dependent strategic asset. Key enablers of Q4.0 are real-time data and their processing that provide valuable information and support for decision-making processes. The emergence of CPS and IoT has ensured that it is possible to capture large amounts of data (Big data) from processes, machines, devices, products, and people. Q4.0 changes traditional quality control charts to real-time monitoring of all quality specifications and quality-related data. It enables organisations to take actions and changes on time in processes to prevent nonconformities and improve efficiency, e.g. optimisation of resource utilisation, logistics, warehousing, workflow. Real-time data are captured at different locations in the value chain and can be streamed back to all involved parties from product design to final delivery and vice versa. Thus, transparency and traceability are enhanced within the entire value chain (Antony et al., 2022). It is possible to track the product even after sale and gather information about its performance during operation. Shared information helps to track and resolve quality issues, standardise quality practices, and improve performance. Interconnected and smart networks are increasingly used to dynamically regulate and improve total system performance (Janssen et al., 2017).

Artificial intelligence enables adaptive learning that supports self-induced processes and system correction and adjustment. Machines learn how to self-regulate and manage their own efficiency and quality. Adaptive learning is a fundamental concept in artificial intelligence that describes how the algorithms should autonomously learn and adapt in production as new data with new patterns comes in. Continuous and rapid adaptive learning from data characterises innovation and improvements in value creation involving the entire value chain. Q4.0 integrates the vast array of enabling technologies, artificial intelligence, and augmented human intelligence, combining the strength of human intelligence with the power of machine intelligence to create effective and powerful cooperation. The symbiotic human and machine relationship, in which virtual and real worlds co-exist, enables them to react, learn, make decisions, optimise processes, and increase quality, effectiveness and efficiency.

Q4.0 supports cross-functional collaboration (CQI, 2021). It shifts quality from a specific quality team mission to every department within and out of the organisation, including suppliers, sales, marketing, and other partners. Q4.0 helps organisations address long-standing quality issues due to ineffective or poor communication across the value chain, lack of cross-functional ownership, and fragmented data sources and systems that are not interconnected (Sony et al., 2020). Many organisations consider fragmented data sources and systems as their main challenge in achieving quality objectives.

Q4.0 facilitates a value co-creation process and enhances communication and interaction with customers, suppliers and partner organisations that create value. Co-creation brings a unique blend of ideas from direct customers or stakeholders, which, in turn, gives the organisation a plethora of new ideas (Naeem & Di Maria, 2022). Intelligent technologies have been transforming the interface, in which organisations communicate with customers and suppliers. Smart products act as boundary objects that digitally mediate the suppliers-customers interactions, thereby enabling value co-creation. In this sense, an organisation, connected to customers, collects customer data from the connected objects, transforms them into information and makes improvements and co-creating value with its customers. Other examples are co-creation platforms, designed to enable the contributions of co-creators (customers, suppliers, partners).

(2) Quality 4.0 elements

The process of digital transformation of Quality Management should consider the following dimensions where Quality 4.0 principles are manifested by people, processes, technology, suppliers, and customers.

People. Implementation of the Quality 4.0 concept requires top management commitment. Q4.0 strategy as a part of the overall digital strategy of an organisation and relevant Key Performance Indicators (KPIs) should be clearly defined by the top management. The formation of organisational culture plays a significant role. Therefore, the top management should develop a culture that supports Q4.0, which will be addressed in the next sub-chapter. Competencies for Q4.0 are important to be ensured and developed by training or recruiting employees (Sader et al., 2022). Resources for training need to be assigned, and training activities need to be planned to close the competence gap. Competencies can be developed using a variety of technologies in a Q4.0 environment.

Processes. Intelligent technologies ensure the connectivity of processes of quality management and real-time data access. Advanced analytics provide information for rapid decision-making up to the self-optimization of processes. Processes of quality management are connected and integrated with other processes and information systems vertically and horizontally as well. It eliminates the quality data siloes and disconnections and helps to streamline and synthesise quality practices to improve compliance and increase efficiency within the entire value chain (Antony, 2022). Integrated QMS platforms and solutions can support automated workflows, centralised real-time data analytics, predictive quality checks (e.g., simulation of processes using digital twins), and automated feedback loops.

Technology. Q4.0 relies on intelligent technologies for data collection, analysis, communication, and cooperation. It includes technologies like IoT, big data, cloud computing, virtual and augmented reality, artificial intelligence, machine learning and blockchain. IoT and cloud computing ensure the connection of processes, devices, products, and people. Integrated IT/OT data models support a data-driven approach and enable vertical integration and cross-functional collaboration. Big data and analytics using AI and ML provide advanced insights for the optimisation of processes and products. The various apps can help to streamline and synthesise quality processes. Quality 4.0 offers advanced applications that use mixed reality and virtual reality to improve the system's quality.

Suppliers. Integration of the entire value chain thanks to advanced technologies (IoT, CC) allows connection, flexibility and a higher level of collaboration and transparency among all parties. Suppliers can be connected and involved, and problems due to supplier quality issues can be traced and reported to suppliers in real-time. Blockchain technology enables tracking of product history (origin, production line even operator) and quality, especially when supply chains are deep and versatile. Shared information helps to track and resolve quality issues, standardise quality practices, and improve performance. The supply chain becomes a completely integrated ecosystem that is fully transparent to all the players involved. Quality 4.0, starting from research and development to customer support and sales service, will play an enormous part in the entire value chain of an organisation.

Customers. Q4.0 leads to a completely new level of customer orientation and personalisation. Intelligent technologies create new channels of customer interaction to understand their needs and expectations. A strong, personalised relationship with a customer can be nurtured through automated learning. Data are used from connected, intelligent tools to understand a product's performance and customers' interactions with it, and thus relationship, with customers and partners deepens.

Customers are an integral part of the innovation process thanks to intelligent technologies and engage themselves in the product development process. 3D printing, Web 3.0, and digital twins have enhanced customers' ability to co-create.

Only a few Q4.0 models have been published by academics and private consultation companies. The most frequently cited Q4.0 model is the one developed by the LSN company. It consists of 11 elements. It can be used by organisations to interpret their current state and identify what changes need to be done to move to the future state. The elements of the models are the following (LSN, 2017; Chiarini & Kumar, 2022):

- culture – employee engagement, responsibility, credibility, cross-functional empowerment,
- leadership – clear Q4.0 goals, their alignment and set KPI, executive ownership,
- competency – expertise, experiences, appraisal, individual competencies,
- quality management systems – robotic process automation, connected processes, autonomous processes, autonomous systems,
- compliance – automated compliance, analytics to alert breaches, blockchain providing automated audibility,
- scalability – cloud computing, infrastructure as a service, platform solutions,
- data – big data collection and leverage, data transparency,
- analysis – prescriptive analytics with the use of BD analytics, machine learning and artificial intelligence,
- connectivity – connection between business information technology (IT) and operational technology (OT), connected people, devices, products,
- collaboration – cross-functional and global; social media, blockchain,
- applications development – applications usage, advanced apps utilising virtual and augmented reality, mashups.

(3) Principle of Vertical, Horizontal and End-to-End Integration

The capture of the right quality data, their processing and flow are inevitable for fact-based decision-making and the improvement of quality management systems. Horizontal and vertical integration is enabled by advanced technologies and the interconnection of IT systems within and outside of the organisation. Machines are connected (Machine to Machine, M2M) as well as products and people. Vertical and horizontal integration enables quality data and information flow in real-time and helps to take the right actions, improve the quality and efficiency of processes, and enhance customer satisfaction. Horizontal and vertical integration within and across the organisation is shown in Figure 2.1.

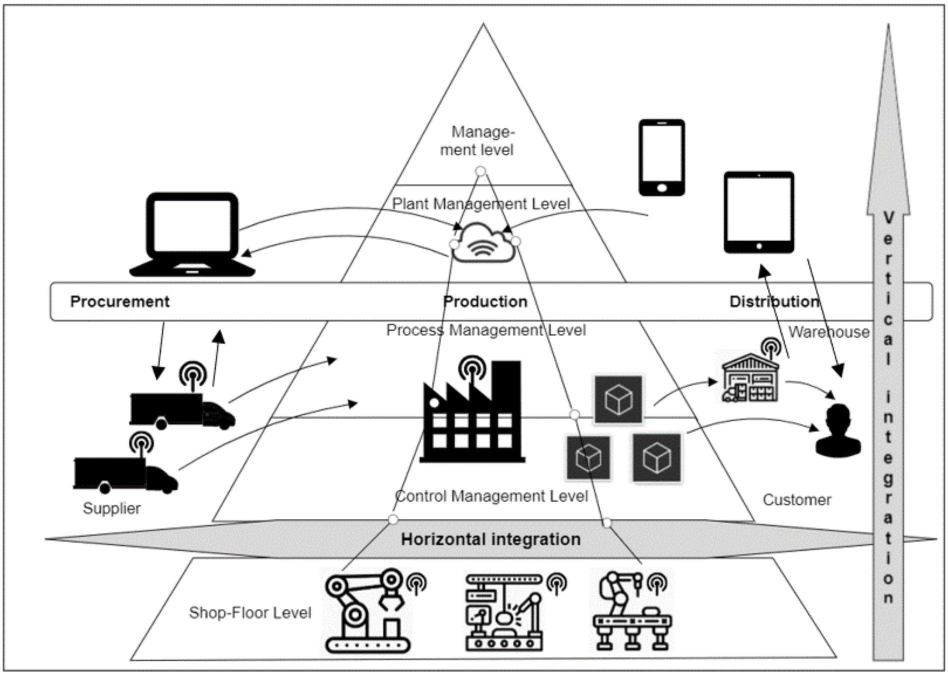

Figure 2.1. Horizontal and vertical integration

Source: own elaboration.

Horizontal and vertical integration help to ensure the creation of so-called quality feedback loops within the entire value chain. It helps to boost a holistic approach to quality management. Engineers can see new relationships between each node in the feedback loop, and new mechanisms can be put in place to ensure quality at every stage. Quality feedback loops represent quality-related data and information from processes, machines, systems, products, and customers circled back and used as inputs for continuous improvement.

Quality management system standards like ISO 9001:2015 and IATF 16949:2016 contain several requirements on vertical and horizontal quality feedback loops (e.g. requirements on communication with customers and customer satisfaction measurements, communication with external providers and their control and monitoring and requirements on management review inputs) as well as the EFQM model addresses this issue within the selected criteria. Implementation of Quality 4.0 helps to provide feedback loops in real time for fact-based decision-making, enabling the increase of effectiveness and efficiency of processes, quality of outputs, and flexibility. The implementation of Q4.0 technologies supports three main types of quality feedback loops: vertical, horizontal and end-to-end.

Vertical quality feedback loops refer to the integration of different hierarchical levels of organisation. Quality data and information flow are retrieved from the shop floor level through the level of production management up to the corporate management level. Data flows freely and transparently up and down the layers, so decision-making and optimisation can take place on several levels.

Vertical integration feeds data up to tiers with more accumulated data (requests, analysis, and forecasting), which provides feedback for optimisation. Vertical integration permits QM data to be used for strategic planning, human resource management, procurement, maintenance. It shifts quality control from being only a single shop floor activity to every management level's activity, given its integration with the Enterprise Resource Planning (ERP) system, Product Lifecycle Management (PLM) system, etc. Vertical integration reinforces the integration of quality policy within the organisation and the achievement of quality goals. Various informational subsystems within the organisation are connected to the ERP system, which results in a flexible production system that can autonomously adapt to customer demands (Chopra et al., 2022). Vertical quality feedback loops create a continuous improvement culture within the integrating subsystems in an organisation and help to enhance customer value.

Horizontal feedback loops are enabled by the integration and connection of the entire value chain, including suppliers, distributors, partners, and customers. It creates opportunities for collaboration, networking, and a fully automated value chain. Horizontal integration often reforms the business model from linear to networked form. Data and information flow both upstream and downstream of the value chain thanks to connected systems. This creates transparency and flexibility across the value chains, from purchasing through production to sales or from the supplier through the organisation to the customer. Quality problems due to supplier quality issues can be traced and reported to suppliers in real-time.

Horizontal integration ensures the efficient working of QM processes. For example, a real-time translation of Voice of Customer (VOC) data gathered at the planning stage into Critical to Quality (CTQ) metrics helps in achieving dynamic control of technical specifications of products or services (Prashar, 2023). Dynamic integration of QMS with the market needs through customer relationship management (CRM) and other systems results in the real-time reconfiguration of processes in the organisation and in the horizontally integrated supply chain. Such a mechanism results in the delivery of personalised products and services based on the user's needs in the shortest possible time, and the required quality and resources are allocated efficiently. Organisations will use new technologies to listen to and analyse VOC and to build customer-centric ecosystems. Horizontal integration helps control the production process and supply chain and can ensure consistent quality standards throughout the value chain. For horizontal integration, it is vital to define and establish communication standards for data security and to avoid data manipulation.

End-to-end quality feedback loops are enabled by the integration of engineering activities across the entire product life cycle. It covers all the stages from identification of customer requirements, product design and development, production planning and realisation, services, and maintenance to end-of-life activities such as repairing and recycling. It helps to create maximum value throughout the entire value chain and enhance customer satisfaction. It provides end-to-end transparency and facilitates optimised decision-making. The end-to-end integration is the extension of the horizontal integration to become the integration of the entire product life cycle management (PLM). Product design and development activities are realised so that the complete value chain is considered. Robust, high-quality manufacturing and service processes are the result of a fully integrated, cross-functional design approach and involvement, supported using virtual models and simulation tools. Data analytics allow manufacturers to gather customer feedback and preferences, tailoring products to meet specific demands. End-to-end engineering is based on the information stored in smart products. It enables tracking of every stage of a product's lifecycle (Sony, 2018).

(4) Systems integration for connected quality management system

Industry 4.0 technologies enable the integration of operational technologies and information technologies. OT is hardware and software that monitors or controls industrial devices, processes, and infrastructure. It deals with the physical world. The main function of IT is to ensure that all data is managed, processed, and stored securely (Stouffer, 2023). Quality Management is in the IT domain, while Quality Execution is in the OT domain and bidirectional communication across the OT/IT is important. It increases the amount of real-time data available, and consistent data management enables seamless traceability. Integration of the systems helps to create flexible and closed-loop quality management and connect real-time quality data from the field to upstream functions like ERP, QMS, PLM, and to maximise efficiency. The OT/IT integration begins with close collaboration between IT and OT personnel. Both departments need to work together to identify mutual problematic points and begin prioritising objectives.

The five-layer industrial automation pyramid is a commonly used framework that provides a structured approach to designing and implementing automation systems in an organisation. Figure 2.2 shows the five-layer industrial automation pyramid from the field level (interfacing with the production process via sensors and actuators) through the control level (Programmable logic controllers (PLCs) can deliver automatic control functions based on sensor inputs), supervisory level (supervisory control and data acquisition – systems used for controlling, monitoring, and analysing industrial devices and processes and visualization of data), manufacturing operations system level including Manufacturing Execution System (MES), Quality Management System (QMS), Warehouse Management System (WMS), up to business operations level including Enterprise Resource Planning (ERP) system, Product Lifecycle Management (PLM) and others. ERP system integrates Finance Resource

Management (FRM) system, Supply Chain Management (SCM) system, Human Resource Management (HRM) system, Customer Relationship Management (CRM). PLM system manages all the information and processes at every step of a product lifecycle (Zhu et al., 2022). It acts as a centralised repository for product specifications, engineering specifications, supplier details, CAD drawings and files, change management, KPIs, plans for testing.

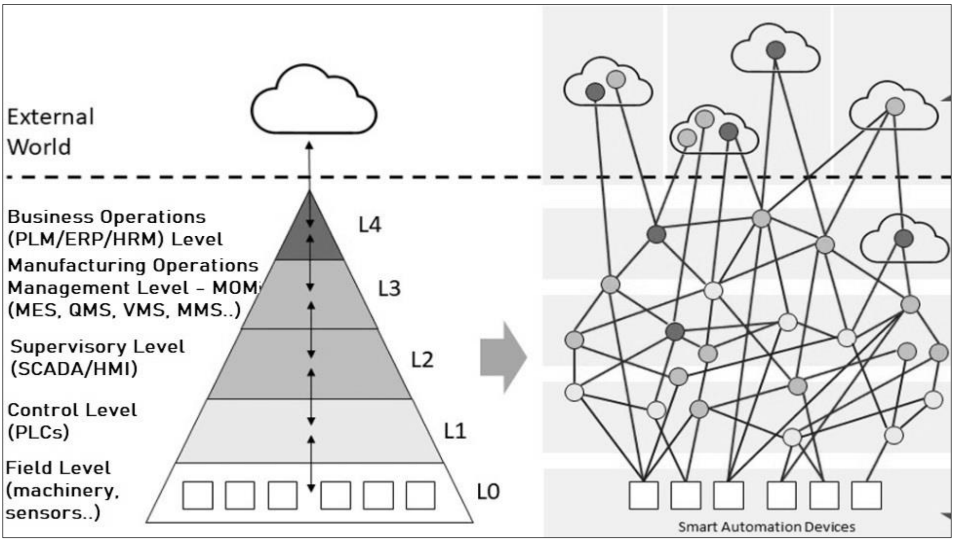

Figure 2.2. Automatisation pyramid and automatisation based on CPS

Source: based on (Alcácer & Cruz-Machado, 2019; Foidl & Felderer, 2016).

On the other hand, there is an integrated network of systems based on CPS in Figure 2.2. Vertical integration makes the traditional automation pyramid view disappear. The same goes for several systems and applications across these levels. The field level is connected to various levels up to ERP. Quality data from the shop floor are transferred to each decision-making level and vice versa, which in turn supports the ERP system in optimising the entire manufacturing management.

Usually, there are still many data silos and knowledge bases in organisations within different departments that have to be broken down and interconnected. Quality team often operates in a silo, making it impossible to get insight into other information systems in which key data resides. Disconnected quality data are common quality management challenges that organisations face. Integrated quality data are the basis for continuous improvement. There is a need for bi-directional feedback between product development, quality, manufacturing, supply chains and customer service (Javaid et al., 2021).

Interconnection of QMS with PLM, MES and ERP drives design for quality, when a real-time translation of voice of customer data gathered at the planning stage into critical to quality metrics helps in achieving dynamic control of technical specifications of products or services (Prashar, 2023) and subsequently dynamic control of parameters of processes (resulting from FMEA and control plans). Once the product design has developed to a point where resources need to be managed, the integrated ERP system ensures that there is resource planning for production. Often, PLM and QMS systems are not integrated as they are managed by different teams or departments. It increases the risk of failure of design processes due to a lack of feedback. Integration helps quality function to become integral to the product development life cycle, right from design to providing service and support. Non-conformance detected in the QMS system can be linked to the corresponding product record in the PLM system, prompting corrective or preventive action (Enríquez et al., 2019). This kind of integration helps to practice a holistic approach to quality or ensure quality within end-to-end.

(5) Big data analytics for empowered decision-making

The ability to take advantage of all available information has become a critical ability for organisational success. Big data has revolutionised how decisions are made in organisations. Big data is a high-volume, high-velocity, and high-variety information asset that demands cost-effective, innovative forms of information processing for decision-making. It empowers organisations to make more informed, agile, and customer-centric decisions. The creation of value from data requires combining large datasets originating from different and heterogeneous data sources. Big data analytics creates value from the data. It helps to detect quality problems early and proactively address them, improve resource utilisation, enhance efficiency, and boost customer satisfaction (Taleb et al., 2018).

The big data ecosystem is organised as a value chain lifecycle from data acquisition to visualisation. Figure 2.3 shows the big data value chain.

Various data sources generate huge amounts of data like sensors, machines, devices, and social media. These data are gathered in different formats (unstructured: raw text data with no schema, semi-structured: metadata, graph structure as text) and are transferred into storage data centres. Raw data must go through a pre-processing phase in which activities such as data cleaning, de-duplication, compression, filtering, and format conversion take place. The next stage of processing and analytics involves the application of data mining algorithms, machine learning or artificial intelligence to process the data and extract useful insights for better decision-making.

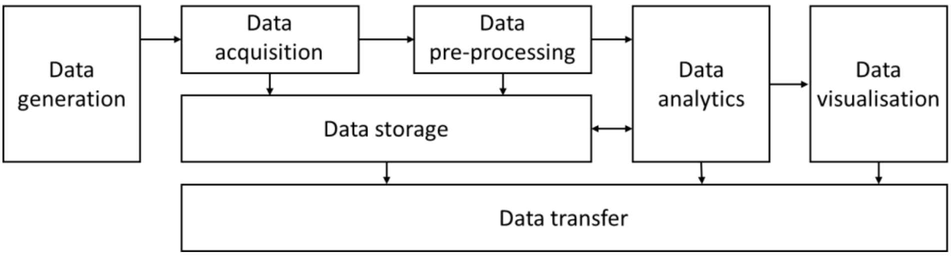

Figure 2.3. Big data value chain

Source: based on (Faroukhi et al., 2020).

The best way of assessing the value of processed data is to examine it visually and make decisions accordingly. Quality specialists should be able to interpret the outcomes of big data analytics and have knowledge about the relationships among variables to make the right decisions. Interactions with others involved in the BD chain result in higher decision-making quality. The ability to collaborate among BD providers, analysts, and decision-makers is a key condition for overcoming fragmentation and creating a BD chain.

Data analytics convert data into actionable knowledge and insights. There are four types of data analysis, which are shown in Figure 2.4. However, these categories are all linked together and build upon each other.

Descriptive analytics presents a clear picture of what happened in the past. But it cannot make interpretations or advise on future actions. Descriptive analytics are the backbone of reporting – it's impossible to have business intelligence (BI) tools and dashboards without it.

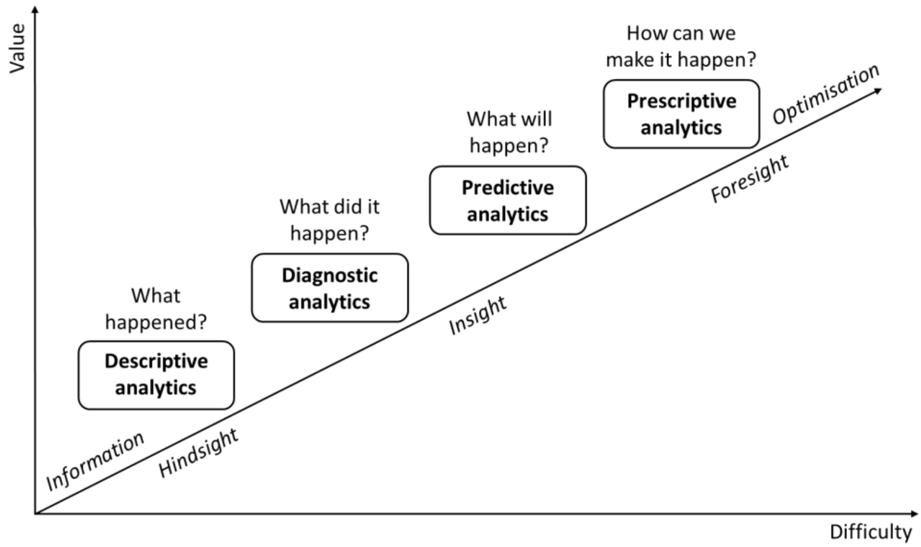

Figure 2.4. Types of data analytics

Source: based on (Sharma et al., 2022).

Diagnostic data analytics is the process of examining data to understand cause or why something happened. It is usually used to uncover any hidden patterns which help to identify any factors that are directly or indirectly causing effect or problem.

Predictive analytics may be the most used category of data analytics. Organisations use predictive analytics to identify trends, patterns, and relationships. Predictive analytics extrapolates from available data and tells what is expected to happen in the near future. The tools used for extrapolation are time series analysis using statistical methods, neural networks, and machine learning algorithms (Al-Sai et al., 2022).

Prescriptive analytics identifies, based on data gathered, opportunities to optimise solutions to existing problems. AI and big data help predict outcomes and identify what actions to take to achieve a goal. Prescriptive analytics can help answer questions such as "What if we try this?" and "What is the best action?" It enables testing the correct variables and even suggests new variables that offer a higher chance of generating a positive outcome. Prescriptive analytics algorithms can provide two levels of human intervention for decision-making:

- the first level of intervention is the decision support system – or instance, when algorithms provide recommendations for quality of design, quality improvement; the larger solution set from these algorithms will warrant human intervention in an assisted manner to finalise the best options,
- the second level of prescriptive analytics will be based on intelligent algorithms which will result in decision automation through machine learning – this type of prescription algorithm will help in implementing the prescribed action in an automated and self-regulating manner.

Prescriptive analysis algorithms in terms of the first level will be very beneficial in quality planning and quality improvement, as they will provide a large number of solution options. Prescriptive analysis in terms of decision automation will be more helpful for quality control because decisions such as conformance to specifications can be automated by analysing data.

2.2. Human factor in Quality 4.0

(1) Human cyber-physical systems

The adoption of Industry 4.0 has been reshaping the way people work, learn, manage, and interact with each other. Employees are facing challenges regarding the application of new, intelligent technologies that enable the reduction of time-consuming manual tasks and focus on more creative and value-adding activities. A smart manufacturing system represents a human cyber-physical system (HCPS) where humans, physical systems, and enabling cyber technologies are interconnected through complex interactions to accomplish a certain goal. This contrasts with a conventional perspective where the human is treated as an isolated element who completes the tasks by himself or operates and uses the system. Within the HCPS many repetitive manual tasks are automated and cyber systems help humans with the necessary perception, analysis, decision-making, and control of physical systems so they can run optimally. Figure 2.5 shows the HCPS, where substantial mental and physical work is replaced by CPS systems. However, humans are the users of CPS and remain in the central position and possess and have the highest right to make decisions and enact control. Humans will take on the role of the creative problem solver when confronted with complex problems, as a last instance inside the HCPS system (Wang et al., 2022).

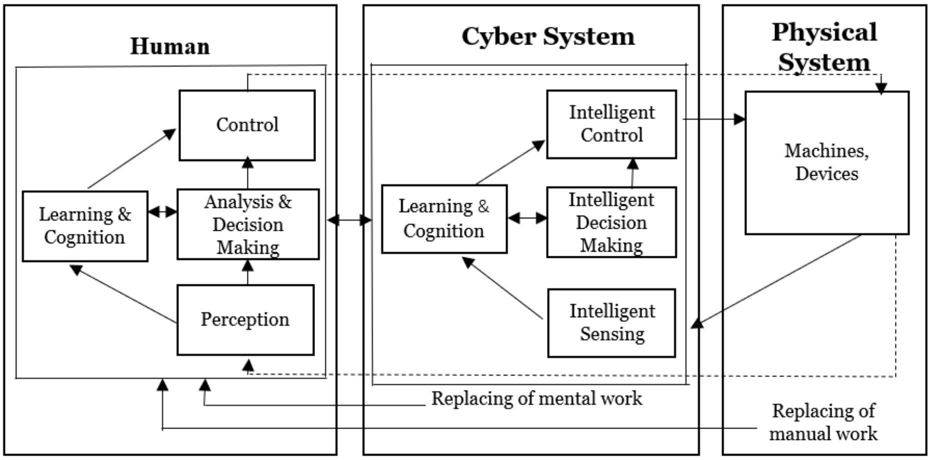

Figure 2.5. Human cyber-physical system

Source: based on (Zhou et al., 2019).

Smart manufacturing presents many uncertain and complex problems that cannot be solved by human intelligence or by cyber systems alone. Humans are good at teamwork, understanding complex situations, and making high-level decisions, while machines are good at computing or performing high-precision tasks. The knowledge base in the HCPS is jointly built by humans and by the self-learning and cognition module of the cyber system (Zhou et al., 2019). The knowledge constantly upgrades itself through self-learning and cognition during the application process. Human-machine hybrid intelligence including human and autonomous decision-making components is a typical characteristic of HCPS. It utilises the strengths of human and artificial intelligence so that they can perform better than either of the two separately. During close interaction and collaboration, humans and machines can learn from each other, from the sensed operational environment, and from actions taken in an operational environment. Synergic integration of the advantages of human intelligence and machine intelligence results in increased efficiency and innovation.

From the organisation's perspective, a smart manufacturing system integrates through the industrial network multiple intelligent units (corresponding to HCPS unit level) that participate in a value creation process from product design and development, manufacturing, sales to service and include people from their own organisation, suppliers, customers. This means that human tasks will focus on broader functions that cover a larger scope of operations, which is characterised by an increased amount of information being processed. Information and data from a wider range of sources and processes are collected, analysed, and consequently used for decision-making or innovation processes. In addition, a higher number of resources and complex processes need to be coordinated. It will shift human work to tasks that are more complex, requiring to understand how different processes and resources interact. Humans will need to be able to interact with several different actors across departments and processes and across organisational borders. The CPS affects the degree of job autonomy perceived and the focus shifts to higher-level decisions related to the strategic, and innovation issues and modification and maintenance of CPS.

(2) Human-machine interaction

Industry 4.0 transforms working conditions through the implementation of unprecedented human-machine interaction. Human-machine interaction (HMI) refers to the communication and interaction between a human and machine via a user interface available on wall screens, tablets, smartphones or in smart glasses. They can use virtual or augmented reality. Useful and user-friendly HMI solutions integrated with promising industry 4.0 technology have a great potential to improve the effectiveness and efficiency of processes by digitising and centralising data for a viewer (Lodgaard & Dransfeld, 2020). Figure 2.6 shows an example of human-machine interaction, where a human provides an input for the system and interprets the output of the system.

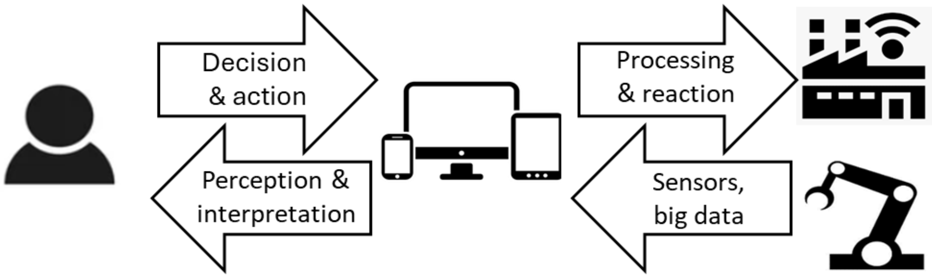

Figure 2.6. Human-machine interaction

Source: own elaboration.

With VR and AR, relevant information can be directly added to the worker's field of vision, and it allows the user to simulate and interactively explore the behaviour of a smart manufacturing system. VR and AR are gaining a stable presence in different industries and also in quality management. VR is a technology that creates immersive, computer-generated environments or simulations. AR is a combination of the real world and virtual objects. It does not replace the real world with the virtual but complements or changes the perception of the real world. While VR creates a completely virtual environment that transports the user into an alternate reality, AR augments the real world with digital information by embedding it directly into the surroundings.

VR and AR have found their application within quality management in, e.g., design and development processes and enable engineers and designers to view key features of products and interact with products without creating physical prototypes and also allow them to participate in the design and development process collaboratively (Kreuzwieser et al., 2023). There have also been VR and AR simulation environments developed to involve customers, non-designers in design processes in organisations. The technologies also support effective and efficient layout planning that considers safety and ergonomics and enables the identification of potential problems before making physical changes. VR and AR have significant usage in guiding operators in quality inspection processes, training employees to accelerate learning curves.

Digital twin provides an opportunity to enhance HMI by offering more comprehensive information to users. The digital twin is a virtual representation of the system (twin) that is continually updated with the performance and maintenance status data throughout the physical system's life cycle.

Interconnection between physical and virtual representation enables permanent data exchange and update. It provides a novel way to assist humans in understanding the physical world from a multi-time dimension, including the past, present and future. It has been widely applied in all stages of the product lifecycle, including design, manufacture, and service. DT can be applied at component level, product and asset level, process level and system level. It enables to realise quality status monitoring, prediction, and adjustments in physical spaces. Virtual and augmented reality provide convenience and a sense of reality to the data obtained and complements the benefits provided by digital twin technology. Users can either visualise the digital twin in their physical environment or immerse themselves entirely in a world that accurately mimics real life. For example, AR can show a digital twin on top of a physical machine (it overlays a physical model) and provide information that maintenance technicians wouldn't otherwise see while they can use AR goggles or glasses. The digital twins provide enhanced HMI that helps humans in, e.g.:

- design and development process, where engineers can simulate product functionalities and use a virtual prototype generated by digital twin to test different product characteristics – real-time sensor data can be used to populate simulation applications that then emulate the physical product and enable design improvements,
- process design and optimisation, where DT helps engineers to observe processes under multiple performance conditions and eliminate problems before they occur – that allows quality engineers to move from being reactive to predictive and reduce costs,
- remote maintenance, where engineers can remotely monitor assets' performance and diagnose issues with greater speed and agility

without physically inspecting them – they may also use the available data to improve preventative maintenance practices, increasing the longevity of assets,

- collaboration with interested parties – DT provide access to each stage of the manufacturing process and product lifecycle and promote collaboration and knowledge sharing among stakeholders.

VR and AR-assisted DT address two classes of challenges: VR, AR-collaboration and human disturbance protection to ensure the high effectiveness of the solutions.

(3) Competencies for Quality 4.0

Competencies and Industry 4.0. According to ISO 9001, competency is defined as an "ability to apply knowledge and skills to achieve intended results" (ISO 9001, 2015). Competence is a combination of knowledge, skills, and attitudes. Skills are often divided into hard and soft. Hard skills relate to the technical aspect of tasks performed within a job position and frequently take into account the acquisition of knowledge. Soft skills are intra and inter-personal skills, essential for personal development, social participation, and workplace success (Flores et al., 2020). Competencies can be also categorised as (Nardo et al., 2020):

- technical competencies – they are made up of a set of knowledge and skills for the workplace position,
- methodical competencies – they are made up of skills and abilities for solving problems and decision-making,
- social competencies – they are necessary for effective communication and building positive relationships with others,
- personal competencies – they are formed by individual values, motives, and attitudes.

Industry 4.0 affects job content and autonomy and requirements for employees' competencies. Many studies have presented the lack of knowledge and skills of employees among the main barriers to successful digital transformation of organisations. New specialised hard and soft skills are required to fully utilise the potential provided by Industry 4.0. Deployment of intelligent technologies results in the automation of certain tasks (manual, repetitive) and the disappearance of some jobs; however, it brings new job positions. The competencies required to perform most of the jobs are shifting significantly. Simple and monotonous processes are being automated while other processes become more complex. New required competencies relate to higher responsibility and empowerment. Employees must be able to take on more strategic, coordinated, and creative tasks. The skills in I4.0 are increasingly multi-disciplinary and include both the developer side – how to develop technologies and processes in I4.0, and also the user side – how to make use of the capabilities offered to the employees in the I4.0 working environment.

The World Economic Forum published core competencies in 2022 and core competencies that are expected to rise in the next five years are presented in Table 2.1.

Table 2.1. Top 10 competencies in 2022 and on the rise in the next 5 years

Top 10 competencies of 2022	Top 10 on rise
Analytical thinking and innovation	Creative thinking
Active learning and learning strategies	Analytical thinking
Creativity, originality, and initiative	Technological literacy
Technology design, programming	Curiosity and lifelong learning
Critical thinking and analysis	Resilience, flexibility, and agility
Complex problem-solving	Systems thinking
Leadership and social influence	AI and big data
Emotional intelligence	Motivation and self-awareness
Reasoning, problem-solving and ideation	Talent management
System analysis and evaluation	Service orientation and customer service

Source: (WEF, 2023).

Competencies of Quality Professionals in Quality 4.0. The specification of competencies differs depending on the job position. Due to the onset of I4.0 and the development of quality management towards Q4.0, quality professionals face new challenges that can be summarised as follows:

- real-time data gathering and monitoring and large volume of data (from processes, devices, products, and customers) and complex data sets,

- real-time decision-making based on data,
- advanced analytical tools for BD analysis and applications (descriptive – generation of information; diagnostic – pattern recognition; predictive – forecast; prescriptive analytics – decision making),
- automation of certain tasks,
- advanced human-machine interfaces,
- new technologies and smart media,
- scalable software solutions for quality management,
- cross-functional collaboration,
- connected supply chain, end-to-end integration and quality assurance,
- understanding customer needs to the next level,
- new leadership challenges.

In Q4.0, a range of new knowledge and skills are required for quality professionals and training will play a major. Advanced technologies automate low-skill repetitive tasks like quality inspection and testing, and tasks shift towards more strategic ones. Quality 4.0 relies heavily on data collection to support decision-making. Quality professionals need the right tools (beyond current statistical knowledge applications) to know how to interpret large data sets generated from processes and products in real-time. They need to focus on prevention to avoid any non-conformities and inefficiencies. Data from various sources will be vast and complex, requiring employees to have the capability to identify the appropriate data which would be most beneficial to solve particular problems. Q4.0 requires considerable data analysis and interpretation abilities. Data visualisation, predictive modelling, and usage of machine learning tools for advanced prescriptive analysis of big data are becoming a part of a quality professional's job. It requires higher technical and media skills. The roles of quality professionals will be more strategic. They will have access to information to identify value-creation opportunities for stakeholders.

Due to the automation of processes and tasks, most roles of quality professionals are transforming to more strategic ones, with more responsibility and authority also due to the decentralised environment. Quality 4.0 supports connectivity and end-to-end integration, which requires integrated system thinking and the ability to solve complex problems. End-to-end integration and increased virtual work require quality professionals to have improved virtual communication and collaboration capabilities to be able to work and deal with people from different departments, global, multicultural teams, customers and suppliers. Due to the use of IoT technology and information on servers, there is a need for quality professionals to be aware of data security and have knowledge of the field of cybersecurity (Kannan & Garad, 2020).

Quality professionals must be motivated to learn to adapt to more frequent work-related changes. They must have state-of-the-art knowledge and skills in a changing environment and support the exchange of tacit and explicit knowledge within the organisation (Escobar et al., 2021).

The required competencies of quality professionals for Quality 4.0 can be summarised as follows:

- technical competencies – state-of-the-art knowledge, knowledge of technology and processes in the organisation (multidisciplinary), big data and data mining knowledge and skills, database knowledge (e.g. SQL, Oracle), programming skills, digital media skills, machine learning theory and algorithms, IT security and data protection knowledge and skills,
- methodological competencies – creativity, complex problem-solving, system thinking, analytical skills, conflict-solving,
- social competencies – intercultural skills, language skills, communication skills (also virtual communication skills), networking skills, ability to transfer knowledge and leadership skills,
- personal competencies – flexibility, emotional intelligence, ambiguity tolerance, openness to change, motivation to learn, self-management, resilience, sustainable mindset.

To meet the demands for new competencies because of changes in the work of Quality Professionals, organisations should adopt a proactive approach to upskilling and reskilling their workforce. Some strategies to consider include:

- assess the current competencies of employees and identify areas for improvement,

- develop training programs tailored to individual needs and career goals,
- leverage online learning platforms and resources to provide flexible and accessible training options,
- encourage a culture of continuous learning and development within the organisation,
- collaborate with educational institutions and industry partners to develop relevant training programs.

(4) Organisational culture in the context of Quality 4.0

The organisational culture is a set of values, beliefs and behavioural patterns that, conscious or not, build the organisation's identity and constitute the basis for assigning meaning and identifying employees with the organisation (Hofstede, 2000). Organisational culture can be also defined as a set of shared values, beliefs, and norms that influence the way employees think, feel, and behave in an organisation (Shein, 2004). Organisational culture influences the behaviour of organisation members, communication, behaviour and decision-making. Depending on the configuration, it may limit the development of the organisation by promoting passive behaviour or, on the contrary, encourage even moderately engaged people to propose improvements and changes. The climate of acceptance, agreement, and common goals favours the development of the organisation and increases efficiency. Therefore, it is sometimes difficult to explain, looking only from the outside, why an organisation with less potential than its competitors was able to grow into a market leader.

Quality culture is a specific configuration of organisational culture in which goals and values, work style, approach to improvement and procedures encourage employees to constantly search for better solutions. It does not result from control, supervision, or issued orders but from employees' own beliefs, belief that this is the right way of acting, and sometimes a sense of mission. The key aspects of quality culture include: appropriate attitude, planning of activities, attention to proper preparation, possession and improvement of necessary skills, diligence in performing tasks, good communication and coordination, striving to eliminate all types of waste, continuous improvement.

Achieving high quality in an organisation requires a change in the approach to management and the selection of an appropriate form of leadership. The role of management should be to create an appropriate culture and then entrust quality achievement to teams of employees. This requires trust and real leadership. In practice, quality is not determined by the manager alone but to some extent by every member of the organisation, supplier, assistant, consultant or collaborator. Each of them contributes something to the overall image of the quality of the delivered results (Santorella, 2017; Skelton & Pais, 2019). Each team member decides to deliver the highest quality they can, risking their safety. If he makes a mistake, it will cause problems for the team. Therefore, it is important to appreciate this courage, as well as to appreciate the mistakes and weaknesses that must inevitably appear in such a case. The key here is to offer real support and help in solving problems rather than pointing out those responsible for errors.

Quality culture should lead to the involvement of all project team members in achieving the highest possible quality of solutions and improving work processes. In the form of a quality spiral, this will translate into a further increase in motivation, commitment, striving to improve competences, cost reduction and increased work efficiency. At the same time, it is necessary to prevent the previously discussed situations that destroy the quality culture.

In order to successfully foster a quality culture in an organisation, management must recognise the importance of developing the necessary skills and capabilities in their quality professionals. Quality 4.0 professionals need to possess a range of skills, including creative thinking, leadership, communication, teamwork, and knowledge of new technologies such as cyber-physical production systems (Santos et al., 2021). They must be able to motivate their teams, embrace change, make decisions, manage conflicts, and control their own emotions. Creativity will be a key skill for quality professionals in the future as the exchange of ideas becomes prioritised over the exchange of goods (Santos et al., 2021).

For top management to create an environment where quality professionals can excel, it is essential to provide the necessary resources and support for professional development. Quality professionals should have access to training and knowledge about new technologies as they emerge, enabling them to make informed decisions based on data analysis. They should be empowered to advocate for the design and production of high-quality products, champion the interests of customers within the organisation, and create value for stakeholders (Santos et al., 2021).

It is also important for management to foster a culture of trust, collaboration, and continuous improvement. By entrusting quality achievement to teams of employees and appreciating their contributions, management can cultivate a sense of ownership and commitment to delivering the highest possible quality. Mistakes and weaknesses should be seen as opportunities for learning and improvement, and support should be provided to help solve problems rather than assigning blame (Skelton & Pais, 2019).

Organisational culture is, therefore, considered to be a tool that helps to achieve organisational goals and success. Organisations that are aware of the significance of their employees and culture in fulfilling their goals have a greater competitive advantage. Culture is a social glue that keeps organisations integrated and controlled through informal, non-structural means. Organisational culture influences members of the organisation – their behaviour, performance, and the organisation's external environment.

Although Quality 4.0 is primarily driven by technologies, the success of the Q4.0 implementation requires an approach that addresses the whole scale of strategic, cultural, and technological issues. The change in organisational culture is a prerequisite. Appropriate management approaches play an important role in changing the culture of an organisation. Top management should initiate a cultural change by promoting innovation and formulating a clear digital vision and strategy. An effective digital strategy aligns technology initiatives with overall organisation goals, ensuring a cohesive and forward-thinking approach. Incorporation of Quality 4.0 into the organisation's strategy is critical for facilitating Quality 4.0 implementation in quality planning, assurance, and improvement. Key performance indicators or incentive structures should be aligned with the strategic goals of the organisation.

Quality 4.0 implementation involves a programme of wide-ranging organisational change initiatives. The most difficult aspects relate to the major changes to be made in organisational structure and business processes, as many tasks formerly conducted by people will become automated, while previously unknown tasks and new responsibilities will appear. Leaders must advocate for a data-driven mindset and encourage employees to gain new knowledge and adopt new technologies and approaches. There is a need to identify skill gaps and provide training and development opportunities in an organisation that supports digital transformation. Leaders must foster a continuous learning culture that helps them acquire the required skill set and stay up to date all the time.

The changes could meet resistance from the employees. Overcoming resistance requires effective change management strategies, clear communication, introducing how the changes will help to achieve organisational goals, and engaging employees in the process. It helps employees to develop the required digital mindset and work habits to fully leverage the new technologies. Leaders should act as role models in displaying openness to change and adopting new behaviours. Typical cultural characteristics of Quality 4.0 are (Capgemini, 2017):

- leadership commitment,
- enhanced customer centricity,
- openness to new things and disruptive thinking,
- support and appreciation of creativity and innovations,
- data-driven mindset,
- empowered decision-making and engaged employees,
- support of open communication and cross-functional cooperation,
- knowledge sharing and continuous learning.

Connected assets, processes, analytics, and applications improve a culture of quality through shared information and knowledge. Cross-functional collaborative teams allow employees to share knowledge, skills, and expertise with a broader audience within the entire value chain. It helps to develop new ideas and solutions, enabling organisations to adapt to rapid technological changes. It is necessary to ensure that traditional siloed working cultures and boundaries no longer exist. Collaborative culture also promotes consistent communication from the top management down to the manufacturing floor. This improves mutual understanding of work and helps to resolve conflicts and increase performance. Hierarchical organisational cultures need to be transformed into a flexible, adaptable, adhocracy culture without bureaucratic policies or procedures. This change involves empowering employees to make decisions on their own where necessary. It helps to make the decision-making process faster, take appropriate actions and accelerate innovation.

A highly skilled workforce with a high degree of individual responsibility in a dynamic environment, collaborating within the entire value network, is of great importance. The workforce of the future organisation must be configured so that it is dynamic and must be prepared to change the tasks performed regularly and collaborate with different teams. A culture that encourages knowledge-sharing, upskilling, and staying curious fosters an environment where employees are motivated to embrace change and welcome innovation, which enables meeting customers' changing requirements and demands. Quality 4.0 leads to a completely new level of customer orientation and helps to build a culture that supports the value creation for all stakeholders.

2.3. Quality 4.0 and quality management systems

(1) Quality management systems (QMS) according to ISO 9001

Approaches to quality went through several development stages from inspection to Total Quality Management (TQM) as it was described in the first chapter. With the onset of I4.0 and the deployment of smart technologies in quality management, a new concept of Q4.0 has emerged.

TQM is a management philosophy that enforces continuous improvement of processes, products, and services to meet customer needs and expectations. It focuses on a combined effort of both top management and employees of an organisation to formulate effective strategies and policies and operate effective processes to deliver high-quality products and services which not only meet but also exceed customer satisfaction. There are several quality management models that help organisations adopt TQM philosophy, among others:

- ISO quality management system standards,

- European Foundation for Quality Management (EFQM) model,
- Deming prize,
- Malcolm Baldrige criteria for performance excellence.

ISO 9001 is a globally recognised standard for QMS. In comparison with the above-mentioned models, it is a standard used for auditing and certification purposes. The other models are used for self-assessment and provide criteria for the evaluation of organisations and awarding of prizes. It is applicable to any organisation, regardless of its size, type, and activity. There are more than 1.2 million valid certificates worldwide confirming compliance of QMS with the ISO 9001 standard requirements in organisations. ISO standards were published for the first time in 1987, and since then, the standards have been revised several times. Standards of ISO 9000 series consist of:

- ISO 9000 – contains fundamental concepts and vocabulary of QMS and defines 7 basic principles that all the standards are based on,
- ISO 9001 – specifies requirements for a QMS of an organisation; the certificate of QMS according to ISO 9001 demonstrates the compliance of QMS in an organisation with the standard,
- ISO 9004 – gives guidelines for enhancing an organisation's ability to achieve sustained success – it provides a self-assessment tool to review the extent to which the organisation has adopted the concepts described in ISO 9004.

ISO 9001 is based on a process-oriented approach and the Plan-Do-Check-Act (PDCA) cycle ensuring continuous improvement of processes and the whole QMS in an organisation. ISO 9000 defines a quality management system as a part of a management system with regard to quality involving the establishment of quality policy, objectives and processes to achieve quality objectives.

Figure 2.7 shows the QMS model according to ISO 9001 based on the PDCA cycle. PDCA cycle ensures continuous improvement of processes and the whole QMS in an organisation. The standard consists of 10 chapters, however, the requirements for QMS are described in chapters 4 to 10 as it is visible in the figure.

Top management plays an inevitable role in the implementation, operation, and improvement of QMS and shall demonstrate leadership and commitment with respect to QMS. Top management shall formulate quality policy and objectives, which should be aligned with the strategy of an organisation. Responsibilities and authorities in QMS shall be assigned by the top management and engagement and support of people to contribute to the effectiveness of QMS shall be ensured. Building and driving a culture of quality where leaders involve the people and empower them to make decisions with respect to customer needs, where collaboration, communication, and knowledge sharing are supported to ensure continuous improvement and fulfilment of customer needs is essential for the effective functioning of QMS.

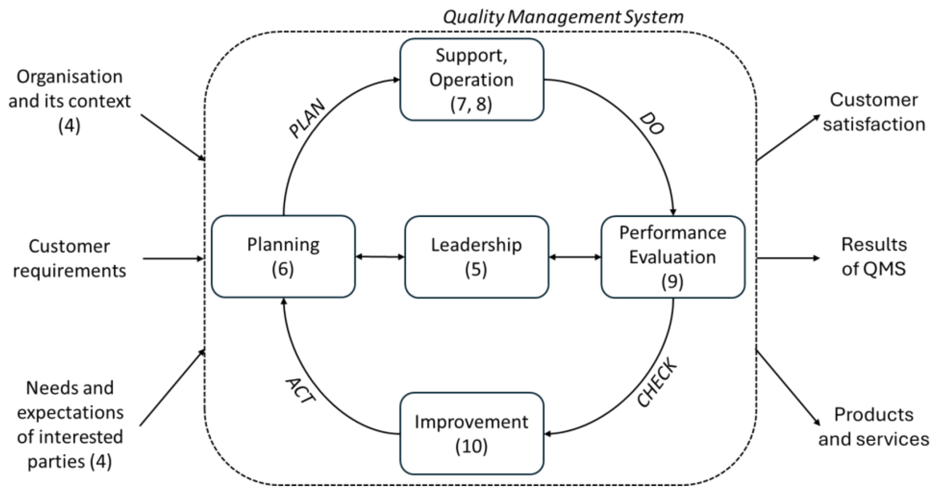

Figure 2.7. QMS model according to ISO 9001

Source: based on (ISO 9001, 2015).

The process approach is a core principle of QMS and includes establishing the organisation's QMS processes to operate as an integrated and complete system. The process approach involves the systematic definition and management of processes and their interactions to achieve intended results in accordance with the quality policy and strategic direction of the organisation. Figure 2.8 shows the individual process elements required to be defined according to the ISO 9001 requirements like inputs and output of the process, resources used in the process and control mechanisms to ensure outputs of required quality as well as effectiveness and efficiency measurement of the process as input for continuous improvement of the process. The standard incorporates risk-based thinking and requires addressing risks in the processes and taking preventive actions that are reflected in plans, procedures, control plans and checkpoints.

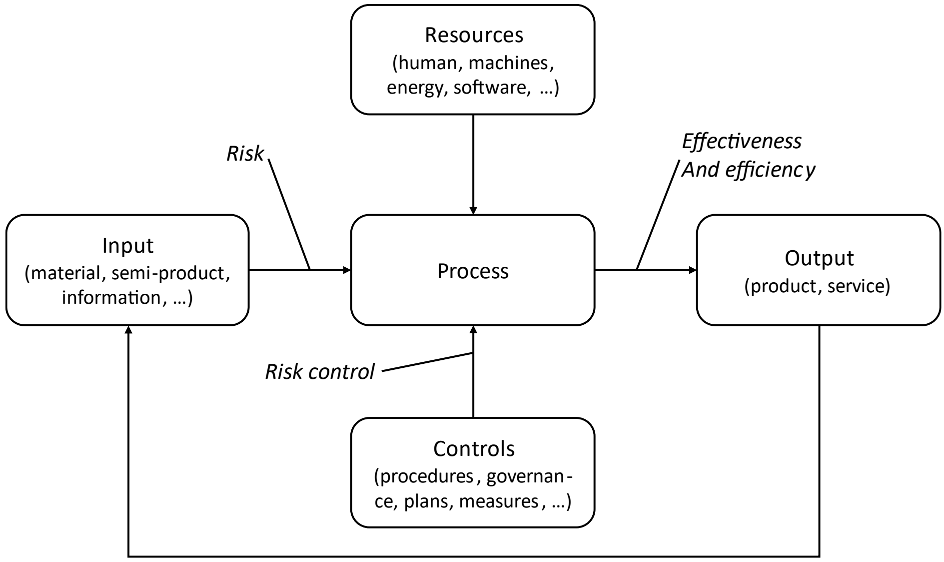

Figure 2.8. Process elements

Source: own elaboration.

The standard requires monitoring and measuring of processes and performance evaluation of the whole QMS. Control of documented information is a part of QMS and involves documented information necessary for its effective function. ISO 9001 establishes the requirements for creating, updating, and controlling documented information to support the operation of the quality management system. There are requirements for 4 mandatory documents to be controlled (scope of QMS, quality policy, quality goals, procedure for the control of outsourced processes and products) and 18 mandatory records in the ISO 9001.

The standard incorporates risk-based thinking. Risk-based thinking ensures that risks are identified, considered, and managed throughout the design, maintenance, and improvement of the QMS. Risk is defined as a positive or negative effect of uncertainty on objectives (on different levels – strategic, tactical, operational). Risk management represents coordinated activities to direct and control an organisation with regard to risk (ISO 9000, 2015). Risk is usually expressed in terms of risk sources, potential events, their consequences, and their likelihood. A source of risk is anything that may contribute to the risk event occurrence (ISO 9004, 2018). Risk can be expressed according to the following formula:

$$Risk = Likelihood\ of\ Event\ Occurrence \cdot Severity\ of\ Consequence$$

Risk-based thinking is built into the whole QMS. It makes preventive action part of the organisation's routine. Not all the processes of the QMS represent the same level of risk in terms of the organisation's ability to meet its objectives. Some need more careful and formal planning and control than others. The ISO 9001:2015 requirements related to risks and opportunities do not require a formal risk management system or concrete risk assessment techniques to be applied. However, there are requirements for the determination of risks that need to be addressed, as well as requirements for planning preventive actions and their integration into the QMS.

ISO 31000 standard provides a uniform guideline on a structured approach to risk management. It can help organisations increase the likelihood of achieving objectives, improve the identification of risks and opportunities and effectively allocate and use resources for risk treatment. The standard involves recommended steps in the risk management process like communicating and consulting, establishing the context and assessing, treating, monitoring, reviewing, recording, and reporting risk. Communication and consultation activities with external and internal stakeholders deliver valuable inputs for the risk management process. At the beginning of the risk management process, the organisation should also define the scope of its risk management activities, as the risk management process may be applied at different levels. It should also consider the external and internal context (specific environment of the activity to which the risk management process is to be applied) and define criteria of risk (the amount and type of risk that an organisation may or may not take relative to objectives and criteria to evaluate the significance of risk). The outputs from communication and consultation activities and determination of scope, context and criteria of risk are inputs for risk assessment that involves the following steps (ISO 9004, 2018):

- risk identification – recognition of the risks,
- risk analysis – understanding the risks,
- risk evaluation – comparing the results of the risk analysis with the established risk criteria.

Likelihood \ Severity	Negligible	Minor	Moderate	Significant	Severe
Very likely	Low Med	Medium	Med Hi	High	High
Likely	Low	Low Med	Medium	Med Hi	High
Possible	Low	Low Med	Medium	Med Hi	Med Hi
Unlikely	Low	Low Med	Low Med	Medium	Med Hi
Very unlikely	Low	Low	Low Med	Medium	Medium

Figure 2.9. Risk assessment matrix example

Source: own elaboration.

Based on the results of risk assessment and the identified level of the risk, the next step in the process, risk treatment, should focus on the selection and implementation of options for addressing risk. The options for addressing risk can be, e.g.:

- avoiding the risk by deciding not to start the activity,
- removing the risk source,
- changing the likelihood,
- sharing the risk.

There are various methods and tools that can be used within the steps of the risk management process to ensure an effective risk management process in QMS. The selection depends on the risk scope of risk management activity and context. ISO 31010 guides the selection and application of techniques for assessing risk in a wide range of situations, and it supplements ISO 31000 standards. It contains a range of techniques and references to other documents which describe selected techniques in more detail (ISO 31010, 2019). The standard refers to multiple techniques that, among others, include risk identification (FMEA, scenario analysis, hazard and operability studies, and others); determining sources, causes and drivers of risks (root cause analysis, Ishikawa analysis); understanding likelihoods and consequences (failure tree analysis, business impact analysis, Monte Carlo simulation); analysing dependencies and interactions (causal mapping, cross-impact analysis).

(2) Quality 4.0 in the context of the ISO 9001

Q4.0 helps to boost the implementation of the seven QMS principles in the organisation. Table 2.2 shows Quality 4.0 capabilities in connection with the seven QMS principles on which the idea of quality management system based on ISO standards is built.

In the era of Industry 4.0, QMSs become more proactive, data-driven, and integrated. By implementing Quality 4.0 principles in QMS, the organisation can unlock new opportunities to enhance its quality management processes. By implementing elements of the Quality 4.0 concept, an organisation can more easily meet and go beyond the ISO 9001 standard requirements with its culture of quality and improved processes.

During the process of QMS transformation towards QMS 4.0, the organisation should consider the elements and requirements of ISO 9001:2015 standard in the context of Quality 4.0. Tables 2.3 – 2.9 show elements and requirements of ISO 9001 included within individual chapters of this standard and Quality 4.0 aspects and elements that need to be considered (Chiarini & Cherrafi, 2023).

Table 2.2. Quality 4.0 capabilities in the context of the 7 QM principles

7 QM Principles	Quality 4.0 Capabilities
Customer focus	Flexible response to customer demands, forecasting of future needs, mass customisation, customer co-creation.
Leadership	Better resource planning and allocation, real-time performance evaluation systems, decision support systems.

Engagement of people	Connectivity, flexible communication channels, support of collaboration, knowledge sharing, culture of change and innovation, better performance evaluation.
Process approach	Real-time data access from processes, early prediction of problems, process simulation, self-learning, and self-optimization of processes.
Evidence-based thinking	Real-time data capture from multiple sources, information availability thanks to real-time data and advanced analytics, acceleration of decision-making.
Relationship management	Transparent supply chain, early detection of problems in a supply chain, value co-creation, effective communication, and cooperation with partners.
Improvement	Dynamic interaction with a market, reconfiguration of manufacturing processes according to changes in demands and business environment.

Source: own elaboration.

The following tables reflect ISO 9001 standard requirements in context with the Quality 4.0 aspects.

Table 2.3. Context of Organisation and Quality 4.0

Context of organisation	**Quality 4.0 integration**
4.1 Understanding the organisation and its context	The impact of Quality 4.0 shall be considered as an external issue affecting the QMS. Within the SWOT analysis, it might be categorised as either a threat or an opportunity, both of which have associated risks.
4.2 Understanding the needs and expectations of interested parties	The needs and expectations of relevant interested parties regarding the Quality 4.0 shall be determined. The organisation should use CPS, advanced platforms, and applications to determine the requirements of relevant interested parties.
4.3 Determining the scope of the QMS	–
4.4 QMS and its processes	Connection and integration of QMS processes (horizontal, vertical) and real-time data capturing, and analysis (advanced big data analysis) shall be ensured for evaluation and improvement of processes.

Source: own elaboration.

Digitalization and so-called Quality 4.0 should be considered an important issue and should be taken into account from the perspective of the needs and expectations of interested parties. Quality 4.0 principles and tools should be applied to establish, implement, maintain and improve QMS processes.

Table 2.4. Leadership and Quality 4.0

Leadership	Quality 4.0 integration
5.1 Leadership and commitment	Top management shall demonstrate leadership with respect to the integration of Quality 4.0 into QMS and promote Q4.0 principles that will be reflected in policy and goals. Top management shall ensure resources for Quality 4.0 integration and develop a culture supporting Quality 4.0.
5.2 Policy	Quality policy should include Quality 4.0 principles that should be aligned with the overall digital strategy of the organisation.
5.3 Organisational roles, responsibilities, and authorities	Top management shall ensure that responsibilities and authorities relating to Q4.0 are assigned, communicated, and understood, specifically for integration of Q4.0.

Source: own elaboration.

Leadership plays an important role in integrating Quality 4.0 principles and tools into the existing QMS systems of organizations.

Table 2.5. Planning and Quality 4.0

Planning	Quality 4.0 integration
6.1 Action to address risks and opportunities	When planning Quality 4.0 integration the organisation should determine risks and opportunities that need to be addressed. The organisation shall plan actions to address these risks and opportunities and plan how to implement these actions into QMS.
6.2 Quality objectives and planning to achieve them	Organisation should establish Quality 4.0 goals for relevant functions, levels and processes needed for QMS.
6.3 Planning of changes	The needed changes to QMS related to Quality 4.0 integration should be carried out in a planned manner.

Source: own elaboration.

Risks and opportunities of Quality 4.0 should be considered in the planning of QMS and related goals and plans should be defined. On the other hand, it helps to force preventive or even prescriptive approaches to QMS.

Table 2.6. Support and Quality 4.0

Support	Quality 4.0 integration
7.1 Resources	The organisation should determine and provide resources for the integration of Quality 4.0: people, infrastructure (CPS, enabling technologies, autonomous robots, AI, intelligent platforms, and applications), environment for the operation of processes (sensors enabling real-time monitoring of environment and control), monitoring and measuring resources (in-line measurement devices, remote calibration, online calibration information), organisation knowledge (systems integration help to transfer knowledge in the organisation).
7.2 Competences	The organisation should determine the necessary competence for Quality 4.0 and ensure that persons are competent on the basis of appropriate education and training.
7.3 Awareness	The organisation should ensure that persons are aware of Quality 4.0 reflected in policy, and objectives and it should raise awareness of persons' contribution to Quality 4.0.
7.4 Communication	The organisation shall ensure vertical, horizontal and end-to-end integration and automated ways of communication relevant to QMS – data collected over the IoT and specification of what, when, how and whom to communicate and display.
7.5 Documentation control	The organisation should ensure the digitalisation of documentation and online access to documents reflecting the current status. Automated document control system – workflow automation in routing, review, approval, change, revision, and distribution of documentation shall be ensured.

Source: own elaboration.

For effective application of Quality 4.0 principles it is necessary to allocate resources needed. It supports communication processes and makes the documentation control to be carried out in a much more effective manner.

Table 2.7. Operation and Quality 4.0

Operation	Quality 4.0 integration
8.1 Operation planning and control	The organisation shall ensure the integration of information systems (vertical, horizontal, end-to-end) for the dynamic establishment of criteria for processes, products, and services and resources needed based on real-time customer requirements. Organisation should use Quality 4.0

	tools for the prediction of potential risks in processes and for control of processes.
8.2 Requirements for products and services	Integration of systems shall be ensured (vertical, horizontal, end-to-end) and IoT, platforms, web applications should be used to communicate with customers. In determining changing and statutory and regulatory requirements advanced tools like AI and Chatbots can be used. On the basis of requirements, the organisation can use advanced Quality 4.0 tools to conduct a feasibility study to determine whether it is able to meet requirements for products and services.
8.3 Design and development of products	PLM software solution should be implemented and integrated with QMS and ERP that help to streamline design and development process. PLM tools support real-time collaboration while interfaces between persons involved are defined. Design and development changes shall automatically lead to end-to-end changes, from customer interfaces to products in the field, including production, logistics processes.
8.4 Controlling externally provided processes	The organisation shall implement principles of horizontal integration for control of externally provided processes, products, and services. Integration of an organisation's ERP modules with systems of external providers enables the exchange of data and information in real-time. Horizontal integration enhances traceability in the supply chain and ensures real-time monitoring of external providers' performance and their control.
8.5 Production and service provision	The organisation shall ensure the integration of systems (CRM, QMS, MES) in the organisation for real-time control of processes based on the required characteristics of products and services and defined results to be achieved. For the identification of outputs and their traceability, specific Quality 4.0 enabling technologies like sensors and RFID shall be used to identify the status of outputs. A similar shall be used to identify property belonging to customers and have it under control. The end-to-end integration of systems, CPS, and IoT shall be applied to an effective meeting of post-delivery activities. Data collection shall be conducted over IoT from products and services, e.g., product maintenance should be performed based on data. Integration of systems and IoT technology ensures dynamic control of changes in production and service provision.
8.6 Release of products and services	The organisation shall implement Quality 4.0 technologies (e.g. sensors, machine vision, AI) to enable automated in-process and final inspection.

8.7 Control of nonconforming products	Nonconforming outputs shall be automatically detected and identified using technologies such as RFID and smart sensors that can automatically change their identification status. Data related to nonconforming outputs shall automatically reach the people responsible for the appropriate actions and decisions or the customer.

Source: own elaboration.

Quality 4.0 principles and tools affect the operation of QMS and should be applied according to goals and plans defined on the strategic level.

Table 2.8. Performance Evaluation and Quality 4.0

Performance evaluation	Quality 4.0 integration
9.1 Monitoring, measurement, analysis, and evaluation	Monitoring and measurement should be conducted automatically thanks to enabling technologies. Data collected from IoT should be analysed by machine learning, AI.
9.2 Internal audit	Workflow automation should be done through software, data analytics tools, robotic process automation (RPA), and AI within the internal audit lifecycle (planning, conducting, evaluation and improvement).
9.3 Management review	Decision support systems equipped with intelligent tools should be used to help management make decisions.

Source: own elaboration.

Quality 4.0 technologies help to perform monitoring, measurement and analysis of QMS and management review processes more effectively and efficiently.

Table 2.9. Improvement and Quality 4.0

Improvement	Quality 4.0 integration
10.1 General	Opportunities for improvement shall be determined through both machine and human actions.
10.2 Nonconformity and corrective action	Advanced analytics should be used to determine the root causes of nonconformities, and if similar nonconformities exist or could potentially occur. AI can be used to help identify optimal corrective action to be taken.
10.3 Continual improvement	The organisation shall continually improve the suitability, adequacy and effectiveness of the QMS and its integration within the organisation and entire value chain as well as the utilization of intelligent technologies.

Source: own elaboration.

Quality 4.0 technologies help to perform monitoring, measurement and analysis of QMS and management review processes more effectively and efficiently.

(3) Transformation towards QMS 4.0, benefits and barriers

Successful implementation of Quality 4.0 principles and tools and their integration with the QMS of an organisation should be systematically managed as they will have a huge impact on QMS's existing practices. Many quality professionals are being challenged with transitioning QMS to a technology-driven QMS 4.0. QMS 4.0 is not an “off the shelf” product that can be bolted onto an old QMS solution; rather, it is a phase through which quality management is progressing and a means by which organisations can re-examine what they do and how they do it. It is the next development stage of QMS, which results from technological advancements that need to be followed. For the successful transition of the QMS, several steps need to be considered.

Achieving quality excellence through QMS 4.0 requires a leadership commitment. Implementation of Quality 4.0 has to be a strategic decision of the top management. Without a clear digital strategy supporting transformation throughout the organisation, the development of QMS towards QMS 4.0 cannot be successfully realised. The transformation strategy has to be a part of the overall digital strategy of an organisation and must contribute to its fulfilment. Many organisations have implemented partial solutions, and intelligent tools are applied to selected processes (mostly production) or sub-processes. Still, in many cases, a holistic approach to the implementation of QMS 4.0 is often missing due to the lack of top management support and the lack of an existing or unclear QMS 4.0 and overall strategy.

The organisation should clearly define QMS 4.0 goals and align them with the overall strategic goals of an organisation. It should prioritise which dimensions and components of QMS 4.0 to focus on to achieve the set goals.

When planning the integration of QMS 4.0 in the organisation, an assessment of the current state should be conducted, which helps to identify the organisation’s readiness for the QMS digital transformation.

Comparing the results with the desired state defined by the set QMS 4.0 goals helps to determine the gap. Key areas of assessment can cover quality processes, data flow and management, technology infrastructure, organisational culture, governance and risk management, and competencies.

Assessment of the current state helps to determine the size and impact of change related to the transition from QMS to QMS 4.0 principles and elements and their consequences. For example, adoption of sensors detecting heat, vibration, noise on machines will change how the maintenance will be scheduled and performed and changes in the maintenance process will be necessary.

Organisations should create a comprehensive plan that includes targets, metrics, milestones, timelines, and resource allocation to ensure a smooth transition towards QMS4.0. Organisations should establish the IT infrastructure needed to support the new technologies. They should plan training activities to ensure the required competencies. Development of a culture of learning in which leadership support, communication, and cross-functional sharing of insights and processes is key need to be realized.

In this stage, the organisation executes strategic plans to achieve targets within the established timeframe and with assigned resources to make a successful digital transition of QMS, incorporating Q4.0 principles and elements.

Organisations should systematically collect and analyse data to assess the progress of the QMS transition against the set goals, and targets. The data collected during monitoring is used to track progress and identify areas that need improvement. Evaluation of the performance of QMS4.0 against its goals, objectives, and targets is necessary to ensure improvement.

ISO 9001:2015 standard provides a framework for ensuring quality processes are in place and continuous improvement is running. It helps organisations enhance customer satisfaction through the effective application of a system and the operation of processes to ensure conformity and improvement. Quality 4.0 principles and tools can be integrated with the QMS to create a powerful tool for achieving quality excellence and innovation. The integrated approach leading to QMS 4.0 can yield significant benefits like:

- optimisation of processes,
- increased effectiveness and efficiency of processes,
- reduced costs of poor quality,
- increased traceability and audibility,
- enhanced customer orientation,
- increased flexibility,
- fostered culture of learning and continues improvement,
- accelerated and successful innovations.

External environment significantly affects the organisation and results of QMS. Therefore, the ISO 9001 standard requires the understanding context of an organisation and determining external and internal issues that are relevant to the organisation's purpose and strategic direction of organisation and affect the intended results of QMS.

Industry 4.0 phenomenon as an external factor needs to be taken into account. Organisations have to consider the potential benefits and risks of digital transformation. It will affect the organisation's strategy, structure, processes, and people. It will impact every part of an organisation and, therefore, also the organisation's QMS. Implementation of QMS 4.0 as a part of I4.0 describes a process of change through which the quality management practices undergo. This change includes the increased digitisation of organisations and their processes. It will affect the context in which a QMS operates, how it is set up and documented, the resources needed, external and internal communication, processes involved within the entire value chain and, of course, the associated risks and opportunities.

Organisations that are not willing to undergo digital transformation should consider related risks that might include loss of competitiveness and customers due to insufficient fulfilment of customer requirements, insufficient flexibility, lack of innovation, and insufficient effectiveness and efficiency of processes in comparison to competition.

Among the main barriers that avoid integration of Q4.0 into existing QMS are:

- high investment costs,

- insufficient commitment of top management,
- missing a clear Q4.0 strategy as a part of I4.0 strategy,
- lack of competencies in an organisation,
- existing organisational culture that is not supportive,
- concerns regarding cybersecurity,
- the return-on-investment horizon is not clear.

Organisations that are not willing to undergo digital transformation should consider related risks that might include loss of competitiveness and customers due to insufficient fulfilment of customer requirements, insufficient flexibility, lack of innovation, and insufficient effectiveness and efficiency of processes in comparison to competition.

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Chapter 3. Implementation of quality management 4.0 in the organisation

3.1. Digital transformation

(1) Customer convenience

As we indicated in chapter 2, implementing Quality 4.0 is situated within the much larger digital transformation (DT) framework, which requires a significant restructuring of business models (Lui & Shum, 2022). It is important to distinguish between three interconnected concepts: digitisation, digitalisation, and digital transformation. These terms are not synonymous, and understanding their differences is crucial for the successful implementation of Quality 4.0 and, correspondingly, digital transformation.

Digitisation refers to converting analogue data into a digital format that computers can process. This process forms the basis of a large part of our digital world, facilitating the transmission and comprehension of information. On the other hand, digitalisation involves applying digital technology to change business models, optimise processes and create additional customer value. This is a step beyond digitisation, enhancing user experience and fostering efficiency in business operations. The digital transformation describes a holistic change in business practices across all domains. It incorporates new business models that capture and create value, leveraging digital technologies for cross-border stakeholder interactions. Hence, DT transforms the organisation to maximise existing competencies and develop new ones (Lui & Shum, 2022).

There are two primary approaches to digital transformation: the technology-driven approach, which predominantly relies on the functions of software and technologies, and the people-driven approach, which focuses on human interaction and culture. In the context of quality management, the latter approach is more appropriate. The people-driven approach fosters employee involvement and encourages a culture of transformation, which are necessary elements for successfully implementing Quality 4.0. While technology is a crucial component of Quality 4.0, it must be used as an instrument of change, not the driving force. Organisations must strive to develop a culture that encourages people to explore new possibilities, express their ideas freely, and engage with the DT process. The people-driven approach to DT better aligns with Quality 4.0, emphasising workers' education, fostering a culture of change, and leveraging technology as a tool, not the goal (Lui & Shum, 2022). The road to Quality 4.0 is steeped in digital transformation, but at its heart, it remains a journey people navigate.

The digital era creates new opportunities for businesses ready to harness their potential through digital transformation (Furr et al., 2022). Quality and customer experience optimisation are crucial to achieving a successful DT. However, focusing solely on technology can lead organisations astray. As the beneficial effects of DT rely significantly on how it impacts a business's internal processes (Kretschmer & Khashabi, 2020), corporations must understand that digital transformation is not just about technology. It is concerned with fundamentally changing the way businesses operate and deliver value to customers.

Digital transformation points to a broad array of strategies and business models, all facilitated by new information technologies. Simply put, DT is not a one-size-fits-all strategy. It is not an end state but a strategic choice unique to each organisation (Furr et al., 2022). Each entity must determine what customer convenience means in their unique circumstances concerning their products and services. Unfortunately, many organisations face a gap between strategy formulation and implementation. This is often due to a lack of leadership vision regarding digital transformation (Ramadan et al., 2023). Organisations should approach DT with a clear understanding of the challenges of accelerating technological change, commitment levels among employees, the skills possessed by tech players, and other environmental factors. Digital transformation necessitates business model innovation. This involves creating new value systems or modifying existing ones. This approach challenges organisations to rethink their operations, customer relationships, and value propositions (Chwiłkowska-Kubala et al., 2022). However, adjustments to existing business patterns are necessary for DT to have a positive impact (Singh et al., 2021).

Ultimately, achieving the highest customer convenience is synonymous with successful digital transformation. It merges seamlessly with quality management and the principles of Quality 4.0. Ultimately, every exercise in digital transformation should aim to design compelling experiences for the customer (Lui & Shum, 2022). Businesses can unlock unimagined value by refocusing on the customer experience rather than technological tools.

The example ideas that increase customer convenience are:

- including the importance of customer convenience in driving digital transformation,
- understanding and meeting customer expectations in the digital age,
- offering seamless and personalised customer experiences across all touchpoints,
- leveraging digital tools and technologies to enhance convenience and accessibility,
- optimising website and mobile app interfaces for ease of use and navigation,
- implementing self-service options and automation to minimise customer effort,
- integrating multiple channels and touchpoints to provide a unified and consistent experience,
- using data analytics and customer insights to anticipate and fulfil customer needs,
- investing in robust customer relationship management (CRM) systems to track and manage customer interactions,
- ensuring secure and user-friendly online payment and transaction processes,
- empowering customers with real-time access to information, order tracking, and support,
- utilising chatbots and AI-powered virtual assistants to provide instant and efficient customer support,
- emphasising agile and iterative development to quickly respond to changing customer needs,
- collaborating with partners and third-party platforms to extend convenience and enhance offerings,

- measuring and monitoring customer satisfaction and loyalty metrics to continually improve convenience,
- cultivating a customer-centric culture throughout the organisation to drive digital transformation efforts.

The importance of customer convenience in driving digital transformation cannot be understated. As businesses reinvent their operations with digital tools and technologies, customer convenience is a central force propelling this change. Today's customers expect fast, seamless, personalised experiences that align with their needs and preferences. It is not just about delivering products or services but about crafting an effortless, enjoyable and effective customer journey. Understanding and meeting customer expectations in the digital age is crucial. Digital technologies have changed how customers interact with businesses. They now expect instant service, personalised attention and the flexibility to engage with companies through various platforms. Businesses that cater to these changing expectations are poised to thrive, while those that fail to adapt risk being left behind.

Businesses can elevate their brand appeal and cultivate loyal customers by offering seamless and personalised customer experiences across all touchpoints. This involves optimising website and mobile app interfaces for intuitive navigation and ease of use. Furthermore, integrating self-service options and automation can minimise customer effort, creating a more convenient experience. Digital tools are increasingly being leveraged to enhance convenience and accessibility. Businesses are integrating multiple channels and touchpoints to offer a unified customer experience. Data analytics and customer insights are used to anticipate customer needs, while robust customer relationship management (CRM) systems track and manage customer interactions.

In e-commerce, secure and user-friendly online payment and transaction processes are fundamental for customer convenience. Equally important is the empowerment of customers with real-time access to information, order tracking, and support. Innovations like chatbots and AI-powered virtual assistants are increasingly helping businesses provide instant and efficient customer support. Agile and iterative development are emphasised to quickly respond to changing customer needs, with a dedication to cultivating a customer-centric culture throughout the organisation.

Partnerships with third-party platforms and collaborations can further extend convenience, enhancing offerings and improving the customer experience. Businesses should continually focus on measuring and monitoring customer satisfaction and loyalty metrics, utilising the insights gathered to refine their strategies and processes. The pursuit of customer convenience is at the heart of digital transformation. It is about more than just leveraging technology. It is about reinventing business models to put the customer first. By doing so, businesses will be well-poised to thrive in today's dynamic digital arena.

(2) Elements of digital transformation

Digital transformation has become an imperative for businesses across industries, redefining traditional business models and operations to capitalise on technology-enabled possibilities. Every organisation is unique – in its business operations, culture, people, and existing technology landscape – and thus demands a customised approach to DT. This transition is invariably more challenging for well-established companies with intricate processes embedded over time. The sheer complexity, depth and width of their operations make this digital migration a nuanced affair, in contrast to the relatively more straightforward transformation journey for start-ups. Unlike established businesses, start-ups essentially have a clean slate, unencumbered by legacy systems or processes, enabling them to embrace digital at the core of their operations from inception (Kozak-Holland & Procter, 2020).

Irrespective of the company size or industry, the pivotal factor in the success of any digital transformation lies in its people. Employees, the enactors of this transformation, must be at the heart of DT strategies. It is critical to foster an environment of trust, ensuring transparency in the transformation process. The credibility of the leadership is inevitably a strong determinant of success as they navigate the organisation through this business overhaul. Their role in articulating a clear vision, facilitating skills enhancement, and driving engagement is indispensable for effective change management. Undoubtedly, digital transformation presents an enormous opportunity for businesses to innovate, improve efficiency and gain a competitive edge. However, this journey is intricate, requiring an intricate balance of technology integration, customer-centricity, data management, and people management. Proceeding on this path without understanding its various facets can lead to half-baked execution and sub-optimal outcomes. Each element of DT plays a critical role; in concert, it can drive a successful transformation (Abbu et al., 2022). Table 3.1 shows the elements of digital transformation.

Table 3.1. Elements of digital transformation

Element	Description
Technology adoption	Digital transformation requires organisations to adopt and integrate emerging technologies such as cloud computing, artificial intelligence, data analytics, and the Internet of Things (IoT) into their operations and processes.
Customer-centricity	Shifting focus towards understanding and meeting customers' evolving needs and expectations through digital channels and personalised experiences.
Data-driven decision making	Leveraging data and analytics to drive insights, make informed decisions, and optimise business processes and strategies.
Organisational agility	Developing a flexible and adaptive organisational culture that embraces rapid experimentation, continuous learning, and quick iteration to respond to changing market conditions.
Process optimisation	Streamlining and automating existing processes to improve efficiency, reduce costs, and eliminate unnecessary manual tasks.
Talent development	Building a digitally skilled workforce through training, upskilling, and hiring individuals with expertise in digital technologies and innovation.
Ecosystem collaboration	Collaborating with external partners, startups, and other industry players to foster innovation, explore new business models, and drive collective growth.
Cybersecurity and data privacy	Strengthening cybersecurity measures to protect sensitive data and ensure compliance with data protection regulations.
Customer insights and personalisation	Utilising customer data and advanced analytics to gain actionable insights and deliver personalised experiences that drive customer loyalty and revenue growth.
Change management	Implementing effective change management strategies to ensure buy-in, enthusiasm, and adoption of digital transformation initiatives among employees at all levels.
Digital culture and leadership	Developing a digital-first mindset across the organisation and nurturing digital leadership to champion and drive the transformation efforts.
Continuous innovation	Encouraging a culture of innovation, experimentation, and continuous improvement to adapt and stay ahead of the rapidly evolving digital landscape.
Integration and connectivity	Ensuring seamless integration and connectivity between different systems, departments, and stakeholders to enable real-time communication and collaboration.
Customer journey mapping	Mapping and understanding customer touchpoints, pain points, and expectations across various digital channels to optimise the end-to-end customer experience.
Scalability	Building scalable digital infrastructures and solutions that can adapt to future technologies and market disruptions.

Source: own elaboration.

(3) Digital transformation impact on Quality 4.0

Quality 4.0 represents a new paradigm in managing and achieving outstanding quality standards. It requires a take-off from the conventional methodologies with comprehensive use of the accrued knowledge from previous quality standards while recognizably integrating the revolutionary implications of digital transformation. Technology is just an enabler and an accelerator. It cannot replace the necessity of other crucial elements, such as customer orientation or employee involvement. Ignoring these prerequisites would inversely lead to a project's failure rather than success (Alzahrani et al., 2021).

However, at the heart of Quality 4.0 lies a dual-natured approach. On one hand, it adopts an avant-garde outlook towards data management by revolutionising how data is captured, processed and analysed. Despite radical technological advancements, achieving a quality-oriented organisation necessitates a more evolutionary approach than a revolutionary one, similar to the growth seen through Total Quality Management (Sony et al., 2021).

Though with a more sophisticated approach, TQM's fundamental principles remain important in Quality 4.0. Quality is not achieved through revolutionary tactics or drastic process reengineering. Instead, it must be nurtured and fostered through consistently advancing strategies and processes. As we delve into the core tools of Quality 4.0 enabled by digital transformation, this delicate balance between revolution and evolution becomes increasingly apparent (Zonnenshain & Kenett, 2020). Table 3.2 presents chosen Quality 4.0 tools and methods enabled in the company's digital transformation processes.

Table 3.2. Quality 4.0 tools and methods enabled through digital transformation

Tool/Method	Description
Enhanced data collection and analysis	Digital transformation enables the collection of vast amounts of data from various sources, such as IoT sensors, machines, and customer interactions. This data can be used to gain insights into quality performance, identify trends, and make data-driven decisions for process improvement in Quality 4.0 initiatives.
Real-time monitoring and control	Digital technologies enable real-time monitoring of quality metrics, such as defects, anomalies, and process variations. This allows for immediate detection and mitigation of quality issues, reducing the risk of product defects and customer complaints.
Predictive maintenance	Digital transformation enables the implementation of predictive maintenance practices, where data analysis and machine learning algorithms are used to identify potential equipment failures or quality deviations in advance. This approach helps to avoid costly downtime, ensures uninterrupted production, and improves product quality.
Process automation	Automation plays a critical role in Quality 4.0, where digital technologies such as robotic process automation (RPA) and intelligent automation can optimise and standardise quality control

	processes. Automation reduces human errors, accelerates response times, and improves overall process efficiency and effectiveness.
Improved supply chain and supplier management	Digital transformation facilitates end-to-end visibility and traceability across the supply chain, enabling organisations to identify and address quality issues at every stage. It also allows for better integration and collaboration with suppliers, ensuring that quality requirements are met consistently.
Continuous improvement and innovation	Digital transformation provides the tools and capabilities for continuous improvement and innovation in quality management. With real-time data and analytics, organisations can identify areas for improvement, test new quality initiatives, and iterate quickly to continuously enhance quality performance.
Employee engagement and empowerment	Digital transformation empowers employees by providing digital tools and platforms to collaborate, share knowledge, and contribute to quality initiatives. This enhances employee engagement, as they can actively participate in problem-solving and decision-making processes, leading to improved quality outcomes.
Advanced analytics and AI	Digital transformation enables the utilisation of advanced analytics techniques, such as machine learning and artificial intelligence, to analyse complex quality data and detect patterns or anomalies. By leveraging AI, organisations can predict quality issues, optimise processes, and ensure consistent quality across products and services.
Customer-centric quality	Digital transformation allows organisations to gather and analyse customer feedback and sentiment data in real-time, enabling them to understand customer preferences, expectations, and pain points. This data-driven approach helps organisations deliver products and services that meet or exceed customer expectations, enhancing overall quality and customer satisfaction.
Regulatory compliance and risk management	Digital transformation helps organisations ensure compliance with industry regulations and quality standards. By digitising quality documentation and implementing robust risk management systems, organisations can streamline audits, track non-conformities, and proactively address quality risks.

Source: based on (Paraschivescu, 2021).

3.2. Economic aspects of implementing quality management

(1) Quality and economics

Many publications on quality management ignore the economic aspect. The reader may then get the impression that quality is a noble idea, detached from the realities of company management. Meanwhile, the economic benefits of achieving high quality are measurable and significant. Research in this area has been conducted in many countries since the 1970s. At that time, companies recorded quality costs that often exceeded 30% of sales value (Moyer & Gilmore, 1979; Wheelwright & Hayes, 1985). At the turn of the 20th and 21st centuries, this level was much lower and reached up to 20% (Campanella, 1999; Dale & Plunkett, 1999). However, at the beginning of the 21st century, the European Commission estimated low-quality costs in the construction industry at 5-10% of the contract value without considering social costs (Sellés et al., 2008). However, losses due to poor quality are not limited to companies or investors. Research conducted in Great Britain in 2007-2011 on the population of enterprises generating a total of over 80% of GDP showed that if it were not for the use of quality programs in enterprises, the value of the Gross Domestic Product would be lower by 6.02% (Solomon & Hogan, 2012).

The organisation's activities require incurring the costs of quality assessment, returns, complaints, and settlement proceedings. Using a pro-quality approach by all contractors reduces these costs and leads to mutually beneficial cooperation based on trust. Mastering the processes leads to an increase in the probability of achieving the intended results. As a result, it becomes possible to limit quality control only to critical places or those where processes have not yet been fully mastered.

Eliminating some control activities and reducing the number of tasks repeated due to insufficient quality directly shortens the task completion time. A decrease in costs related to repeat work or complaints while the product price remains unchanged leads to an increase in the margin. This also translates into long-term effects. With a better image, high customer satisfaction and confidence in quality, an organisation can charge a higher rate for its products and services.

Quality costs are a measure that allows for a precise economic assessment of projects and the organisation's activities. Their recording and analysis should be the basis for making quality-oriented decisions. The idea of quality costs was first presented by J.M. Juran in 1951. He defined quality costs as all costs that an organisation would not incur if there were no non-conformities (Juran & Godfrey, 1999). Quality costs evaluation was intended to complement statistical methods. It turned out to be a good tool supporting management's decision-making. It presents results in monetary terms and is compatible with economic evaluation methods used in this area. It provides management with information on the functioning of the quality system presented in a synthetic and understandable form. Juran postulated the reduction of costs that do not create added value and losses related to low-quality products.

The first structured approach to quality costs was proposed by A.V. Feigenbaum, who demonstrated a link between expenditure on prevention and the reduction of assessment and defect costs. The development of these relationships led to the creation of the PAF model, which includes prevention, assessment, and internal and external failures as quality costs (Feigenbaum, 1961). In 1979, P.B. Crosby proposed a more radical division into the costs of compliance and non-compliance. Decreasing non-compliance costs may indicate an increase in an organisation's quality. This resulted from his previous assumptions that quality is compliance with requirements and the quality standard is "zero defects". This approach was the basis for the later-developed process cost model (PCM) (Crosby, 1979).

The PAF model divides quality costs into three groups: costs of prevention, research and evaluation, and failures. It is most common in the literature. It takes into account costs directly related to the quality function (e.g. functioning of quality controllers, costs of employee training), indirectly related costs, costs of an excessive number of elements manufactured, scrapped materials, repeated activities, searching for solutions to quality problems (BS 6143-2, 1990). In addition to the obvious costs, easy to observe and measure, the mentioned categories include a large group of hidden, non-obvious, and sometimes difficult-to-measure costs, e.g., reduced productivity, overtime, additional control equipment, time spent on solving problems, costs of expedited shipments to the customer, extensive complaints, having complaints department, loss of reputation, loss of sales markets (Sellés et al., 2008; Yang, 2008). The main measures are the total cost of quality, the total cost of defects, the costs of control, and the costs of preventive actions. They are related to labour costs or sales value (BS 6143-2, 1990).

Aggregating quality costs at the entire enterprise level facilitates and shortens the analysis, reducing the required amount and detail of data. It is usually based on monthly reports and does not require significant employee involvement. Its disadvantage is that it makes finding the causes of the problem challenging. Minor problems solved within one calculation period are often omitted from the records. The picture is blurred by averaging the meter values, and it is not easy to objectively and accurately measure some of the values used in the model. Criticism of the PAF model also concerns the connections between its components. It assumes that achieving 100% good quality is impossible for technological reasons and that trying to achieve this value will result in total quality costs rising to infinity. Nowadays, however, it is believed that the appropriate model is one that allows for 100% quality of production at finite costs (Schneiderman, 1986).

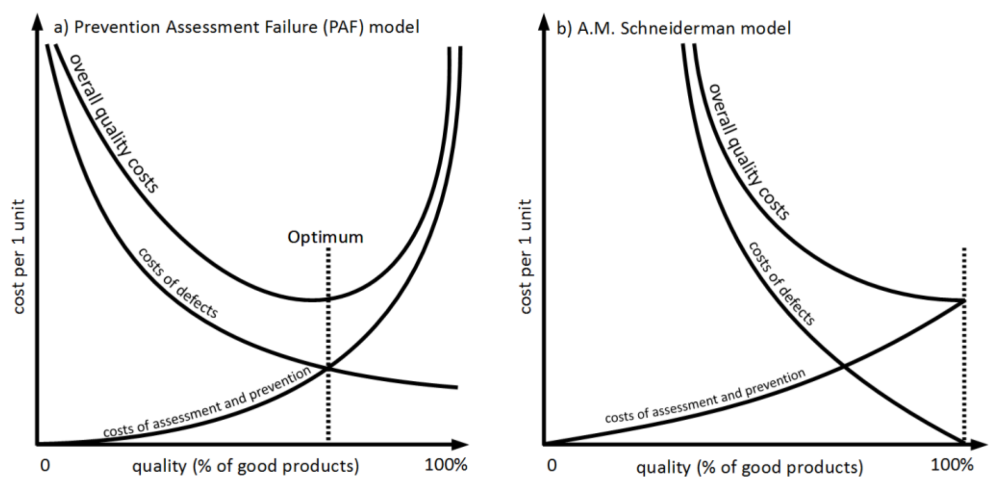


Figure 3.1. Comparison of the PAF and AM Schneiderman models

Source: based on (BS 6143:1981; AM Schneiderman 1986).

Initially, it was assumed that the optimal level of quality costs occurs with reliability below 100% (Figure 3.1a). However, as technology and automation progress, it has been noticed that the optimum level is associated with an increasingly lower percentage of defects. Therefore, nowadays, it is believed that it is theoretically possible to achieve complete reliability at a finite value of costs (Figure 3.1b) (Juran & Godfrey, 1999). It should be emphasised that the level of 100% compliance of products is still unattainable in practice. Schneiderman's model only indicates, based on research, that the costs of achieving this level do not tend to infinity.

Schneiderman's proposal is one of the variants of the Process Cost Model (PCM) proposed by Crosby. In PCM, costs are identified for all components of each process (employees, equipment, materials, environment), which are then classified as compliance or non-compliance costs. Compliance costs are defined as the lowest possible costs that must be incurred for the fully effective implementation of the process (in accordance with the specifications). However, the costs of non-compliance are the result of all manifestations of inefficiency in the use of resources, processing errors and losses. Both categories should be improved, with the organisation's management having the most significant influence on them (BS 6143-1, 1992). Using a process approach to examining quality costs allows for shortening the distance between where the problem arises and the place where decisions are made, thus, for more efficient implementation of continuous improvement.

The main objection to the PCM model is the discretionary nature of qualifying costs, which had an extensive classification in the case of PAF. However, from the perspective of the objectives of implementing quality cost accounting, this objection loses significance. For management, it is more important to efficiently identify the causes of increased costs and eliminate them than to classify them precisely. The second objection relates to Crosby's perception of quality, on which the PCM model is based. Compliance with specifications is a narrowing of the modern understanding of quality. When applying a process approach to quality costs, identifying costs related to lost opportunities and damage to the environment and society is much more difficult. It is also challenging to analyse costs that are incurred separately from the place and time of their cause, e.g. costs of court proceedings and compensation (Tang et al., 2004).

The division into compliance and non-compliance costs used in the PCM model assumes that no loss occurs as long as the processed element is within tolerance limits. Analysis of a series of consecutive operations may show that the element was compliant at each stage, but due to the sum of the deviations from the individual operations, the entire product is non-compliant. Taguchi drew attention to this when formulating the quality loss function and the concept of loss for society. In his opinion, any deviation, even within the tolerance limits adopted by the manufacturer, causes a loss at further stages of production, in sales, at the customer's or when disposing of the product. A quadratic function with a minimum determines the amount of loss at the point of full compliance with the specification. Losses increase when the compliance level drops according to the quadratic function. The goal should, therefore, be not to reduce the number of products exceeding tolerance limits but to minimise any deviations (Taguchi & Clausing, 1990).

The use of the quality loss function to analyse quality costs allows for the estimation of hidden and difficult-to-measure costs, a more reliable economic assessment of the profitability of undertaking improvement activities, measurement of the progress in implementing improvement activities, as well as an assessment of the degree of achievement of pro-quality goals (Albright & Roth, 1992). Moving from PAF or PCM-based quality costing to a loss function immediately increases quality costs because there is no way to hide deficiencies within tolerance bands that are too wide. Taguchi's proposal does not create a separate model for assessing quality costs but should be treated as improving the process model.

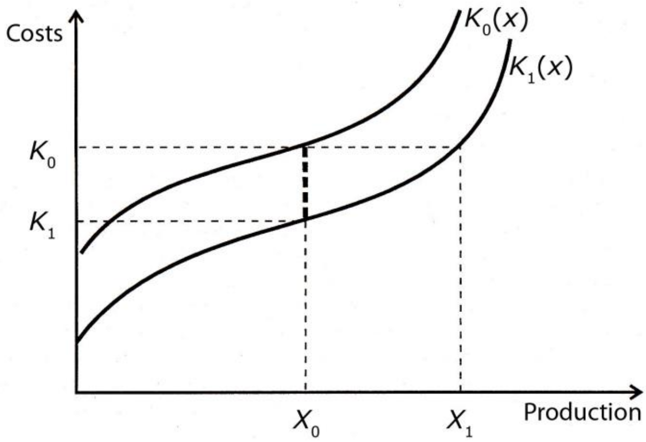
(2) A broad approach to quality costs

The modern understanding of quality costs, also as costs for society, forces organisations to redefine the concept and method of measuring the profitability of pro-quality activities. It was initially analysed in the context of production defects within the production department; then, the analysis was extended to include the activities of research and development, marketing, sales, service and other departments. The modern approach even covers the problems of product disposal after its use. This aspect is essential in sustainable project management.

It should be emphasised that extending the analysis of quality costs beyond the company's boundaries was already raised by Gryna, who proposed considering consumer costs. Polish researchers extended this proposal to include the social costs of quality, which, in addition to the costs of quality borne by the producer, also include the costs of quality borne directly by sales intermediaries and the consumer. Ultimately, the costs of quality are borne by society (Wawak, 1980). Further research led to the development of accounting methods for these costs related to the product life cycle. The drawn account of social costs of quality covers a product's production and use chain, from raw material producers through their processing into a product, trade, up to the end user. At the detailed level, the following are distinguished for producers: costs of prevention, assessment and failures, and opportunity costs. However, the categories of costs incurred by trade and users are differentiated depending on the product characteristics (Wawak, 1995). Unlike Taguchi's proposal, it is based on the deterministic PAF model, which provides a detailed classification of quality costs and cost measurement at the point of origin.

The change in approach was forced by new consumer expectations, competition and increasingly strict legal regulations. At the same time, there is a noticeable differentiation between the quality classes of the products offered by producers, adapted to the financial capabilities of consumers and the legal provisions applicable in individual countries. For example, car manufacturers have cheaper brands that use cheaper, easier-to-produce technologies, usually older and less efficient. Lowering the price of a product is possible by reducing quality costs. Investing in design quality makes it possible to recognise the market and customer needs (Oyrzanowski, 1997). As a result, although the designed product does not have all the functions of its more expensive counterpart, it meets customer expectations. It is characterised by a low level of social costs of quality for its level of quality.

Effective implementation of a quality program leads to a reduction in quality costs and thus a reduction in the total production costs (Figure 3.2). With the exact total costs, the company can increase production ($X_0 \rightarrow X_1$) or produce an unchanged number of products at a lower total cost ($K \rightarrow K_1$).



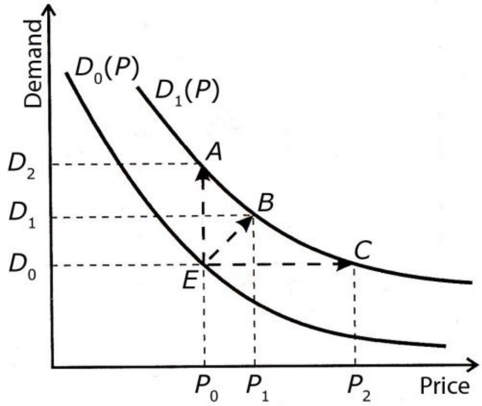
$K_0(X)$ – total production cost function before the introduction of the quality improvement program, $K_1(X)$ – total production cost function after the introduction of the quality improvement program.

Figure 3.2. The impact of an increase in the level of product quality on the level of total manufacturing costs

Source: (Wawak, 1997).

If consumers feel the increase in quality, the company can also benefit from increased revenues. Depending on the production potential and the market situation, it may decide to meet the increased demand at a constant price ($D_0 \rightarrow D_2$, with P_0 *constans*) or to increase the price while the level of demand remains unchanged ($P_0 \rightarrow P_2$, with D_0 *constans*). It is also possible to use a mixed strategy, symbolised by changing $P_0 \rightarrow P_1$ while changing $D_0 \rightarrow D_1$ (Figure 3.3). In each situation, the company's profit increases.

The link between proper implementation and positive economic effects should be emphasised. If an enterprise declares the implementation of a quality program (e.g. obtaining an ISO 9001 certificate) and at the same time shows increased operating costs and unchanged revenue levels in the long term, such implementation should be considered counter-effective.



$D_0(P)$ – demand for the product before the increase in the product quality level,
$D_1(P)$ – demand for the product after the increase in the product quality level.

Figure 3.3. The impact of an increase in the level of product quality on the volume of demand

Source: (Wawak, 1997).

(3) Importance of quality for the customer

In 1972, Gryna proposed looking at quality costs from the customer's point of view, not only from the manufacturer's, as before. He saw this as a benefit for customers and producers who, by better understanding the life cycle, could optimise quality in a way that positively impacted sales revenues (Gryna, 1972).

When deciding to purchase a product, the consumer aims, among others, to optimise the benefits of a specific level of quality. For this purpose, it relates its use value to costs. The primary figure taken into account is the acquisition cost. A consumer who knows the markets, products and has experience also considers other costs, e.g. those related to operation, renovation, repairs, accidental losses, depreciation, and mandatory inspections (Oyrzanowski, 1989). Such analysis is cumbersome and time-consuming, which is why many consumers give up on it, and producers take advantage of this approach. For example, printers from renowned manufacturers are available at low prices, but cartridge costs are correspondingly high. Additionally, manufacturers install electronic circuits in the cartridges that limit the number of copies that can be made, which means that an ordinary user cannot refill them with toner and use them. However, a specialist can often omit the limitations and use the cartridge longer without deterioration of the print. According to the manufacturers' rhetoric, this is supposed to ensure higher quality, but it primarily ensures higher revenues for the producers.

The optimal level of quality varies over time for each consumer and depends, among others, on income level, lifestyle changes (e.g. increasing consumption of healthy food), price changes, and unavailability of a specific type of product on the market. Marketing services' efforts to convince consumers that their product meets all needs and expectations are also important. A counterbalance to these activities may be online portals where customers can evaluate products. In recent years, however, we have seen more and more frequent cases of false opinions, which undermines the credibility of this source of information.

According to Skrzypek, consumers have more and more competencies that allow them to assess the quality and optimise their decisions. They contribute to this (Skrzypek, 2010):

- better information and greater awareness of where and how to purchase goods and services on the best terms,
- new sensitivity to costs and the ability to manage budget,
- greater awareness of consumer rights and a more rational attitude to the market offer, which may result in a tendency to decrease loyalty to products and brands,
- the need for social connections expressed in new forms, e.g. in small groups of friends, the appreciation of goods and services that shape social interactions,
- multiculturalism of the consumer, on the one hand, submission to globalisation, and on the other hand, striving to maintain identity and cultural distinctiveness,
- greater consumer mobility both in space and in social life,
- increasing ecological awareness, anxiety about the future, and demand for product-related information and guarantees.

The manufacturer can average consumer needs and develop one product that best meets the average values. However, for most products, more significant benefits may be achieved by introducing varieties that suit several consumer groups. Each variety should optimally meet the needs of a specific group. Although the manufacturer reduces the economies of scale of production, at the same time, he has the opportunity to increase sales among customers from lower and higher income groups. For people with lower incomes, the value of money is relatively higher, so they would not purchase more expensive products, even if they meet additional needs. In turn, for consumers with higher incomes, the relative value of money is lower, so they are willing to pay more for additional features than their actual value.

Deming believed that in the 21st century, only companies that have transformed their way of functioning based on quality will last. The remaining ones were to disappear from the market (Bagiński, 2004). This sentence came true, although not entirely in the way its author had imagined. Modern enterprises consciously plan and achieve economically justified product quality. Sometimes, it is very far from the maximum level that can be achieved. The level that will be considered economically justified depends on the type of product, its grade, the manufacturer's policy, the position, competencies and income of consumers, and legal regulations.

(4) The importance of quality for society

Product quality affects not only a country's economic performance but also society. The low quality of purchased products and services deteriorates citizens' quality of life. Quality of life is defined as the degree of fulfilment of the requirements determining the level of material and spiritual existence of individuals and the entire society. It is the degree to which a person's life needs are met (Kolman, 2013). Quality of life is studied by many disciplines, often in isolation from others. Therefore, several research perspectives can be distinguished (Sirgy et al., 2006):

- economic perspective – assesses the quality of life based on economic indicators of countries and regions,
- psychological perspective – assesses the subjective quality of life of individuals,
- social perspective – objectively and subjectively measures the quality of life,
- health care perspective – assesses the impact of diseases, including chronic ones, and therapies on patients,
- marketing perspective – assesses the values important to customers and other stakeholders in product development,
- management perspective – assesses employee performance, determines appropriate motivation factors, working and rest conditions.

Nowadays, two approaches are used to assess the quality of life: objective and subjective. The first is based on indicators measuring objective people's living conditions. The second one uses subjective assessments formulated by individuals (Diener & Suh, 1997).

Low-quality products and services have a multidimensional impact on the quality of life of an individual. Due to the different nature of the purchased goods, it is impossible to determine one sphere of life that it affects. The importance of product quality for the quality of life depends on which and how many different spheres of quality of life it affects. For example, the need to make a repeat purchase limits financial resources, conducting complaints or court proceedings requires spending additional time and using a defective product is a source of stress.

Low product quality is poorly reflected in quality of life indicators. Repurchase costs and increased stress levels translate, for example, into wealth and life expectancy indicators. However, it is impossible to determine the impact of individual products. It is easier to notice the impact of purchased products on the subjective assessment of the quality of life. Their low quality may prevent an individual from achieving their goals, e.g. resting during a purchased holiday trip, regaining health due to a service provided by a healthcare facility, or obtaining income thanks to a purchased machine. Moreover, low quality may be counterproductive if health deteriorates due to poorly provided service or the individual suffers losses due to device failure. Low quality affects not only the person purchasing the product but everyone using it. This is particularly important if the product is used in business activities (e.g. road transport, tomography).

Finally, considering the economic aspects, it is worth noting that considering quality may also be forced by the provisions of national and international law. Membership of countries in the European Union obliges entrepreneurs to apply the requirements set out in directives, transferred to national law, specifying their obligations towards customers and state institutions.

New Approach directives define framework requirements for products, their safety of use, health protection and the environment. Delivery of a product requiring declaration or obtaining a CE conformity mark imposes additional tasks on the project team.

National legal regulations regarding the obligations of entrepreneurs are, to a large extent, a form of implementing European requirements. The main legal acts that may influence the implementation of projects include those related to general product safety, counteracting unfair market practices, compliance assessment and market surveillance. In individual industries, a growing number of legal acts force enterprises to be managed in a specific way. The use of pro-quality ideas is therefore forced not only by the competitive market but also by legal regulations.

To conclude the above considerations, the quality of products affects the results of the company that supplies them and other market participants. This impact is economic and non-economic. Low quality of products negatively affects the economy and simultaneously reduces society's quality of life. Therefore, high-quality products and services are in the interest of entrepreneurs and the state. Through enacted laws, the state introduces regulations on issues that the market cannot regulate in a sufficiently short period of time (e.g., environmental protection, product liability, product safety). At the same time, it should be emphasised that it is necessary to find a golden mean because excess regulations, especially with the low quality of the law, will not improve the quality of products and society's quality of life.

3.3. Change management

(1) The model of organisational growth

The Greiner model, developed in 1972 and expanded in 1998, provides a comprehensive framework for understanding the growth stages and crises organisations encounter as they evolve. This model delineates a series of distinct phases that organisations commonly pass through (Figure 3.4). Each phase is characterised by unique management styles and challenges, which are pivotal for organisations to recognise and navigate effectively (Greiner, 1998).

The first growth phase identified in the Greiner model is the phase of creativity. In this phase, organisations are typically small, flexible, and often led by a dominant founder. The high creativity of organisational members typical of this phase leads to rapid growth. However, it becomes a cause of problems. A small organisation is not able to develop in many directions at the same time. It should choose strategic development directions so as not to fail. A leader must show direction. In this way, the organisation moves to the phase of direction. In that phase, decision-making is centralised, and the organisation's success is linked to the founder's vision and leadership. However, the model points out that as the organisation grows, centralised decision-making becomes a bottleneck that hampers the further development and expansion of the organisation.

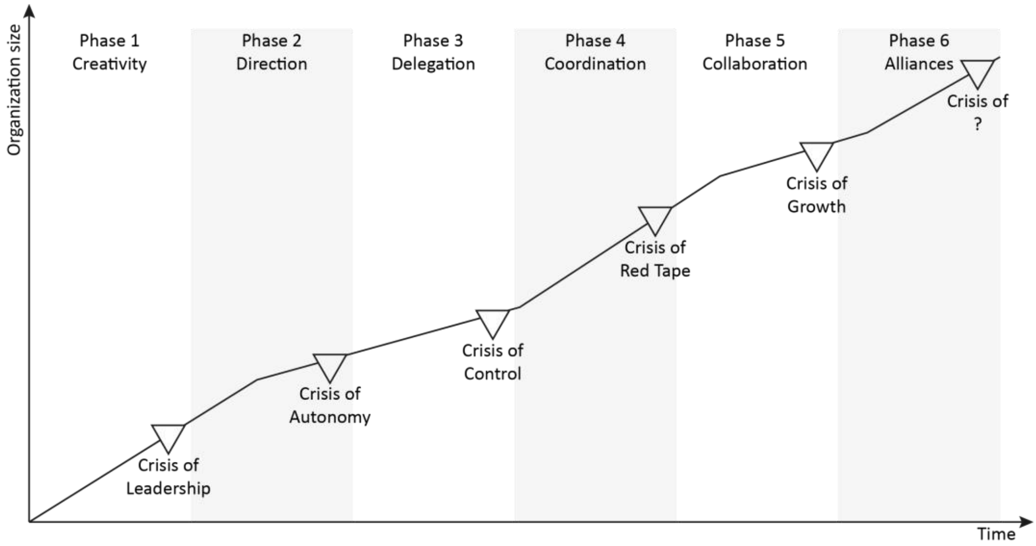


Figure 3.4. The Greiner model

Source: based on (Greiner, 1998).

As organisations progress, they enter the phase of delegation. This phase is marked by the emergence of middle managers and the essential need for delegating decision-making authority to cope with the increasing workload and complexity of operations. Here, the focus shifts from the founder's central role to building a management structure that effectively distributes responsibility and decision-making power.

Subsequently, organisations move into the phase of coordination. This stage is characterised by a period of centralised control as coordinators or departments are established to manage the increasing complexity and interdependence within the organisation. The emergence of this need for coordination signifies a critical juncture for the organisation, as its structure and processes come under pressure to adapt to the growing demands.

Following coordination, organisations transition into the phase of collaboration. As the organisation grows, coordination alone becomes insufficient to manage the size and complexity. The need for collaboration across different parts of the organisation becomes increasingly apparent, demanding inter-unit collaboration and often necessitating the adoption of matrix organisational structures.

The final stage is the phase of alliances. In this phase, organisations seek partnerships with other entities to manage growth effectively and to access new resources and markets. This phase may involve mergers, joint ventures, or other forms of strategic alliances, and it represents a significant shift in the organisation's approach to growth and expansion (Greiner, 1998).

The Greiner model's identification of these growth phases provides a clear roadmap for understanding the evolutionary trajectory that organisations typically experience. Understanding these phases is crucial for change management practitioners to anticipate and address the challenges at each stage, ultimately guiding organisations through successful transformations and sustainable growth.

(2) Detailed description of the phases

During the **creativity phase** of the Greiner model, the organisation experiences a period of high creativity and enthusiasm, typically characterised by the founding team's strong vision and entrepreneurial drive. This phase is marked by rapid growth and a focus on seizing new opportunities. However, as the organisation expands, it faces challenges sustaining this early momentum.

A signal of the coming crisis is the decline in the pace of development in many directions. This means that the organisation is exhausting its resources and cannot cope with the rapid pace of development on many levels. A high commitment of the organisation's members and a democratic management style favour the establishment and rapid development of the organisation in the initial phase. However, limited resources lead to a **leadership crisis**.

To overcome the crisis, the organisation's leader must take on the role of a strategic decision-maker. As a result, development in less prospective directions should be stopped, and all resources redirected to more promising ones.

The success of this procedure leads the organisation to the **direction phase**. It is characterised by a higher level of centralisation of decision-making, which promotes uniformity and coherence. At the same time, it requires the leader to have up-to-date knowledge of all dimensions of the organisation's functioning. It is possible as long as the organisation is small.

One of the key symptoms of an incoming crisis during this phase is the bottleneck created by the founder's centralised decision-making. While the founder's leadership was instrumental in the organisation's initial success, it becomes increasingly clear that their hands-on approach limits the organisation's ability to adapt to new complexities and demands. The founder's directive management style loses effectiveness as the organisation grows, resulting in an **autonomy crisis**.

The crisis during the direction phase revolves around the founder's ability to evolve from an entrepreneurial leader to a manager capable of sustaining the organisation's growth. This shift requires the founder to acknowledge their limitations and embrace professional management. It also necessitates the delegation of authority and the establishment of more formalised decision-making processes.

To overcome this crisis and progress to the next phase of the Greiner model, the organisation must transition from a founder-centric management structure to a more inclusive and professionally managed approach. This may involve recruiting experienced executives, establishing clear organisational roles and responsibilities, and implementing processes to facilitate effective decision-making. Indeed, the organisation's ability to navigate this crisis and adopt a more structured management approach is crucial for its continued growth and success.

In the **delegation phase** of the Greiner model, the organisation experiences rapid growth that necessitates delegating decision-making authority. This phase is characterised by the emergence of middle managers and the distribution of decision-making power throughout the organisation. As the workload increases, specialised departments or teams may be established to handle specific functions, fostering an environment of decentralisation.

However, along with the growth and delegation of authority comes the risk of a **control crisis**. Symptoms of incoming crisis in this phase may include managers or teams struggling to operate independently or failing to align their efforts with the overall organisational goals. This can result in a lack of coordination and alignment among various parts of the organisation, leading to inefficiencies, conflicts, and duplicate efforts.

Navigating this crisis is crucial for the organisation to progress. To overcome the challenges posed by the delegation phase, it may be essential to introduce more formal coordination mechanisms. For instance, implementing standard operating procedures, defining clear performance metrics, or establishing cross-functional teams can address the autonomy crisis and improve organisational alignment. These mechanisms can help mitigate the symptoms of crisis and facilitate a smoother transition through this phase of the Greiner model, fostering a sustainable growth trajectory for the organisation.

In the **coordination phase** of the Greiner model, organisations experience a critical period marked by the need to establish more formal structures and processes to handle increasing complexity and interdependence. As the organisation evolves, centralised control becomes more prevalent, establishing coordinators or departments to manage specific functions or business units. This shift often results in the organisation becoming more hierarchical and bureaucratic in its approach to management and decision-making.

However, despite the initial intentions of enhancing coordination, the coordination phase is also characterised by the emergence of a **red tape crisis**. This crisis manifests as rigid and stifling systems and procedures that impede innovation and adaptability. The organisation’s bureaucratic nature may lead to a decline in creativity and responsiveness to changing market dynamics.

Typically, the crisis during the coordination phase manifests as bureaucratic inertia, slow decision-making processes, resistance to change, and decreased employee motivation and morale. These symptoms signal a need for the organisation to navigate this challenging phase effectively to continue its growth trajectory.

Organisations must address the red tape crisis to overcome the inherent challenges of the coordination phase and progress to the next stage of development. This typically involves embracing decentralisation, empowering lower-level employees, and creating more flexible and innovative structures and processes. In practice, this can entail flattening the organisational hierarchy, fostering a culture of innovation, and encouraging cross-functional collaboration to break through bureaucratic barriers and infuse the organisation with renewed vitality and adaptability.

During the **collaboration phase**, organisations face the daunting task of fostering greater inter-unit collaboration and implementing matrix organisational structures to manage size and complexity. This phase emphasises creating a more networked and interconnected organisation, with a significant emphasis on cross-functional collaboration and teamwork. During this phase, matrix or project-based structures become more prevalent as the organisation seeks to adapt to its evolving needs.

However, as the organisation navigates through the collaboration phase, it may encounter incoming **growth crisis** symptoms. This crisis is often characterised by increasing complexity, slow decision-making processes, and conflicts from implementing matrix structures and cross-functional demands. The organisation’s ability to efficiently adapt and respond to these complexities may become strained, leading to the potential escalation of internal crises.

Internal conflicts, power struggles, communication breakdowns, and a lack of clarity in decision-making authority and accountability are typical crises that may manifest during the collaboration phase. These crises can significantly hinder the organisation's ability to operate smoothly, deliver on its objectives, and maintain cohesive working relationships.

The organisation may need to take proactive measures to overcome the crises that arise during the collaboration phase. Streamlining decision-making processes, clarifying roles and responsibilities, establishing effective mechanisms for resolving conflicts, and aligning cross-functional efforts are essential steps to move past this phase successfully. It requires a concerted effort to address these challenges and create a more cohesive and agile organisational structure that can effectively navigate the complexities of the collaboration phase.

In the **alliances phase** of the Greiner model, an organisation transitions from primarily focusing on internal development and expansion to seeking growth and development through external partnerships and alliances. The identification of this phase is marked by the organisation's realisation that it needs to collaborate with other entities to access new resources, manage growth, and enter new markets. As a result, the organisational behaviour becomes highly networked, outward-looking, and oriented toward building and maintaining external partnerships and alliances. This phase often sees the organisation seeking expansion through mergers, acquisitions, or strategic alliances to diversify its capabilities and reach.

However, as the organisation delves into this phase, it may start experiencing symptoms of incoming crises, which can emerge as demands associated with managing external partnerships, integrating acquired entities, or accessing new markets stretch the organisation's capacity to manage and adapt effectively. The typical crisis manifestations at this stage include challenges integrating acquired entities, cultural clashes in alliances, managing diverse networks, and balancing internal and external priorities.

The organisation needs to develop strong integration capabilities to overcome this crisis and break through the alliances phase. It must also nurture a culture of collaboration and adaptability and foster a shared vision and purpose across its network of partnerships and alliances. This entails aligning the values and goals of the various entities involved and ensuring that all parties are committed to the collective success of the partnerships. Additionally, the organisation must pay close attention to managing the cultural implications of alliances and acquisitions to ensure that the new entities are smoothly integrated into the existing organisational framework. Balancing internal and external priorities and managing diverse networks becomes crucial in navigating the alliances phase and moving towards sustained growth and success.

The phases of the Greiner model provide insights into the stages of organisational growth and the corresponding crises that demand changes in management approach and structure. By recognising the signs of each phase, understanding the nature of the accompanying crises, and implementing appropriate strategies to overcome these challenges, organisations can navigate growth effectively and transition to the next development phase.

(3) Implications for change management

The implications for change management based on the Greiner model bring forth crucial considerations for effectively navigating organisational growth challenges. Understanding and leveraging these implications can significantly enhance the change management process and facilitate smoother transitions across different phases of organisational development.

By recognising the typical organisational behaviours and impending crises associated with each growth phase, change management professionals can adopt a proactive stance towards change. Anticipating change needs enables organisations to prepare in advance, identifying crucial opportunities for innovation and tackling emerging challenges before they escalate. This foresight allows for a more strategic and pre-emptive approach to change management, minimising disruptions and maximising growth potential (Sukova, 2020).

The dynamic nature of organisational growth, as depicted in the Greiner model, necessitates a corresponding evolution in management style and structure. Change management practitioners must collaborate with leadership to facilitate this adaptation, ensuring that the organisation's management approaches align with the evolving requirements of each growth phase. This might entail transitioning from a more entrepreneurial and informal structure to a more formalised and structured approach, aligning roles and responsibilities with the changing demands of the organisation.

With a clear understanding of the crises associated with each growth phase, change management professionals can design and execute targeted interventions to address imminent challenges. These interventions focus on breaking through existing limitations and propelling the organisation towards the next growth phase. Strategic initiatives, such as restructuring, process optimisation, leadership development, and cultural transformation, address the organisation's specific needs to effectively navigate the challenges at hand.

The Greiner model underscores the importance of fostering change capability throughout the organisation's growth journey. Change management practitioners are pivotal in nurturing a culture of continuous improvement, resilience, and adaptability, which are essential for effectively managing and navigating change. Building change capability equips the organisation with the readiness and adaptability required to respond to the demands of each growth phase, enabling it to embrace necessary transformations with agility and confidence.

A clear strategic vision is imperative at each stage of growth. Change management practitioners collaborate with organisational leaders to develop and communicate a comprehensive strategic vision that guides the organisation through the challenges and opportunities associated with each growth phase. This involves setting precise goals, establishing a roadmap for change, and aligning organisational direction with the anticipated growth dynamics (Sukova, 2020).

By meticulously considering these implications, organisations can harness the power of the Greiner model to anticipate change needs proactively, adapt management approaches, implement targeted interventions, build change capability, and create strategic visioning, resulting in a more effective and seamless change management process as they progress through different phases of development.

(4) Greiner model applicability

The Greiner model offers a robust framework for change management professionals to understand and navigate the intricacies of organisational growth. Its applicability spans various facets of change management and organisational development, making it a valuable tool for effectively managing change. Firstly, the model's relevance lies in unravelling the dynamics of organisational growth. It helps comprehend the distinct stages of development and the crises accompanying each phase. This understanding becomes instrumental in strategic planning as it informs leaders and change management professionals about the challenges that may arise during growth, enabling them to prepare tailored strategies for effective change management.

Moreover, the model's applicability extends to identifying change triggers. Change management practitioners can proactively recognise warning signs of impending crises, allowing strategic intervention to address emerging challenges. This facilitates a proactive approach and helps capitalise on growth opportunities. Furthermore, the model can be utilised for tailoring change interventions at different growth phases, addressing specific organisational needs, and mitigating the impact of crises.

The Greiner model's relevance is not limited to these aspects only. It also guides leadership development efforts by understanding the shifting demands on leadership style and capabilities at various growth stages. This insight informs leaders' selection, development, and coaching to adapt their approaches and skills effectively. Additionally, the model promotes organisational resilience and adaptability by emphasising the need to build change capability and foster a culture of continuous improvement and readiness (Brzeziński & Stefańczyk, 2013; Schmitt, 2018).

In terms of strategic decision-making and change readiness assessment, the applicability of the Greiner model is undeniable. It provides a roadmap for understanding organisational needs as they evolve, informing strategic planning, resource allocation, and vision alignment. Furthermore, change management practitioners can use the model to assess an organisation's readiness for change at different growth stages, allowing for the development of tailored strategies for successful transitions.

(5) The Greiner model criticism

While a valuable tool for understanding organisational growth and change management, the Greiner model has faced criticism from various perspectives. One primary critique concerns its oversimplification of organisational growth dynamics. Critics argue that the model's linear progression through distinct phases may not accurately represent the diverse and non-linear paths that organisations often follow as they grow and develop. In reality, organisational growth is influenced by many internal and external factors, leading to complex and non-linear trajectories that may not neatly fit into the Greiner model's predetermined stages.

Another significant criticism revolves around the model's limited consideration of external factors that can profoundly impact an organisation's growth. Critics argue that technological advancements, market shifts, regulatory changes, and industry disruptions are influential external forces not adequately addressed within the model. This oversight leads to a narrow view of organisational growth dynamics, overlooking the significant impact of external factors (Schmitt, 2018).

Furthermore, the Greiner model has been challenged for its limited applicability across industries and organisational types. Its development was primarily based on observations within a specific context, potentially overlooking diverse growth experiences and challenges organisations face in different sectors and environments.

Critics also emphasise the model's inadequate focus on organisational cultural and human dynamics. While the model prioritises structural and managerial changes, it may overlook the critical role of organisational culture, employee behaviour, and interpersonal dynamics in shaping an organisation's growth journey (Awasthy, 2015).

The model lacks adaptive and dynamic elements to account for organisational change's iterative, non-linear nature. By presenting growth as a fixed and sequential process, the model fails to capture the reality of organisational change as an ongoing and iterative journey involving cycles of growth, adaptation, and renewal.

The Greiner model has also been accused of neglecting small, innovative startups, non-hierarchical structures, and non-traditional business models. Its focus on conventional, hierarchical organisations limits its applicability in capturing the growth dynamics of organisations that diverge from traditional structural norms.

Critics also argue that the model offers limited guidance for change management strategies. While it identifies crises at each growth phase, it may not provide comprehensive and actionable guidance for change managers to address these crises and facilitate organisational transitions effectively (Brzeziński & Stefańczyk, 2013).

The criticisms highlight the potential disconnect of the model from contemporary business realities, such as the impact of digital transformation, globalisation, and the evolving nature of work. The model's development in the 1970s may limit its relevance in understanding the complexities of today's rapidly changing business landscape.

The Greiner model, while valuable, comes with limitations that may benefit from a more nuanced and dynamic approach. Recognising these criticisms can lead to a more comprehensive understanding of organisational growth and change management, ensuring that change practitioners consider broader factors and dynamics in managing organisational transitions.

(6) Steps towards implementing the change

The methodology of implementing the change in the organisation proposed by Clarke is founded on a series of carefully constructed steps designed to usher organisations through the complex change process in a strategic, deliberate, and sustainable manner. Her approach emphasises the critical role of leadership, communication, and organisational culture in driving successful change initiatives. The Clarke's approach to change encompasses the following essential steps:

1. Establishing a sense of urgency.
2. Creating a guiding coalition.
3. Developing a vision and strategy.
4. Communicating the change vision.
5. Empowering broad-based action.
6. Generating short-term wins.
7. Consolidating gains and producing more change.
8. Anchoring new approaches in the culture.

Each step shapes how organisations approach change, laying the groundwork for successful implementation and sustained progress. Organisations can navigate change with clarity, purpose, and resilience by understanding and applying these steps. Clarke's approach reflects a deep understanding of the intricacies of organisational dynamics and the imperative of effective change management in today's rapidly evolving business environment (Clarke, 1994).

Establishing a sense of urgency is the crucial foundation for successful change management. This step begins with a comprehensive assessment of the organisation's current state. It emphasises the need for an honest evaluation of existing challenges, risks, and opportunities, ensuring that the change initiative is rooted in a deep understanding of the organisation's dynamics.

Furthermore, external factors are pivotal in driving the need for change. These encompass market trends, technological advancements, competitive landscape, regulatory changes, and evolving customer preferences. Such external forces pressure the organisation to adapt and innovate to remain competitive and meet stakeholder needs.

On the other hand, internal pressures, including declining performance, eroding market share, operational inefficiencies, financial hardships, and cultural issues, contribute to the urgency for change within the organisation.

These internal factors directly impact the organisation's ability to achieve its strategic objectives and sustain long-term success.

The consequences of inaction are critical considerations in establishing a sense of urgency. By highlighting potential risks and adverse outcomes associated with maintaining the status quo, leaders can effectively convey the urgency for change. Loss of market relevance, declining morale, decreased profitability, talent attrition, and diminished stakeholder confidence are potential consequences of inaction, underscoring the need to act proactively.

Effectively communicating the sense of urgency is equally significant. Leaders must craft transparent and compelling messages that articulate the reasons for change and the potential impact of not addressing the identified issues. Empathy and understanding are crucial when communicating urgency, as they can help address potential fears and concerns while inspiring a call to action (Clarke, 1994).

The second step focuses on **creating a guiding coalition**, a critical element in leading and promoting the change effort within an organisation. The guiding coalition comprises a robust and influential group tasked with steering the organisation through the complexities of change. Its purpose extends beyond mere leadership – it is the driving force that exemplifies dedication, expertise, and resilience throughout the change initiative.

Identifying critical individuals for the coalition is a meticulous process that involves selecting influential leaders, managers, and stakeholders who possess the credibility, expertise, and authority to drive the change initiative. Emphasising inclusivity, the coalition's composition should reflect diverse functional areas and levels of the organisation, ensuring broad representation and support. It is crucial to harness individuals' varied insights and perspectives from different backgrounds to enrich the coalition's vision and approach to change.

Assembling a diverse and inclusive coalition holds intrinsic value. When the coalition comprises individuals with different skills, perspectives, and backgrounds, it facilitates a comprehensive and holistic understanding of the change process. This inclusivity ensures that various stakeholder groups' interests are effectively represented, enhancing the coalition's ability to navigate potential challenges and foster broad-based support.

Defining roles and responsibilities within the coalition is vital for its effectiveness. Delineating the expectations and accountabilities of each member fosters accountability and facilitates seamless collaboration. Aligning coalition members with tasks that resonate with their strengths and capabilities enhances their individual and collective contributions, thereby driving meaningful progress in the change initiative.

Creating a shared vision and purpose is pivotal for the coalition's success. Aligning all members around a shared vision and purpose for the change initiative is essential to ensure that every individual comprehends and wholeheartedly commits to the overarching goals and objectives of the organisational change.

Transparent communication about the coalition's leadership role and influence is crucial. Effectively communicating its position and ability to guide the organisation through impending changes helps build trust and confidence, ultimately garnering the support needed to drive the change effort to success.

Finally, the guiding coalition's collective power and influence can be harnessed to mobilise resources, align stakeholders, and propel the change agenda. Its capacity to inspire and motivate others reinforces the impact of collaborative leadership in driving successful change (Cameron & Green, 2019; Hiatt & Creasey, 2012).

Developing a vision and strategy is about setting the course for the organisation's future and creating a roadmap for change. At its core, it involves the development of a compelling vision statement that provides a clear and inspiring picture of what the organisation aims to achieve. The vision should resonate with employees, customers, and other stakeholders, instilling a sense of purpose and direction. It is essential to balance ambition and achievability, ensuring that the vision motivates without overwhelming.

Stakeholder involvement is integral to this step. Engaging key stakeholders in developing the vision fosters buy-in and ownership, enhancing the likelihood of successful implementation. Furthermore, gathering insights and perspectives from employees at all levels enriches the vision, making it more representative and meaningful. By incorporating feedback from stakeholders, the vision becomes more refined and robust, reflecting the diverse voices within the organisation.

The strategy development process involves defining strategic objectives that align with the vision. It is crucial to prioritise these objectives, focusing on critical areas that will propel the organisation forward. A comprehensive strategic analysis is conducted to inform the strategy development. By aligning the strategy with insights from this analysis, the organisation can capitalise on strengths, mitigate weaknesses, seize opportunities, and manage threats effectively.

Resource allocation is another critical aspect of this step. Determining the necessary resources for strategy execution, including financial, human, and technological resources, is essential. The allocation must align with strategic objectives and support the organisation's ability to achieve its vision. Establishing mechanisms for monitoring and adjusting resource allocation as needed ensures adaptability in response to changing circumstances.

Moreover, developing a detailed implementation plan is vital. This plan outlines specific initiatives, projects, and milestones, assigning responsibilities and establishing clear accountability. Timelines and milestones are set to track progress and ensure the organisation stays on course toward its vision. Communication and alignment are equally crucial – effectively communicating the vision and strategy throughout the organisation ensures that all employees understand their role in achieving the vision. Aligning individual and team goals with the overall vision and strategic objectives fosters transparency and accountability, creating a culture that supports the vision and strategy.

Finally, flexibility and adaptability are vital considerations in strategy development. Acknowledging the dynamic nature of the business environment and building mechanisms for continuous monitoring and adjustment fosters agility and innovation within the organisation, enabling it to pivot and capitalise on new opportunities as they arise (David et al., 2019).

The fourth step emphasises the critical nature of **communicating the change vision** to all organisation members. It is imperative to explain the significance of articulating a clear, compelling, and easily understandable vision for the organisation's desired future state. A well-defined vision gives employees a sense of purpose and direction during the change process, aligning their efforts with the organisation's strategic objectives.

Moreover, using multiple communication channels is essential to ensure the change vision reaches employees across different organisational levels and locations. Tailoring communication methods, such as town hall meetings, emails, intranet, and newsletters, to suit diverse employee groups' preferences and information needs is vital. This approach helps engage frontline staff, middle management, and executives, ensuring a comprehensive understanding of the change vision.

Two-way communication becomes pivotal in fostering employee engagement during the change process. Creating opportunities for dialogue and feedback ensures that employees feel heard, can express their concerns, ask questions, and contribute to the change process. It is essential to solicit input from employees regarding the change vision, allowing them to see how their perspectives can influence the direction and implementation of the change.

Leadership alignment is vital in communicating the change vision consistently and authentically across the organisation. Having a unified front among leadership reinforces the credibility of the change vision and fosters trust and confidence among employees. This approach is crucial in ensuring that the entire organisation moves in the same direction and works towards the common goal.

The use of storytelling and visualisation techniques further enhances communication regarding the change vision. Employees can better connect with the change vision by using real-life examples, success stories, and visual representations, such as infographics, videos, or visual boards. This makes the change process more relatable and helps create a shared understanding and emotional connection with the desired future state.

Addressing resistance and concerns about the change is equally important. It is crucial to acknowledge and address potential resistance and concerns that employees may have. Transparent and honest communication about the potential impact of the change, along with addressing fears and uncertainties, helps create an environment of openness and trust within the organisation.

Celebrating progress and milestones that align with the change vision plays a significant role in sustaining momentum. Recognising and publicising early wins and achievements can boost morale and encourage employees to stay committed to the change process. This approach reinforces the idea that progress is being made and that employees' efforts are contributing to the overall success of the change initiative.

Lastly, having a well-structured communication plan is vital for reinforcing the change vision over time. A communication plan outlining the timing, content, and delivery mechanisms for sharing updates, progress, and reinforcement of the change vision ensures consistent and regular communication to sustain momentum and engagement throughout the change process (O'Rourke, 2023; Smith et al., 2014).

Empowering broad-based action is crucial in fostering a participative approach within the organisation. It emphasises the importance of involving employees in the change process and decision-making. By encouraging open discussions and soliciting input from diverse functional areas and levels within the organisation, companies can tap into their employees' wealth of knowledge and experience. This inclusive approach enriches the decision-making process and cultivates a sense of ownership and commitment among the workforce, ultimately driving the success of change initiatives.

In addition to encouraging participation, empowering broad-based action involves providing resources and support to employees. Allocating sufficient resources, including time, budget, and access to expertise, is essential to implement change initiatives successfully. Equally important is ensuring employees have the tools, training, and support to navigate the changes effectively. Organisations can equip employees with the skills and knowledge required to thrive in the evolving landscape by offering coaching, mentoring, and developmental opportunities.

Granting decision-making authority to employees is another critical aspect of empowering broad-based action. Delegating decision-making authority at various levels enables employees to take ownership of their roles in the change effort, fostering a sense of accountability and responsibility. By establishing clear guidelines and empowerment boundaries, organisations can align decision-making with the overall change strategy, ensuring that informed and strategic choices drive initiatives.

Fostering a culture of innovation is also central to empowering broad-based action. Organisations can infuse a spirit of creativity and progress by encouraging employees to explore new ideas, experiment with alternative approaches, and challenge the status quo. Creating a supportive environment that rewards creativity, risk-taking, and learning from failures is essential for driving innovation and adapting to change effectively. Recognising and celebrating innovative thinking and the successful implementation of new initiatives can further fuel a culture of forward-thinking and adaptability within the organisation.

Furthermore, aligning performance management with the change objectives is integral to empowering broad-based action. By updating performance evaluation and reward systems to incentivise behaviours that support the change objectives, organisations can ensure that employees are aligned with the vision and strategy. Communicating how individual and team performance will be assessed in the context of the change initiative and how employees' contributions will be recognised and rewarded helps create a unified focus on driving change (Clarke, 1994; Kotter, 2012).

Generating short-term wins holds significant importance in the overall success of a change initiative. One crucial aspect of this step is the identification of areas where tangible successes can be achieved within a short timeframe. Organisations can generate momentum and build confidence among stakeholders by focusing on these quick wins. This approach not only provides immediate evidence of progress but also serves to rally support and enthusiasm for the broader change effort.

Moreover, setting realistic targets for these short-term wins is essential. Emphasising the need to establish achievable and meaningful goals aligns with the change initiative. Clear and measurable targets track progress and demonstrate success, reinforcing the belief that the change is indeed possible. Communicating these successes effectively is equally vital. By sharing stories of achieved wins and their impact on the organisation, leaders can inspire and motivate employees, creating a positive narrative around the change effort and reinforcing its vision and purpose.

Recognition and celebration play a pivotal role in reinforcing the significance of short-term wins. Acknowledging and celebrating the individuals and teams responsible for delivering these wins fosters a culture of appreciation and teamwork. This recognition not only boosts morale but also encourages continued engagement and dedication. Furthermore, leveraging the momentum from these early successes becomes crucial in driving further change and sustaining enthusiasm. The initial wins act as a catalyst, garnering additional stakeholder support and buy-in, propelling the change initiative forward.

Additionally, generating short-term wins presents an opportunity for learning and adaptation. It allows organisations to capture insights and best practices from successful initiatives, fostering continuous improvement and adaptation of strategies for future stages of change. Aligning these wins with the broader vision and goals of the change initiative is imperative, ensuring that each success contributes to the realisation of the organisation's overall vision and strategy.

Addressing resistance is another key element during this phase. Quick wins can help overcome resistance to change by demonstrating the initiative’s positive impact and potential benefits. By showcasing the tangible outcomes of the change effort, leaders can assuage scepticism and build confidence among those who may be hesitant about the change. Finally, monitoring and evaluating the short-term wins are essential to assess their sustainability and impact. These insights contribute to the overall success of the change initiative by informing future efforts and ensuring that the momentum generated is maintained (Cameron & Green, 2019; Hiatt & Creasey, 2012).

Consolidating gains and producing more change ensures that the progress made during the change process is acknowledged, reinforced, and solidified. Integrating the changes into the organisation's operations, systems, and culture is equally important. It is necessary to highlight the significance of ingraining the changes as an inherent part of the organisation's daily operations. This entails exploring strategies to ensure the changes become deeply rooted in the organisation's fabric, aligning with its values and objectives. Doing so makes the changes more likely to be sustained in the long run and less prone to reverting to previous ways of operation.

In addition to reinforcing and integrating the initial changes, the concept of continuous improvement should be introduced and discussed. The organisation needs to reflect on how to keep the momentum of change going and identify new opportunities for improvement. By promoting a culture of continuous improvement, the organisation can sustain the drive for change and remain agile and responsive to evolving needs and challenges.

Leveraging the momentum from initial successes to tackle more ambitious and transformative changes is imperative. The organisation can pursue broader and more impactful changes by building on past achievements. This approach ensures that the change process is not static but progressive, with each accomplishment opening the door for further improvements and advancements.

As the organisation moves forward with further changes, it is essential to address any remaining resistance to change and discuss strategies for overcoming resistance. This includes addressing complacency and ensuring continued buy-in from stakeholders. By doing so, the organisation can overcome barriers and ensure that the momentum of change is sustained, preventing regression to old habits and practices. This also involves building the organisation's capacity for change and fostering a culture that is receptive to change and equipped to manage future transformations.

Structurally aligning the organisation's processes, systems, and infrastructure with the changes that have been implemented is critical. It involves exploring methods to ensure that the changes are sustainable in the long run and supported by the organisation's structures. This alignment reinforces the changes and ensures that they are embedded in the organisation's framework, contributing to their longevity and continued impact on its operations (David et al., 2019; Hodges, 2021).

Anchoring new approaches in the culture ensures that the changes brought about by the initiative become ingrained in the organisational culture. Cultural integration emphasises the need to align the new approaches resulting from the change with the existing organisational culture. This step involves discussing strategies for identifying elements within the culture that may either support or challenge the adoption of the new approaches. It aims to integrate the change into the organisation's values, beliefs, and behaviours, ensuring it becomes an inherent part of its identity.

A key aspect in anchoring new approaches in the culture is the role of leadership. It is important to emphasise how leaders can model the desired behaviours and champion new approaches to influence the organisational culture. This involves continuously communicating and reinforcing the importance of the change in shaping the culture. By doing so, leaders can help facilitate a smoother transition as they set the tone and example for the rest of the organisation.

Employee engagement is also crucial in this process. Ensuring that employees at all levels embrace and sustain the new approaches helps promote cultural integration and foster ownership of the change. Strategies for fostering a sense of accountability and responsibility among employees to uphold the new cultural norms are also vital in embedding the change within the organisation's culture.

Communication and training play a pivotal role in anchoring the new approaches in the culture. Ongoing communication is necessary to embed the new approaches within the culture, while targeted training programs equip employees with the knowledge and skills required to support the cultural shift. Comprehensive and transparent communication should reinforce the cultural changes and address any resistance.

Rewards and recognition have a significant impact in reinforcing new cultural behaviours and practices. Aligning reward systems with the desired cultural norms incentivises adherence to the new approaches while recognising individuals and teams who actively contribute to anchoring the change in the organisational culture reinforces the desired behaviours.

Aligning organisational systems, processes, and policies with the new cultural norms and practices is also crucial. Ensuring that performance management systems, feedback mechanisms, and decision-making processes support the desired cultural changes enables the integration of the new approaches into the organisation's everyday operations.

Continuous reinforcement is essential for the long-term anchoring of new approaches within the organisational culture. Establishing feedback loops and mechanisms for monitoring and sustaining the desired cultural changes allows for ongoing evaluation and refinement of cultural integration efforts, ensuring that the change becomes deeply rooted in the organisation (Clarke, 1994; Kotter, 2012; Smith et al., 2014).

Chapter 4. Quality 4.0 methods and tools

4.1. Evolution of traditional quality tools

(1) Seven basic and seven advanced quality tools

In most engineering academic courses on quality management, a set of 14 quality control tools plays an important role. These are simple techniques for collecting and preliminary statistical data analysis from production and service processes. These sets were developed for industrial needs in the 1960s. Although they are called quality control tools, they actually serve to find opportunities for quality improvement. Table 4.1 and Table 4.2 present the list of those tools and their descriptions.

Table 4.1. Seven basic quality control tools

Tools	Description
Cause and effect diagram	It is also known as a fishbone diagram or Ishikawa diagram. This tool helps identify and analyse the root causes of a problem by visually mapping out potential causes and their relationships. It is a valuable tool for identifying and solving quality issues by considering various inputs.
Check sheet	A check sheet is a simple and straightforward tool for gathering and organising data or observations. It is used to collect data in real-time during quality inspections or data collection activities. Check sheets can be customised based on the specific quality parameters being measured.

Control chart	Control charts are graphical tools that monitor and analyse process variations over time. They help distinguish between common cause variation (normal process variation) and special cause variation (unusual events or factors causing disturbances). Control charts enable organisations to identify trends, patterns, and out-of-control conditions, and take appropriate actions to improve process stability.
Histogram	A histogram is a graphical representation of a data set's frequency distribution. It provides a visual representation of the distribution of values or measurements to understand the shape, central tendency, and spread of the data. Histograms help identify potential quality issues, such as excessive variations or biases in data.
Pareto chart	Pareto charts are bar charts that display data in descending order of frequency or importance. They help identify and prioritise the most significant quality problems or causes by showing the percentage or cumulative percentage of defects or occurrences for each category. Pareto charts help focus improvement efforts on the vital few issues that contribute to the majority of problems.
Scatter diagram	A scatter diagram is a graph that displays the relationship between two variables. It helps visualise the correlation or lack thereof between the variables. Scatter diagrams are particularly useful in identifying potential cause-and-effect relationships and understanding how changes in one variable may impact another.
Flowchart	Flowcharts are visual representations of a process or workflow, illustrating the sequence of steps and decision points. They help in understanding, analysing, and improving processes by identifying bottlenecks, redundancies, and inefficiencies. Flowcharts are commonly used for documenting and standardising processes and identifying opportunities for improvement.

Source: based on (Wawak, 2011).

Table 4.2. Seven advanced quality control tools

Tools	Description
Affinity diagram	An affinity diagram is a tool used to organise and categorise a large amount of ideas or data into groups based on their relationships or similarities. It helps in identifying patterns, themes, and commonalities that can assist in problem-solving and decision-making.
Interrelationship diagram	An interrelationship diagram, a relations diagram or digraph, helps analyse complex relationships among ideas or factors. It visually represents cause-and-effect relationships,

	dependencies, and influences, enabling organisations to understand and address underlying issues.
Tree diagram	A tree diagram, also known as a systematic diagram, breaks down a problem or goal into its hierarchical components. It provides a structured approach to problem-solving, helping to identify potential solutions, determine root causes, and analyse the logical relationships within a system.
Matrix diagram	A matrix diagram is a visual tool for analysing relationships between multiple factors and prioritising actions. It allows organisations to compare and assess various factors based on their importance, impact, or performance, helping decision-making and problem-solving.
Matrix data analysis	Matrix data analysis, a prioritisation matrix or weighted scoring model, is used to evaluate and prioritise different options based on predetermined criteria. It involves assigning scores or weights to criteria and options, facilitating informed decision-making and resource allocation.
Process decision program chart	PDPC is a tool for contingency planning. It anticipates potential problems or failure points in a process or project, helps identify risks, develops mitigations, and creates alternative strategies to ensure smooth operations and minimise disruptions.
Activity network diagram	An activity network diagram, also known as a network diagram or arrow diagram, is used to visually represent project activities, dependencies, and timelines. It helps in project planning, resource allocation, and identifying critical paths to ensure efficient execution and timely completion.

Source: based on (Wawak, 2011).

At the time of their introduction and in the decades that followed, these tools significantly impacted companies' ability to deliver high-quality products. They have contributed to significant quality improvement in all industries. At a time when computers were not widely used in enterprises, these tools enabled quick and efficient detection of problems, documenting them, and also helped in solving them.

The popularisation of computers with applications supporting data collection and statistical analysis, e.g., spreadsheets, caused the tools mentioned above to evolve. Computers began to be connected in networks. More and more modern manufacturing machines that could be controlled remotely were added to these networks. This allowed for the transfer and collection of many process parameters and their analysis. Nowadays, the amount of transmitted data is so large that it requires big data advanced analytical tools to identify patterns and trends. It is, therefore, worth asking whether these traditional tools, after appropriate adaptation, are still useful in modern quality management.

(2) Evaluation of the suitability of traditional tools

The quality control tools discussed can be divided into two groups. The first are tools that are still useful but were incorporated into more complex, integrated methods or tools. The second group consists of tools that have evolved and, despite significant changes, are still used independently.

Check sheet is a very convenient data recording tool. However, completing it took the employee's time. Therefore, when used in a paper form, only a few selected process parameters could be recorded by an employee. Additionally, the employee had to have measuring equipment enabling reading data from the devices. Connecting the devices to the internal computer network and installing sensors performing automatic measurements allowed to incorporate the check sheet into modern IoT systems. Data is sent in real-time to servers, where it is further analysed using advanced statistical models.

Scatter diagrams enabled even low-skilled employees to analyse the relationships between selected process parameters visually. Every modern machine has a built-in computer that is able to collect and compare defined parameters. The correlation index, if needed, can be displayed on the HMI screen in real-time. Additionally, process improvement teams can use megabytes of historical data stored in the cloud to analyse the correlations of thousands of pairs of process parameters. Thanks to this, it is possible to detect relationships that were not even suspected to exist.

Matrix diagram looks like a simple spreadsheet in which various parameters are compared. In the era of automation and system integration, it has been expanded by real-time data analysis. The use of computers allows for quick multivariate analysis or other types of analyses. The results of using these statistical techniques describe reality with greater detail than the initial version of the matrix diagram. Reports are delivered to management and improvement teams with almost no delays.

Many managers are still accustomed matrix diagrams. They can be very helpful when analysing simple problems but nowadays we usually need more advanced tools. An in-depth understanding of manufacturing processes often requires the simultaneous analysis of thousands of dimensions using machine learning or artificial intelligence tools. This approach can be a starting point for implementing predictive analysis. Decision makers can use an analytic hierarchy process (AHP) or multi-criteria decision analysis (MCDA) in more straightforward cases.

Process decision program chart was used to predict the potential consequences of decisions made. It was possible to indicate the effects of the choices made using a limited number of parameters and steps. The development of risk management methods has made the PDPC redundant. The Monte Carlo method, which was built into popular spreadsheets, allows quick analysis of dozens of scenarios. In more advanced applications, it is possible to use data collected by IoT, as well as generate new, artificial data using simulation and modelling. The combination of big data analyses with regression models, and in the future also advanced AI, makes it possible to suggest the best decisions that can be made in a given situation. These techniques are important elements of predictive systems constructed in quality management.

Tree diagram is a visually attractive way of hierarchizing and categorizing phenomena. It has a number of applications, e.g. in root-cause analysis (RCA) and fault-tree analysis (FTA). However, its limitations are similar to the PDPC. Enterprises have much more advanced tools that allow them to monitor more parameters and steps. Machine learning and AI can be used to detect patterns. Business process management (BPM) tools enable much more advanced simulations than those using tree diagrams.

The growing complexity of today's enterprises means that simple tools for classifying ideas and problems, such as **affinity diagrams**, are no longer sufficient. Mind maps or sticky notes to map more straightforward issues are still in use. However, due to the amount of data that needs to be processed, e.g., thousands of comments on Internet website about the company's products, it is necessary to use tools using natural language processing (NLP) supported by large language models (LLM). AI introduces a paradigm shift in the way affinity mapping is conducted. By leveraging advanced algorithms, AI can analyse and categorise data with unprecedented speed and accuracy. These tools can be integrated into advanced knowledge management systems and provide highly processed reports necessary for managers to make quick decisions.

Histogram is a convenient way to present data. It is used as a tool in multiple quality management methods, e.g., to monitor process parameters or in Six Sigma. Therefore, it will be used in quality management in the coming years. However, the way it is prepared and presented will change significantly. Access to data collected in real-time allows the equipping of HMI or SCADA systems with advanced dashboards that present many parameters simultaneously and constantly calculate the metrics necessary to interpret the results. Dynamically changing histograms are often used in modern business process management systems. These systems allow data to be analysed in the background and only display a histogram or other visualisation when alarm levels are exceeded. This significantly reduces the information burden on employees while maintaining high situational awareness.

The evolution of the **Pareto chart** proceeds in the similar way. Thousands of sensors installed in production processes transmit data about the quality of the products. IT systems process them and provide the results immediately. These systems can be connected to the quality management system and automatically report metrics, nonconformities and even initiate corrective actions.

The **interrelationship diagram** clearly presents the relationships between system elements. The development of systems thinking in recent decades has created tools that enable the construction of much more complex diagrams. They enable the tracking of thousands of relationships and the simulation of the operation of complex systems. One such application is Vensim. System models created with the help of such applications can then be used to conduct simulations, identify acceptable parameter limits, detect anomalies in system behaviour, and generate insights. Another direction in developing the interrelationship diagram is network analysis supported by NLP and AI, which allows the detection of regularities based on weak signals.

The invention of **control charts** was a breakthrough in process control. The cards made it possible not only to monitor processes but also to give hints about the causes of their variability. This opened up completely new opportunities for process improvement. Therefore, control charts are and will remain very important quality control tools. However, they will not be drawn by people because this would mean monitoring too few parameters too rarely. In the near future, every important process parameter will be recorded and sent to the server. Real-time analytical tools will monitor thousands of such parameters and calculate their trends. If negative trends are detected, they will alert employees and suggest decisions. Additionally, AI tools will be able to independently make decisions about making adjustments to the process or turning off the machine for maintenance.

Another tool that will continue to be used in quality management in the future is the **cause-and-effect diagram**. However, it will also undergo significant changes. The collection of large amounts of data by enterprises will enable the automatic generation of diagrams with detailed analyses of the probability and impact of each cause. Automatic data analysis will allow detection of patterns and anomalies in the behaviour of devices and entire processes. Digital twin and the ability to conduct simulations will contribute to better decision-making.

Flowcharts and **activity network diagrams** are tools that have been significantly developed in BPM. The development of notations such as BPMN and UML enabled the transition from simple diagrams to complex systems that monitor the functioning of processes. Modern process management systems understand the relationships between tasks, decisions, workplaces, machines and documents. Properly designed systems allow for achieving high efficiency and monitor any anomalies continuously. Each change can be checked in a series of simulations before implementation. It is possible to dynamically modify processes based on real-time data, e.g., machine failure. Data collected on enterprise servers also allows for the discovery of relations and the prediction of events based on the analysis of system logs.

This review of quality control tools has shown that over the past decades some have become incorporated into larger methods and systems and others have had to undergo significant changes. The era of Quality 4.0 is associated with disruptive changes. And these changes must also affect quality management tools.

4.2. Selected other quality management methods

The use of advanced IT tools, including artificial intelligence, is now within the reach of most enterprises. However, well-known quality management tools and methods may still be sufficient to solve simple problems. These include, among others, A3 technique, SIPOC diagram, internal audit, statistical process control, value stream mapping, FMEA analysis, design of experiments.

(1) A3 technique

Root cause analysis (RCA) was mentioned as one of the basic tools for identifying the causes of problems in quality control. The starting point for developing a diagram is to formulate an effect – an event or phenomenon that needs to be better understood. Usually, the effect is negative. In order to obtain the most comprehensive results, a team of experts with various education and experience is appointed. The team analyses the effect and looks for the reasons for its occurrence. The team members repeatedly ask the question “why?” to find causes. The analysis does not stop after detecting the causes directly affecting the effect. After the first step of the analysis, the team examines each cause and tries to identify sub-causes for it. A complete diagram may contain three to five levels of causes. Cause analysis is only used to identify the sources of problems and, as mentioned earlier, it is not enough for modern use. The classification, understanding and decision-making require the use of other techniques, among which the A3 technique is the most prominent one.

The A3 technique was built around RCA to improve the resolution of identified problems. For a better understanding of problems, a PDCA cycle is used within the technique. Originally, the documentation was written on A3 sheets of paper and put on information boards so that all interested employees could read it. Hence the name of the technique. It is a teamwork technique. It is assumed that all team members have the analytics sheet in sight. All parts of the sheet should be visible at the same time. For this reason, the support of IT tools is rarely used. Much more practical is a board hanging on the wall in the room where the team works on a daily basis.

In practice, various types of A3 templates are used, adapted to the specificity of typical problems occurring in organisations. An example template is shown in Figure 4.1. Three main columns are visible. On the left, basic information about the analysis is given, including: project data, start date, expected end date, and names of members. Then, the problem and its broader description are indicated, which should allow for a better understanding of the phenomenon.

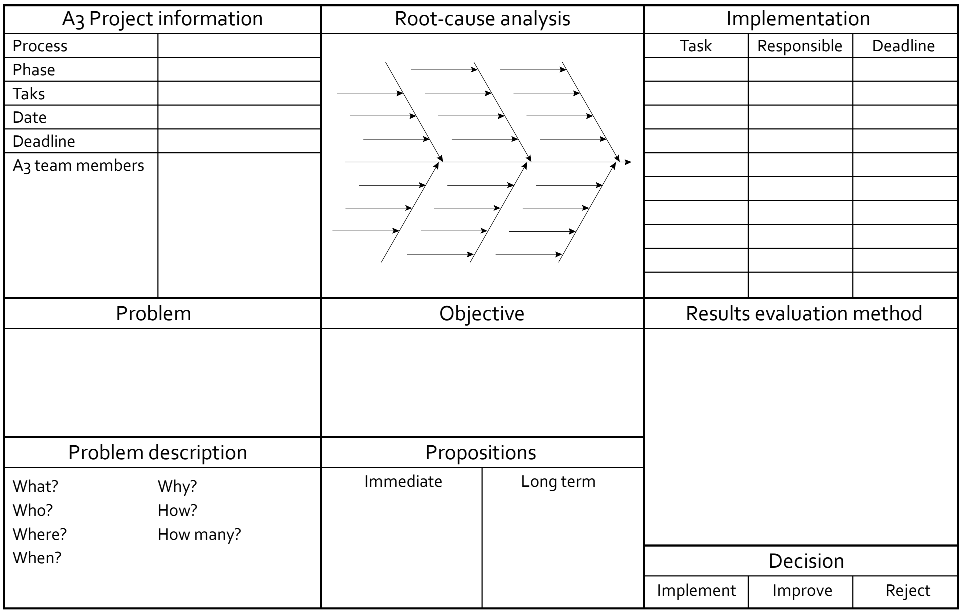


Figure 4.1. A3 technique template

Source: own elaboration.

The middle part is used to find the causes of the problem and propose solutions. The analysis of causes is carried out using the Ishikawa diagram, which allows for a visual presentation of the sources of the problem, their meaning and connections. Then, the goal that the team wants to achieve is indicated, e.g., elimination of selected causes, and a proposal of actions. This proposal may include immediate and long-term actions – systemically solving the problem.

The right part of the template contains a detailed action plan with an indication of responsible persons and deadlines. Usually, these activities concern trials, experiments, and test implementation to a limited extent. Then the actions are evaluated. Based on the results of the assessment, a decision is made to fully implement the results throughout the project or organisation. If the results of the experiments were not completely satisfactory, the team may decide to make adjustments or even reject the results entirely.

The use of the A3 technique will not bring the full expected results if the analysis is carried out by each member independently and not in a team. The strength of this technique is the integration of many points of view and different experiences. It was designed to solve problems of medium complexity, where working alone is not enough. At the same time, large-scale problems, such as those involving the entire enterprise, often require the use of more complex methods.

(2) SIPOC diagram

Quality managers want all processes to work smooth, stable, with minimum variability. The processes should deliver all the important values to internal and external customers. Thus process improvement is one of the key elements in quality management. Process management methods are widely applicable to quality management. One popular tool is the SIPOC diagram.

The name of the SIPOC diagram comes from five components: suppliers, inputs, process, outputs and customers. In fact, however, the name should be COPIS because the construction of the diagram starts with customers and ends with suppliers (Figure 4.2). The method is usually used by the project teams whose task is to improve the chosen process.

Critical to quality (CTQ) shown in the diagram are critical customer requirements that should be met by the process. The identification of stakeholders and the analysis of their requirements provide information about the CTQ. This is the starting point for creating a SIPOC diagram.

The team determines what outputs from the process are necessary to meet the requirements. These outputs include not only intended outputs but also often accompanying unintended outputs or waste, as well as new competencies and information. The latter can be used as inputs to other processes in the organisation.

Based on the outputs, a process is constructed that will reliably and stably deliver the intended results. When developing the process, the team should take into account the resources and competencies it has, limitations related to the technologies it has, space and other factors. The result of this step will be a rather generic process diagram. However, it should take into account all potential problems that may be associated with its implementation.

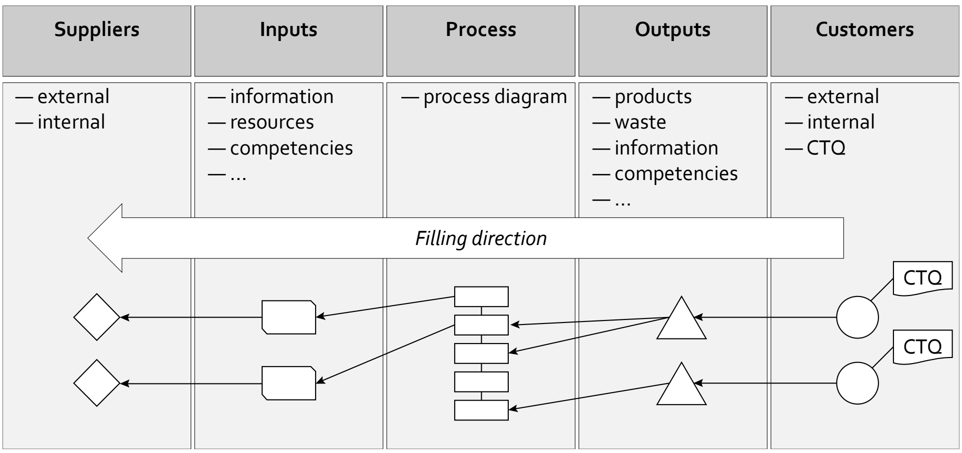


Figure 4.2. SIPOC diagram

Source: based on (BPM CBOK, 2013, p. 109).

Each process requires input in the form of competencies, information, parts or raw materials. The necessary input parameters should be specified at this point. This affects the selection of suppliers. For example, if high-precision machining of parts is required, it may turn out that not every supplier will be able to meet such expectations. It may also lead to a change in the technology used in the process, as high precision is usually associated with higher costs, and is not always necessary to obtain high-quality results. Inputs are provided by suppliers. It is worth noting that the SIPOC diagram is suitable for processes involving external customers and suppliers as well as internal processes where the project team collaborates with other units within the same organisation.

The analysis of the finished diagram makes it possible to detect deficiencies in the possessed technologies, competencies, materials, etc. It also allows for easy tracking of various ways of organising processes and selection of the course that best meets the client's requirements, and at the same time will be optimal from the point of view of the process employees' capabilities.

The presented method allows to obtain an outline of the process and does not have deeper analytical capabilities. This may be enough for solving simple problems and uncomplicated processes. When the team is dealing with greater complexity, it may be necessary to use more advanced process management tools. However, this does not diminish the usefulness of this tool. SIPOC allows to quickly outline the course of key processes and efficiently divide roles and responsibilities.

For complex processes, there may be a need to refine the SIPOC diagram and deep process analysis. Then, Business Process Management Notation (BPMN) can be applied. Additional support can be provided by one of the process management IT applications available on the market.

(3) Internal audit

Internal audit is widely used for quality improvement as it proved to be a very effective method of problem discovery. Internal audit is primarily a meeting and dialogue between the auditor and the auditee. Its purpose is to confirm that the audited process or task is in accordance with established standards, procedures, legal regulations, etc., as well as to find opportunities for further improvement. This does not mean that the auditor does not notice non-compliance. The detection of errors is not the auditor's goal; it is only a side effect. The audit is announced in advance so that everyone interested can prepare accordingly. The role of the auditor is to take a sample on the basis of which he or she will assess the compliance of the area with the requirements. Therefore, the audit does not remove the responsibility from the manager of the audited area but only provides him or her with information that allows to see the potential that can be used.

The cooperation between the auditor and the auditee is necessary as the audit should result in finding opportunities for improvement. Therefore, this tool requires building an atmosphere of trust in the organisation, increasing employee involvement, moving away from drawing personal consequences for non-compliance (except when required by law), creating a culture based on continuous improvement of all aspects of the organisation's functioning.

The auditor is a trained employee of the organisation who remains independent towards the audited process, and in particular is not employed in this process. The task is to answer four types of questions:

- whether employees can do the job properly – the question refers to having sufficient competencies, abilities, as well as the necessary equipment and resources,
- whether employees perform their work correctly – the question refers to compliance between the requirements described in procedures, standards, contracts, etc. and the actual work performed,
- whether the employees performed the work correctly – the question concerns whether the results obtained as a result of the work are in line with the requirements,
- can the work be done better – the question concerns the possibility of improving individual aspects of work performance, e.g., elimination of redundant activities, automation, changing tools, improving competencies, using a different technology.

Doubts may be raised by the similarity of the second and third questions. In practice, it is not uncommon for employees to perform work in accordance with documentation that is not perfect. As a result, despite the correct execution of the tasks, the effects are not satisfactory. Therefore, it is necessary to analyse the correctness of the documents, work and the results separately.

The fourth question concerns opportunities for improvement. It should be emphasised that it is not the auditor's role to impose solutions. Suggestions for changes should be made by the auditee as a result of discussions conducted during the audit. This shows well that the role of the auditor is limited to comparing the expected state with the actual state.

The auditor does not advise or indicate the right course of action. The choice of the method of action belongs to the auditee.

Internal audit is used systematically. Areas selected for monitoring are audited even several times a year. However, subsequent audits differ from each other because the auditors focus on various aspects of the functioning of the processes, and also look for new directions for improvement.

There are organisations where auditing is used in a skewed way and is more like a collecting ticks on a checklist. In this form, this tool does not bring the expected benefits and does not improve the functioning of the organisation. Therefore, efforts should be made to eliminate such pathologies by building a culture of quality, commitment and trust.

The right approach to auditing is fundamental in the case of remote audits. In recent years, audits are increasingly conducted remotely. Thanks to communication technology, the auditor can analyse documents, talk to employees, and observe the operation of processes. VR goggles, dashboards, and other modern tools make it easier to conduct audits in an environment that is very close to the real one. However, it is essential to remember that an audit is also about building relationships. Practice shows that remote audits are much more difficult.

(4) Statistical process control (SPC)

SPC is defined as a method using statistical techniques to monitor and control production processes. Based on statistics of what happened in the production process, it can predict what will happen in the future. It is used to monitor whether the production process is satisfactorily under control. It enables determining whether the process is stable and can produce outputs of predictable quality.

The process is defined as being stable if its natural variation (certain variations are a part of every production process) is due to common causes. The process is then said to be under statistical control and can deliver outputs of predictable quality. If a process is unstable, it is because unusual factors are operating. These factors, known as special causes, result in the process being out of statistical control. Special causes interfere with the process, so it produces outputs that are out of the required specifications. Special causes of process variations can be due to human error, bad raw materials, or equipment failure (Zontec, 2010).

The three main components of an SPC chart are (Figure 4.3):

- central line (CL) – reflects the average value of the measured characteristic,
- lower control limit (LCL) – CL - 3 standard deviations (σ) of the sample,
- upper control limit (UCL) – CL + 3σ of the sample.

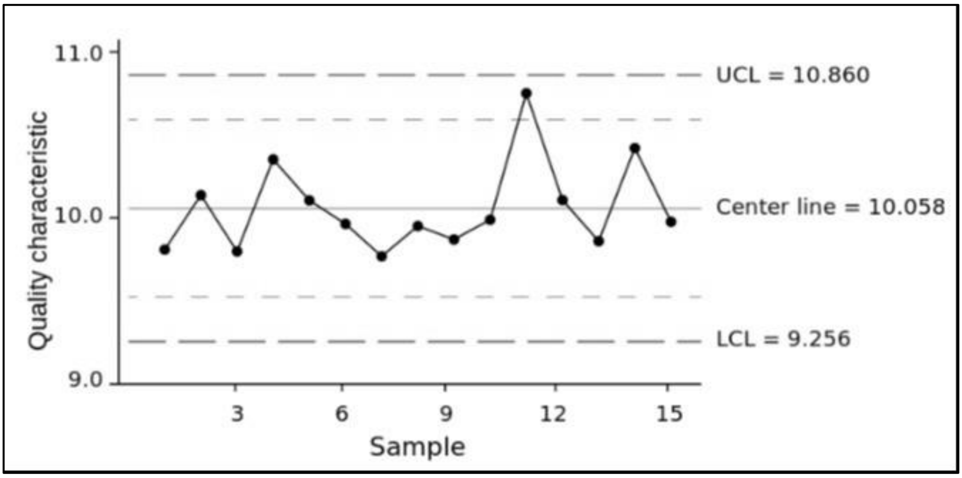


Figure 4.3. Example of SPC Chart

Source: own elaboration.

Control limits are derived from the statistical features of the process data and reflect the natural variation of the process. Control limits are usually wider than specification limits, and they are not fixed. They can change as the process improves or deteriorates. If the data points are within the control limits, it indicates that the process is in control (*common cause variation*). If there are data points outside of these control limits, it indicates that a process is out of control (*special cause variation*). Additional alert lines can be drawn, e.g. at CL ± 2σ. This visually divides the chart into zones: A – between 2 and 3σ, B – from 1 to 2σ and C – from average to 1σ.

To apply SPC techniques, the following procedure should be used:

1. Selection of measurable characteristics of the process that will be monitored and controlled with respect to critical customer or business requirements.
2. Choosing the appropriate measurement method and creating work instructions, including ensuring the measuring capacity of devices.
3. Determining a sample size and frequency based on the product's criticality.
4. Selecting appropriate SPC chart based on data type (continuous or discrete) and sample size.
5. Collecting the data and plotting the SPC chart.
6. Analysing the data to find patterns. Example out-of-control conditions are:
   - beyond limits – one or more points beyond the control limits,
   - zone A – 2 out of 3 consecutive points in zone A or beyond,
   - zone B – 4 out of 5 consecutive points in zone B or beyond,
   - zone C – 7 or more consecutive points on one side of the average,
   - trend – 7 consecutive points trending up or trending down,
   - mixture – 8 consecutive points outside zone C,
   - stratification – 15 consecutive points in zone C,
   - over-control – 14 consecutive points alternating up and down.
7. Identifying special causes of variation by using suitable QM methods.
8. Taking action to correct special causes of variation, i.e. eliminate the root cause of the problem.

Choosing right type of control chart is important to obtain desired information. Figure 4.4 shows the flowchart for the selection of the best control chart based on several criteria.

The ways the statistical process control is used changes due to the disruptive technologies of Industry 4.0. Internet of things and cloud computing enable the collection of data in real time. These technologies enable remote monitoring and control of production processes. Real-time data acquisition allows for more frequent monitoring of process parameters, facilitating timely decision-making and rapid response to deviations. With the use of intelligent technologies, the volume and variety of data available for SPC increase significantly. This includes not only traditional process variables but also additional data sources such as environmental conditions, equipment health, and product quality metrics.

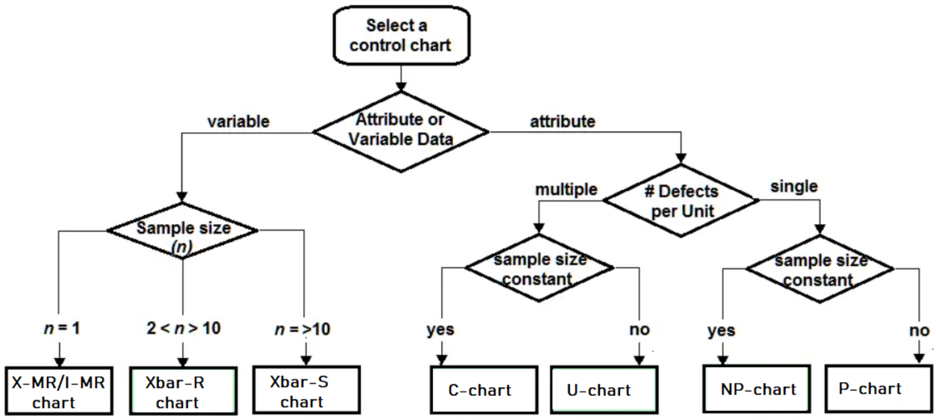


Figure 4.4. Choosing the type of control chart

Source: own elaboration.

Digital twins can be used for SPC purposes to conduct "what-if" scenarios, evaluate the impact of process changes, and optimise control strategies without disrupting production. Machine learning algorithms and deep neural networks can help to predict potential process failures or quality defects, allowing proactive interventions to maintain process stability and product quality. By analysing historical process data and equipment performance metrics, organisations can identify early warning signs of equipment degradation or malfunction and take proactive maintenance actions to prevent unplanned downtime and quality issues. Quality 4.0 transforms SPC by leveraging advanced digital technologies to enhance data collection, analysis, prediction, and control, ultimately leading to improved process efficiency, product quality, and competitiveness.

(5) Value stream mapping (VSM)

VSM is a lean manufacturing method that analyses, designs and manages the flow of materials and information required to bring a product to a customer. The value stream map is a visual tool that displays all critical steps in a specific process and easily quantifies the time and volume taken at each stage (Martin & Osterling, 2014). The roots of VSM can be traced to a visual mapping technique used in Toyota Motor Corporation known as material and information flow. A value stream mapping demonstrates activities that add value to the customer or business (value-added) as well as those that don't (non-value-added). The aim of the method is to help remove the activities that don't add value to the product or service from the perspective of customer in order to improve the process by eliminating waste.

VSM focuses on the duration of the entire process as well as individual tasks. The most important measures of time in this method are (Garcia Marqéz et al., 2020):

- takt time – the time in which products or services have to be produced or delivered to meet customer demands. Takt time is calculated by dividing the time available for production by the number of products required by the customer.
- lead time – represents the total time it takes a product to make it through an entire value stream (includes inventory time, cycle times, value-added and non-value-added activities).
- cycle time – the time from one completed output to the next completed output in the process step or unit.
- inventory and wait time – the time that products or materials spend waiting in inventory or buffers between activities.

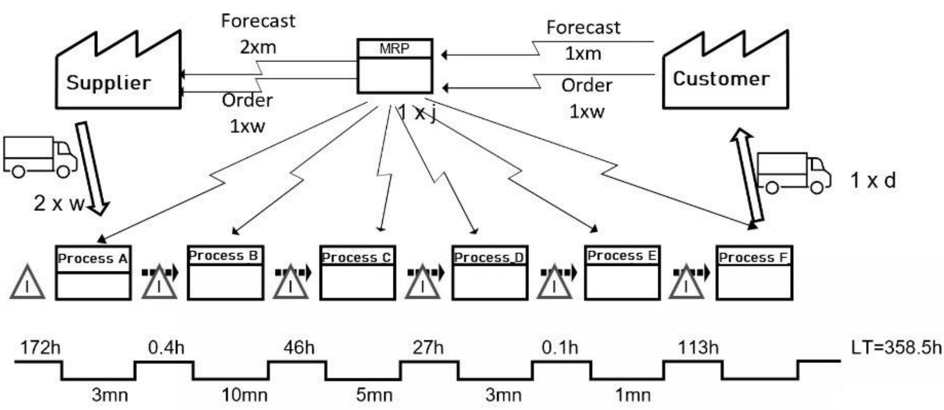


Figure 4.5. Example value stream map

Source: own elaboration.

The value stream maps use standardized symbols. The example of value stream map is shown in Figure 4.5, where can be seen the cycle times, inventory times and total lead time.

The procedure of using VSM consists of following steps:

1. Choosing the process and setting the objective and scope of the analysis. This will require answering the questions: why is this important? why do we need to change? what is the real problem?
2. Mapping the current state of the process, which allows getting an overall picture of material and information flow. It should map how value is created and how the entire production process operates, including above mentioned time measures.
3. Identification of waste generated in the process (e.g., bottlenecks, long cycle times, excessive set-up times, poor quality, rework) and determination of its root causes.
4. Creation of future state map, which reflects an ideal state for the organization, and a target state for all improvement activities. This creates a shared vision and goal for the organization and all of the employees.
5. Creation of the action plan and its implementation. The action plan should include timeline of improvement activities and the stakeholders that will lead these tasks. Once the action plan has been established, the implementation of this plan should begin.

Figure 4.6 shows selected standardised symbols used in creating the VSMs.

The era of Quality 4.0 enables new opportunities for VSM. IoT sensors and connected devices enable real-time data collection from various points within the value stream. This allows for more accurate and timely data on process performance metrics, such as cycle times, lead times, and inventory levels. VSM can leverage this digital data to create more precise and data-driven maps of the current state (Ferreira et al., 2022). VSM can be integrated with digital twin technology to create virtual models of the value stream. This integration enables simulation and optimisation of processes in a virtual environment, allowing organisations to test different scenarios, facilitating better decision-making and communication among stakeholders, identifying improvement opportunities and predicting the impact of changes before implementing them in the real world (Lu et al., 2021). Big data supported by AI models enable the analysis of large volumes of data and uncovers insights within the value stream. Machine learning can identify patterns, correlations, and anomalies in-process data, helping to identify waste, inefficiencies, and improvement opportunities more effectively. VSM can go hand-in-hand with AI-driven analytics to provide deeper insights into process performance and recommend optimisation strategies.

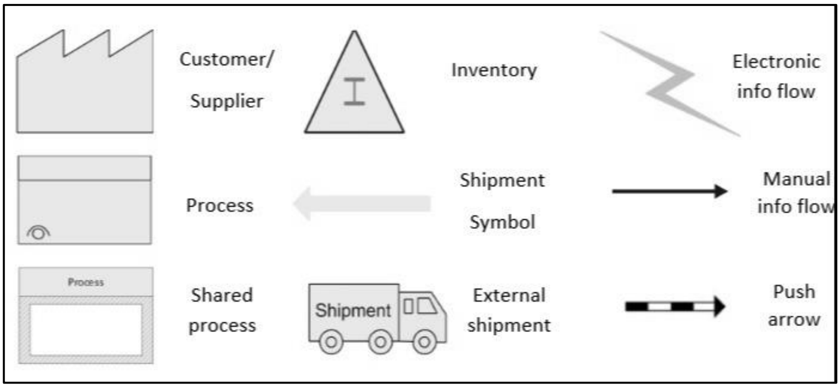


Figure 4.6. Example VSM symbols

Source: own elaboration.

Intelligent technologies enhance the practice of value stream mapping by providing access to real-time data, advanced visualisation tools, integration with digital twins, AI-driven analytics and remote collaboration capabilities. These technological advancements enable organisations to create more accurate, insightful, and actionable value stream maps that drive continuous improvement.

(6) Failure mode and effect analysis (FMEA)

FMEA is a team-based analysis of the potential occurrence of a failure in the product or process. It allows assessment of risks related to the failures. Based on the FMEA results it is possible to design and implement measures leading to the mitigation of these risks. FMEA is an important part of design review, as studies show that its application can detect up to 90% of potential failures (Nenadál, J. et al., 2018). FMEA is a team-oriented, systematic, qualitative and analytical method that is used for (*FMEA handbook*, 2019):

- assessment of possible (potential) risks related to product or process failures,
- an analysis of the possible causes and consequences of potential failures,
- documenting measures to prevent risks and measures to detect failures,
- the design and implementation of risk reduction measures, in particular measures to reduce the likelihood and impact (consequences) of failures.

The FMEA method was developed in the 1960s in the USA and was originally intended for reliability analysis of complex systems in space research, where it was developed by NASA for the Apollo project and in the nuclear power industry (Stamatis, 2003). Very soon, however, it began to be used to prevent the occurrence of nonconformities in other areas, with the greatest spread occurring especially in the automotive industry, where its processing became a mandatory part of the process of approving parts for serial production.

The FMEA method is currently one of the most sophisticated methods of risk management. With the increasing complexity of manufactured products, the development of new technologies and modern industrial process management systems, its use can be expected to develop further.

The FMEA method is mainly used in two basic applications. Either it deals with how well a product is designed in terms of risks of potential failures, or it deals with how well a process is designed in terms of risks of potential failures. A Design FMEA (DFMEA) minimises the risk of potential failures of a designed product during its use, whereas a Process FMEA (PFMEA) minimises the risk of potential failures of a designed process. The main benefits of applying the FMEA method include (Plura, 2001):

- a systemic approach to preventing poor quality,
- prioritisation of actions based on quantification of the risk of potential failures,

- design optimisation, leading to a reduction in the number of changes in the implementation phase,
- creating a valuable information database on the product or process,
- minimal implementation costs compared to the costs that could be incurred if defects occur.

The FMEA method is mainly used for new or innovative products, technologies or processes, but it can also be applied to existing products and processes. In the case of analysis of new products or processes, it should be started early enough, essentially when the first solution concept is developed.

FMEA is a method that must be applied in a team, as it requires the knowledge and experience of experts from different fields. The team should include among others experts from the fields of development, design, technology, manufacturing, quality management, testing, marketing, and service. Proper management of the team's work by an experienced facilitator is important for the effective work of the team. The FMEA of a product or process design generally proceeds in the following three basic phases (Plura, 2001):

- analysis and assessment of the current situation,
- design and implementation of risk mitigation measures,
- assessment of the situation after implementation of the measures.

In particular, the analysis and assessment of the current state identifies potential product failures that could occur in a given product or component during its intended use (DFMEA) or during the manufacturing process and its sub-operations (PFMEA). Each potential failure is then analysed in detail. The consequences of the failure and all causes of the failure shall be analysed, and the significance, probability of occurrence and ability to detect the failure shall be determined. The objective of this phase is to determine the risks associated with the potential failures (defects) and to set priorities for the next phase. In this phase, measures are designed and implemented to mitigate the risks associated with the most significant defects, the purpose of which is to minimise, in particular, the likelihood of the defect occurring or its expected impact (consequence). The third phase consists of evaluating the effectiveness of the measures implemented. The detailed steps were presented in Figure 4.7.

The first step is planning and preparation, where the subject of the analysis is defined, and the entire FMEA project is planned, including the team that will implement it. In the second step, or structure analysis, the product is systematically decomposed into its individual parts in the case of DFMEA, and the process is decomposed into sub-steps in the case of PFMEA. In the third step, a function analysis is performed. For DFMEA, the functions to be performed by the individual system elements (product parts) are identified. For PFMEA, the required functions to be provided by a given process step are identified, e.g. man, machine, material, environment. These first three steps represent the system analysis. From step 4 to step 6, failure analysis and risk mitigation are performed. First, an analysis of possible failures, their possible consequences and causes is performed. Then, a risk analysis is performed, which consists of an analysis of existing failure prevention measures, existing failure detection measures, an assessment of the significance, occurrence and detectability of failures, and prioritisation of risk mitigation measures. The penultimate step is optimisation, which is the design and implementation of risk mitigation measures. In the last step, the results are documented and communicated across the organisation.

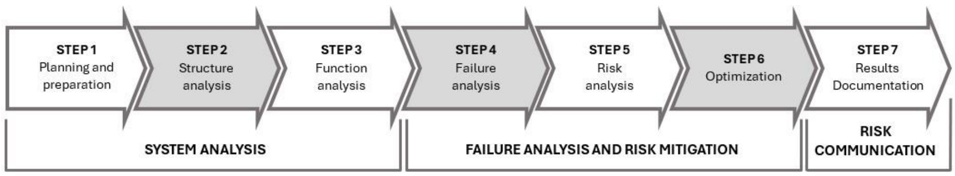


Figure 4.7. FMEA steps

Source: (*FMEA Handbook*, 2019).

Modern technologies associated with the Quality 4.0 concept, or Industry 4.0, will significantly affect the use of the FMEA method, and it can be assumed that technologies such as artificial intelligence, robotics, advanced data analytics and others can strengthen and expand the use of this method. This can ultimately improve the safety, reliability and quality of industrial products and processes. Continued automation and digitisation, and in that context, the use of sensors for automated online collection of large amounts of data from manufacturing processes and storage in the cloud, will provide a rich source of information to perform FMEA analysis. Megabytes of historical data stored in the cloud, its real-time analysis combined with machine learning, and artificial intelligence tools will enable more accurate identification of potential failures and associated risks, contributing to faster response to potential problems.

Already in the first step of the FMEA implementation, it is advisable to visualise the product or process using virtual or augmented reality, which can provide us with information for a better understanding of the entire analysed system. A detailed visualisation and simulation of the entire system or process is also possible with a digital twin. Simulations performed using digital twins make it possible to predict how different changes will affect the system or process. A digital twin can simulate different failure scenarios, which helps identify potential weaknesses in a design or process without the need for physical testing. The digital twin enables a quantified assessment of the impact of potential failures on overall system performance. Simulations can provide data on the frequency and severity of failures, leading to a more accurate determination of the likelihood and impact of individual failures (step 5). By simulating failures and analysing their consequences, the digital twin can suggest the most effective ways to eliminate or minimise the risks of failure. This may include design modifications, changes in materials, or adjustments to process steps (step 6). Once the solution is implemented, the digital twin can continuously monitor the system and provide feedback for the next iterations of the FMEA process. This is particularly valuable for dynamic systems where conditions are constantly changing, and the FMEA needs to be continuously updated. All information and simulations performed using the digital twin can be easily documented and archived, improving decision traceability and facilitating review and audit of the FMEA process (step 7).

Some steps of the FMEA method can be performed using artificial intelligence tools combined with large amounts of historical data collected by sensors connected to an internal computer network and stored in the cloud. Artificial intelligence can automate the data collection and analysis process to identify key components and processes. Machine learning algorithms can analyse large amounts of historical performance and failure data, helping to determine which components or processes should be included in the FMEA analysis (step 1). Artificial intelligence can use predictive modelling to predict potential failures based on existing data (step 4). This technique can identify potential vulnerabilities before actual failures occur, leading to proactive improvements. Artificial intelligence and machine learning algorithms can be used to quantify the likelihood and impact of failure. This includes analysing different failure scenarios and their potential impact on the entire system or process, enabling risk prioritisation. Based on the analysis performed by artificial intelligence, risks can be more efficiently identified and categorised according to their potential impact on functionality and safety, allowing teams to focus on the most serious issues (step 5). Artificial intelligence can suggest effective strategies to minimise or eliminate risks. This may include suggestions for component redesign, process changes, or recommendations for maintenance cycles (step 6). It can also can monitor the effectiveness of implemented corrective actions and automatically adjust methods according to changing conditions or newly acquired data. This enables continuous improvement of processes and the system as a whole. AI can also automate the process of documenting all aspects of the FMEA analysis, contributing to the accuracy and transparency of the process for future auditing and review activities (step 7). Artificial intelligence can link FMEA data and information to other quality management systems or Internet of Things devices for better management and monitoring. These are just a few examples of the potential use of modern technology in implementing FMEA. The specific implementation then depends on many factors related to the specific conditions and capabilities of each organisation.

(7) Design of experiments (DOE)

Successful implementation of products into the production process requires understanding of multiple relations between the product elements, characteristics of materials or limits of machinery. To achieve high quality it is important to know which processes and activities will be affected by the changes related to product implementation. It is also important to understand the causal relationships between the inputs and outputs of a process. This often requires an approach based on the experiments, where the characteristics of inputs are deliberately changed to achieve the best possible outputs. If such an experiment is appropriately designed, it will allow to see which inputs significantly affect outputs, allowing to estimate what the relationship between significant inputs and outputs might look like. This information can then be used to optimise the levels of inputs so that the output, i.e. specific product parameters, is also optimised according to predefined criteria, such as customer requirements.

There are two types of experiments: unplanned (live) and planned ones. They are managed using DOE method. DOE is one of the branches of statistics and quality management. It is an effective tool for planning and improving processes and products (Nenadál, J. et al, 2018).

Design of experiments has its roots in the 17th century. In 1662, the French mathematician and philosopher Blaise Pascal published his work on probability, which introduced the basic ideas of random events and probability. Another important figure in the history of the DOE was the British mathematician and statistician Ronald A. Fisher, who described the principles and methods of designing experiments (Fisher, 1926). Fisher's approach was based on mathematical models and statistical techniques that allowed researchers to systematically and efficiently investigate causal relationships between different variables. During the 20th century, DOE became an important method in industry, where it was used for process optimisation and product quality improvement. Today, there are many variations and applications of DOE. It has become a key method for the research and development of new technologies, manufacturing processes and products, as well as for testing and verifying hypotheses in various scientific fields (Myers et al., 2016). DOE brings a number of benefits to scientific research, engineering, and industrial practice, e.g. (Montgomery, 2020):

- allows the effects of multiple variables to be systematically and efficiently examined simultaneously,

- allows the identification and analysis of interactions between different variables,
- experiments designed using this method help to better understand the relationships between variables and their effects on the system under study,
- allows finding combinations of process inputs that lead to the best results,
- helps to create more robust and reliable products and processes by revealing which factors are critical and how resilient systems are to changes in these factors,
- helps to identify the factors that cause the most variability in results, allowing more stable performance to be targeted,
- increases confidence in the results and conclusions of experiments.

The procedure of a planned experiment usually consists of the following general steps (Montgomery, 2020):

1. Definition of the problem and objectives of the experiment.
2. Selection of factors and levels.
3. Designing the experimental plan.
4. Conducting the experiment.
5. Data analysis.
6. Interpretation of results and optimisation.

A simple but easy-to-understand example of the general DOE process is baking a cake (Figure 4.8). In the first step, it is important to clearly define the objectives of the experiment, particularly the identification of key inputs, outputs, and potential distractors. In the example of baking a cake, key output characteristics were identified, which could be, for example, the taste of the cake, its colour and its consistency. The key inputs (factors) are the equipment in which the cake will be baked and the ingredients needed, e.g. oven, sugar, flour, eggs and possibly others. In the second step, the factors are selected based on the inputs: oven baking temperature, amount of sugar, amount of flour, number of eggs, etc. Typically, two levels (values) of factors are then selected, for example, a minimum (lower factor level) temperature and a maximum (upper factor level) temperature.

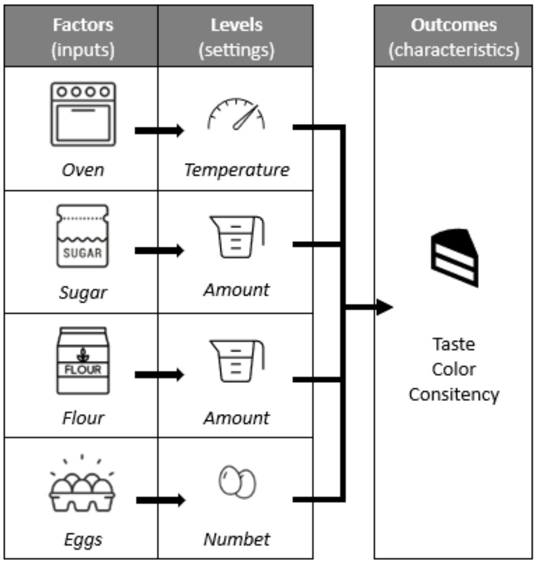


Figure 4.8. Example of DOE application

Source: based on (Moresteam, 2024).

An important step is to create a plan for the experiment. There are several ways of setting up the experimental plans (Montgomery, 2020), according to which each experiment will be conducted. For example, one is to construct a full factorial plan; that is, the experiment plan will include all possible combinations of the two levels for all four factors. The number of experiments is calculated as 2k. The value 2 represents two levels, and k is equal to 4, which is the number of factors. For example, the first trial usually means setting all factors at their lower level. After that, the levels of each factor are gradually changed until all combinations are exhausted. Table 4.3 shows an example of tabular notation for three factors and two levels. The number of trials in this case is 8. Where A, B, and C are the labels of each factor and the "–" sign represents the lower factor level, and the "+" sign represents the upper factor level.

The individual experiments are then executed as planned, with accurate and systematic data collection or measurement (assessment in the case of non-measurable traits) and recording of the actual results during the experiment. In the example of baking a cake, this might be the case for the characteristic (output) colour – right or wrong. In the case of measurable traits, it is the measured values. The data analysis involves using statistical methods to analyse the data obtained (ANOVA, regression analysis) to evaluate the outcomes achieved and the interactions between factors. Significant factors are identified, and their optimal levels are set to achieve the optimal result, i.e. a cake that tastes good, has the right colour and consistency.

Table 4.3. Example of an experiment plan

Experiment No.	Levels of factors			Outcomes
	A	B	C	
1	-	-	-	
2	+	-	-	
3	-	+	-	
4	+	+	-	
5	-	-	+	
6	+	-	+	
7	-	+	+	
8	+	+	+	

Source: own elaboration.

It is clear that modern technologies associated with Industry 4.0 will have a significant impact on the use and development of the DOE method. Digital technologies such as artificial intelligence, the Internet of Things, big data, advanced robotics, and cloud computing are bringing new opportunities to improve DOE implementation. Artificial intelligence can help in automating the DOE process by offering a fast and efficient generation of experimental plans based on the desired objectives and available process data. It can suggest optimal configurations and conditions for experiments, saving time and resources. Using machine learning, artificial intelligence can develop predictive models that forecast experimental outcomes based on historical data. This allows for better planning of experiments by knowing possible outcomes and their probabilities in advance. In addition, it will be possible to identify the most effective combinations of variables to achieve targeted outcomes. It will be possible to adjust experimental parameters in real-time to ensure the best possible performance of the process or product. Based on the online automated collection of large amounts of data, artificial intelligence can monitor the progress of experiments and automatically make adjustments in response to newly acquired data or unforeseen events. This dynamic approach enables more flexible and efficient experimentation.

Cloud services provide fast, on-demand access to vast computing resources without the need to invest in expensive hardware. The cloud makes it easy and secure to store, share and manage the data needed to run a planned experiment. This facilitates collaboration between team members who may be geographically dispersed, allowing them to work on collaborative projects in real-time. The advantage is that cloud computing integrates easily with other technologies, such as artificial intelligence, machine learning and the Internet of Things, expanding the possibilities for conducting experiments. For example, cloud services can process in real time data acquired through IoT and use machine learning for analysis and prediction. Data is regularly backed up in cloud systems and protected through advanced security protocols, minimising the risk of data loss due to hardware failure or other problems.

Digital twins allow simulations and tests to be carried out in a safe virtual environment before experiments are carried out on real systems. In this way, potential problems can be identified, design and procedures can be optimised, and the risks and costs associated with actual physical tests can be minimised. In some cases, it may be impossible or impractical to conduct physical experiments due to high costs, risks, or complexity. Digital twins allow complex experiments to be conducted virtually, expanding the possibilities for research without these limitations. A major advantage is that digital models can be constantly updated with new real-world data, increasing their accuracy and relevance. Therefore, easy integration with other technologies such as artificial intelligence, cloud computing, and the Internet of Things is also important for even more efficient data collection, analysis, and implementation of innovations.

4.3. Selected quality 4.0 tools

With the proliferation of the Industry 4.0 paradigm, the inadequacy of conventional quality management tools has become increasingly apparent. IoT generates massive amounts of quality data from processes, devices, working environment and products. Quality data are collected automatically in real-time and due to their heterogeneity and volume, it is necessary to use advanced analytical tools to make value from data and support decision-making processes.

The difference between traditional quality management methods and tools and Quality 4.0 tools can be described and summarised from the perspectives of automation, complexity and scalability and types of analytics. Traditional QM methods and tools often require significant manual and cognitive effort for data collection, analysis, and decision-making. Quality 4.0 tools can automate many aspects like data collection from various sources within the entire value chain, analysis, anomaly detection, and decision-making. Traditional QM methods and tools may also struggle with complex and large datasets or with detecting subtle patterns and trends. AI and ML enable more sophisticated analysis by handling large and complex data structures, nonlinear relationships, and high-dimensional data. It can uncover insights and correlations that may be difficult or impossible for conventional QM methods to identify. In the third perspective, the traditional QM methods and tools often rely on predefined rules, procedures, and historical data for decision-making. AI-based quality management systems leverage advanced algorithms, machine learning models, and artificial intelligence techniques to analyse vast amounts of data, identify patterns, and make predictions or recommendations autonomously.

Industry 4.0 technologies were introduced in the first chapter. The technologies like big data, virtual reality, augmented reality and digital twin were already described and put into the context of quality management in more detail in Chapter 2. In this chapter, we discuss how selected disruptive technologies, i.e. blockchain, machine learning, deep neural networks and machine vision, can be used to further improve quality management in the enterprises.

(1) Blockchain

Blockchain is a rapidly developing technology of cryptographically secured information storage and sharing mechanisms. The blockchain system is decentralised. It aims to have a peer-to-peer network of nodes, each capable of receiving and storing data. Data can only be stored in a chain of linked blocks. To protect the integrity of data forever, the hash of each block is stored in the next block along with the corresponding data at the time, forming a series of blocks. Blockchain helps to ensure:

- immutable records – once data is added to a blockchain, it cannot be altered or deleted,
- time stamping – blockchain provides an irrefutable time-stamping mechanism for every transaction,
- transparency within the value chain.

Application in quality management involves:

- supply chain management – blockchain helps to track every step of the supply chain process, ensuring that products meet quality standards at each stage.
- auditing and compliance – blockchain provides auditors with a transparent and auditable record of quality-related data,
- smart contracts for quality agreements - blockchain platforms can automate quality agreements between parties involved in manufacturing or distribution. These contracts can enforce quality standards and automatically trigger actions or payments based on predefined criteria,
- quality control – blockchain can be used to provide an immutable record of quality throughout the entire production process, including the quality of inbound materials and the results of quality inspections during manufacturing,
- maintenance – blockchain smart contracts can be used to trigger maintenance based on the machine's condition (equipped with sensors and connected to Industrial IoT) and existing service agreements.

(2) Machine learning

Machine learning is a subset of artificial intelligence in which algorithms learn from input data to make predictions or classifications and identify patterns. Machine learning algorithms can analyse historical quality data to identify patterns and predict future outcomes or even make suggestions about what action to take. Predictive analytics techniques enable organisations to anticipate quality issues, optimise production processes, and reduce the likelihood of defects or failures. Machine learning applications improve with use and become more accurate the more data they have access to. The machine learning process usually consists of the following steps:

1. Problem formulation – definition of the problem that shall be solved with machine learning. This includes understanding the goal, the type of problem (classification, regression, clustering), and the impact of the solution.
2. Data gathering – involves collecting the data for training the model.
3. Data cleaning – data need to be cleaned to be useful, this may involve formatting and vectorisation (turning data into the mathematical constructs that ML models understand).
4. Choosing the right algorithm – depending on the problem and input data (size, dimensionality, distribution), a suitable machine learning algorithm should be chosen to start the training process.
5. Training and building the model – during the training, the algorithm automatically learns from the training data set by searching for patterns and adjusting its internal settings for expected results. The output is the machine learning model.
6. Model testing and refinement – performance of a fully trained model is evaluated on a testing set. It helps to evaluate how well the model can generalise what it has learned. This also provides engineers with insights for further improvements.
7. Model deployment and prediction – once the machine learning model is ready, it can be fed with input data to provide a predicted output

A successful ML model depends on both the data and the performance of the learning algorithms. Supervised learning algorithms take a known set of input data and known responses to the data and train a model to generate reasonable predictions for the response to the new data. Supervised learning often uses classification and regression algorithms to develop machine learning models. Classification algorithms predict discrete responses. Regression algorithms predict continuous data. Figure 4.9 shows various supervised algorithms classified as classification and regression algorithms.

Regression uses an algorithm to understand the relationship between dependent and independent variables. Regression models help predict numerical values, e.g. defect rates, product quality metrics, or process performance based on various input factors. Regression algorithms can help understand the relationship between different process parameters and product quality, allowing optimisation of production processes, predictive maintenance based on input data (e.g., temperature, vibration, usage hours) and the target variable (e.g., time until failure) predict future performance and defects.

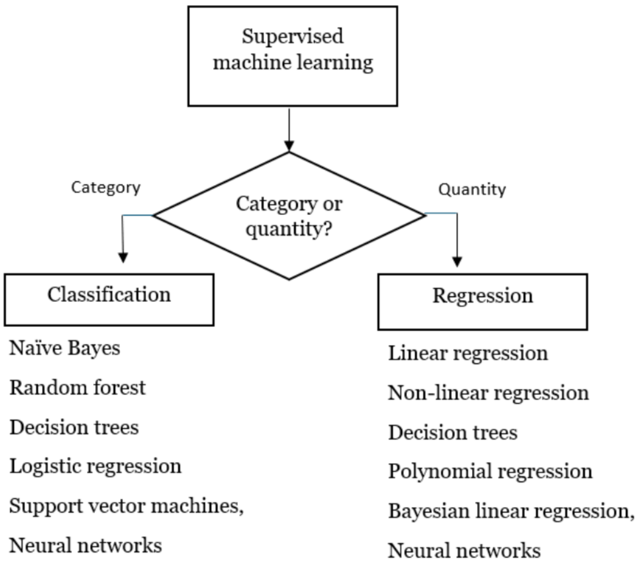


Figure 4.9. Supervised machine learning algorithms

Source: based on (Wolf, 2022).

Classification uses an algorithm to accurately assign test data into specific categories. Predicting the class of given data points can be carried out using structured or unstructured data. For example, spam detection, such as "spam" and "not spam" in email service providers, can be a classification problem (Binary classification). Applications in quality management can involve e. g. automatic defect detection and classification (e.g., various categories of surface defects), classification of products into different quality levels based on various features or attributes, classification of machine or equipment into different failure risk categories, identification patterns and factors contributing to defects – root causes (decision trees), identify factors influencing customer satisfaction or dissatisfaction, classifying process performance on the base of process parameters.

Unsupervised learning algorithms analyse unlabelled datasets without the need for human interference. This is widely used for extracting generative features, identifying meaningful trends and structures, groupings in results, and exploratory purposes. The most common unsupervised learning tasks are clustering, association, dimensionality reduction, etc. Unsupervised machine learning algorithms are shown in Figure 4.15. There are selected algorithms for clustering, association problems and dimensionality reduction.

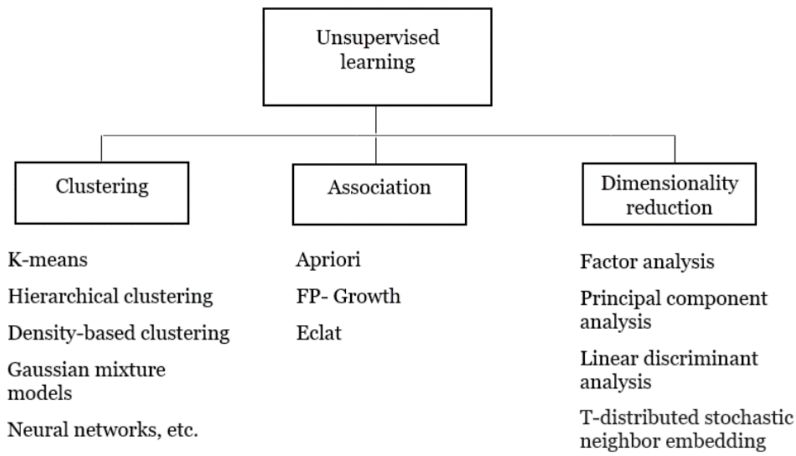


Figure 4.10. Selected unsupervised learning algorithms

Source: based on (Gao et al., 2020).

Clustering algorithms allow grouping a collection of objects in such a way that objects in the same category, called a cluster, are in some sense more similar to each other than objects in other groups. Applications in quality management include defect detection and classification, customer segmentation, root cause analysis, and process optimisation (e.g. clusters associated with efficient process conditions).

Associations help discover interesting relationships, such as "if-then" statements, in large datasets between variables. Typically, the association rule is used for market basket analysis. If a customer buys product A, then he usually buys also product B. Applications in quality management involve root cause analysis, finding combinations of process parameters that are associated with a higher quality of products, predictive maintenance, prediction of customer demands and behaviour.

Dimensionality reduction algorithms seek to transform data from high-dimensional spaces to low-dimensional spaces without compromising meaningful properties in the original data. These techniques are typically deployed during exploratory data analysis (EDA) or data processing to prepare the data for modelling.

(3) Deep learning

Deep learning is a subset of machine learning that uses multi-layered artificial neural networks (ANN) to progressively extract higher-level features from the raw input. It simulates the complex decision-making power of the human brain. Deep learning can be supervised or unsupervised. DL modelling usually employs similar processing steps as machine learning.

The components of a deep neural network are the input layer, hidden layer, and output layer, as it is shown in Figure 4.11. The middle layers are called hidden layers because their values aren't observable in the training set. The more hidden layers a network has between the input and output layer, the deeper it is. Each subsequent layer takes the results from the previous layer as input. The learning process is performed using the distinct stages of abstraction and multiple levels of representation in a supervised or unsupervised manner.

Deep neural networks are trained on large amounts of data to identify and classify phenomena, recognise patterns and relationships, evaluate possibilities, and make predictions and decisions. With automatic feature learning and high-volume modelling capabilities, deep learning provides an advanced analytics tool for smart manufacturing in the big data era. Deep learning offers great potential to boost data-driven quality management. The operation in the deep learning process generally depends on two stages (He et al., 2021):

- training phase – involves labelling large amounts of data and determining their adaptive properties,
- inference step – conclude and label new and unseen data, using their prior knowledge.

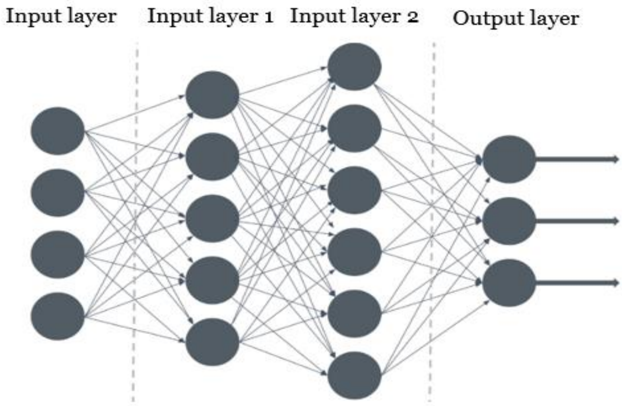


Figure 4.11. Example deep neural network layers

Source: based on (Taye, 2023).

Deep learning is a method that helps the system understand the complex tasks of perception with maximum accuracy. Deep learning can be used to detect defects in real time by analysing images or sensor data, deep learning models can identify deviations from the requirements. It can also be used for quality prediction based on various input data and predictive maintenance by analysing historical data on equipment performance, maintenance records, and environmental factors. Natural language processing (NLP) helps to analyse customer feedback and complaints and identify quality issues and areas for improvement. Some examples of deep learning algorithms include (Papageorgiou et al., 2022):

- deep neural networks with have more than three layers trained to model non-linear problems; used for speech and image recognition (defects detection and classification, customer feedback analysis).
- convolutional neural networks used for image and video recognition and classification (defects detection and classification).

- recurrent neural networks used for predicting data based on time series data, natural language processing (forecast quality-related metrics over time, predict when a machine might produce a faulty product, allowing for preventive maintenance, process optimisation, analyse customer feedback and complaints).

(4) Machine vision

Machine vision encompasses applications in which a combination of hardware and software provide operational guidance to devices in the execution of their functions based on the capture and processing of visual data, like images, videos, or 3D spaces. By pairing optic sensors with artificial intelligence that can analyse and process image data, robots and autonomous vehicles equipped with machine vision systems are able to perform more complex tasks.

Machine vision is an important tool for automatic monitoring and optimisation of production processes. It automates visual inspection, eliminates the need for manual inspection, and reduces human error. With the use of smart cameras, it can quickly identify defects or inconsistencies in products, ensuring that only conforming products are passed through the line (Wang et al., 2019). The benefits of machine vision systems can be summarised as follows:

- highly accurate and can detect flaws or defects that may be missed by human inspectors,
- by automating inspection and analysis tasks, they can significantly increase productivity and reduce costs,
- can be used to monitor and detect potential safety hazards in industrial settings, helping to prevent accidents and injuries,
- don’t physically touch products, lessening the chances of equipment damage and wear and tear,
- by eliminating excessive labour and wasted materials, they can lower costs for businesses,
- facilitate real-time monitoring of the assembly line, which ensures swift corrective actions, preventing the production of substandard products and minimising disruptions,

- with their ability to reduce defects and waste, contribute to a more sustainable manufacturing process compared to traditional quality control methods.

Machine vision systems consist of three main components: camera, processor, and software, and use digital images to detect even the smallest defects or deviations from the standard. The machine vision process consists of:

- image acquisition,
- pre-processing,
- image analysis,
- decision making,
- integration and connectivity.

Deep learning-powered vision systems can detect defects with high accuracy and consistency, ensuring that only products meeting quality standards are delivered to customers. Deep learning algorithms can analyse camera footage to spot tiny imperfections on products, like scratches on car bodies or tears in textiles.

Applications of machine vision involve barcode scanning, print character reading, measurement (surface area, volume, length, and width), quality inspection, navigation of warehouses, robotic guidance, e.g., locating a specific part and ensuring its proper placement – assembly, picking and placing, or packaging.

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Quality 4.0 involves leveraging Industry 4.0 advancements like the Internet of Things, artificial intelligence, and big data to enhance products and services. This encompasses employing sensors and data analysis to oversee production processes in real time, detect flaws, and enhance effectiveness. The objective of Quality 4.0 is to attain elevated standards of product excellence, customer contentment, and operational efficiency by harnessing sophisticated technologies.

Quality 4.0 can be applied across diverse sectors such as manufacturing, and service industries. In manufacturing, for instance, Quality 4.0 solutions enable real-time monitoring of production processes, defect detection, and efficiency enhancement. This entails utilising sensors, IoT devices, and data analytics to monitor production data and pinpoint areas ripe for improvement.

The aim of this book is to introduce the issues of Quality 4.0 to both academic teachers and students. The book was designed to complement the rich literature in the field of quality management. It can be used as an additional guide or textbook for students. The book consists of four chapters.

The book is one of the results of the international project "Improving quality management teaching in the era of Industry 4.0". The project was co-financed by the Governments of Czechia, Hungary, Poland, and Slovakia through Visegrad Grants from International Visegrad Fund. The mission of the fund is to advance ideas for sustainable regional cooperation in Central Europe.

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