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An experimental approach to total quality management in the context of Industry 4.0

PhD dissertation

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CONTENTS

ABBREVIATIONS

IoT	Internet of Things
IIoT	Industrial Internet of Things
AI	Artificial Intelligence
CPS	Cyber-Physical System
EU	European Union
QC	Quality Control
QA	Quality Assurance
TQM	Total Quality Management
QMS	Quality Management System
ISO	International Standards Organization
FMEA	Failure Mode and Effects Analysis
CLH	CLAAS Hungária Kft
RPN	Risk Priority Number
RFID	Radio Frequency Identifier
ASQ	American Society of Quality
ERP	Enterprise Resources Planning
CRM	Customer Relationship Management
AutoML	Automated Machine Learning
API	Application Programming Interface
DMAIC	Define, Measure, Analyze, Improve, and Control” process of Six-Sigma
DMADV	Define, Measure, Analyze, Design, and Verify” process of Six-Sigma
RADAR	Results, Approach, Deploy, Assess and Refine
EFQM	European Foundation for Quality Management

1. INTRODUCTION AND OBJECTIVES

In this chapter, the importance of the research topic is presented, the problem of the study is identified, along with the specific research objectives.

1.1. Introduction

The tremendous development in every technological field reached an outstanding position in the recent decade, communication and networking technologies are quietly advanced, the evolution of broadband and wi-fi connections, Internet of Things (IoT), Big-Data, Artificial Intelligence (AI) and Cloud Computing, paced up an intelligent era symbolled by Cyber-Physical Systems (CPS), which accordingly paved the way for further revolutions in several fields, hence, the industrial fields.

Industry 4.0 is known as the technological development that occurred in the industry from embedded systems to intelligent Cyber-Physical Systems (MacDougall, 2013). It was first suggested and adopted by the German government in its high-tech strategy 2020 (MacDougall, 2013), introduced in 2011 during the Hannover fair event (Qin et al., 2016). Industry 4.0 aims at utilizing the new technological systems such as IoT, Cloud Computing, and Big-Data to revolutionize the industry to intelligent manufacturing systems (Trappey et al., 2016), where production and warehousing facilities are connected to each other in the form of Cyber-Physical Systems (Henning et al., 2013).

Quality management has developed since it was first introduced by quality experts in industrial applications. The scope was expanded from being product-focused using the quality control (QC) techniques, to process and product-focused by applying quality assurance (QA) techniques. Furthermore, the scope has expanded to a more comprehensive approach by applying total quality management (TQM) practices. TQM involved customers, suppliers, people, leadership, processes, and continuous improvement in the quality management scope.

However, the new industrial development in industry, hence, Industry 4.0, changed the way of how TQM practices are implemented. For example, quality control techniques are enhanced by the utilization of advanced sensors and instant analytical techniques. Such advancement improved the way production is monitored and enhanced. However, traditional quality management practices shall be upgraded to meet such advancement in technologies. A new integrated quality management system shall be suggested in order to benefit from the new developments in manufacturing systems. Traditional techniques of yesterday are obsolete to be utilized in the same approach today.

Moreover, since Industry 4.0 has a significant impact on many industrial and socio-economic issues, there are still lagging in addressing its impact on TQM practices. There is a need to analyze the relationship between applying Industry 4.0 technologies and the improvement incurred on TQM in an experimental method. But before doing such an analysis, a literature review is conducted to identify the interface where Industry 4.0 and TQM are interacting. The aim is to answer the genuine question; what is the impact of Industry 4.0 on TQM practices implementation? However, it will be impossible to assess such an impact at all TQM practices, therefore, this research work assessed a single TQM method in an experimental approach.

In this research work, the role of Industry 4.0 in developing TQM practices is discussed through two approaches; theoretical and experimental. The theoretical approach included a comprehensive review of the features, technologies, and applications of Industry 4.0. Such a review is followed by exploring the ISO 9000:2015 standards family as a TQM commonly adopted strategy. These TQM practices are discussed in the context of Industry 4.0. Hence, how industry 4.0 will influence the implementation of TQM principles. As a result, a total quality management-Industry 4.0 interaction interface is identified. This interface is proposed along with suggested key performance indicators that are suitable to assess the impact of Industry 4.0 on TQM practices. Moreover, an integrated Industry 4.0-Quality management-based system is suggested where Industry 4.0 features and technologies are integrated into the traditional QMS functions.

On the other hand, the experimental approach assessed the impact of integrating one of the Industry 4.0 technologies, namely machine learning techniques with one of the TQM practices, namely process monitoring and improvement. In this experimental approach a cloud system that automates machine learning is utilized to enhance failure mode and effects analysis (FMEA) as a process and product quality assurance technique. This experimental approach is conducted in partnership with an agricultural machinery manufacturing company in Hungary, namely CLAAS Hungária Kft (CLH).

In conclusion, the impact of Industry 4.0 on improving TQM practices is examined in a real-case example. The results of this research work are theoretical including the Industry 4.0- QM based system, which is important nowadays to respond to such a development in the practices of quality management, and experimental which are resulted from applying machine learning methods on developing a quality management method which is FMEA.

1.2. Research objectives

The goal of this research is to investigate the role of Industry 4.0 in developing total quality management practices and to examine such an impact experimentally. Within this broad goal, the research has the following specific objectives:

1. To identify an interface where Industry 4.0 can support the most critical practices of total quality management such as the seven TQM principles as in ISO 9000:2015 standard in addition to quality control and quality assurance.
2. To identify the set of qualitative and quantitative performance indicators for the TQM best implementation practices aligned with the Industry 4.0 features and technologies. Accordingly propose their relevant measurement methods tools by using suggested Industry 4.0 features and technologies.
3. To suggest a comprehensive Industry 4.0 - quality management-based system and to examine the actuality of such a system or part of it through a scientific partnership with an industrial company in Hungary.
4. To examine the impact of Industry 4.0 technologies on one of the TQM common practices such as “process monitoring”. Hence: enhancing FMEA using auto-machine learning.

2. LITERATURE REVIEW

In this chapter, a comprehensive literature review for the major components of this research work is introduced. Firstly, Industry 4.0 concepts, features and technologies, and the most known approaches to TQM from which common practices are concluded. After that, the literature on failure mode and effects analysis (FMEA) is reviewed along with the used machine learning methodology. Finally, a literature analysis is made to highlight the research gap especially to the relevant objectives of this research work.

2.1. Industry 4.0

The name, Industry 4.0, stands for the fourth industrial revolution. Fig. 2.1 illustrates the first three revolutions that represent the development of the industry since the first revolution, emerged during the 18th century, and relied on the mechanical power generated from steam and water, this stage was called the mechanization era. The second revolution, known as the electrification era, emerged during the 20th century. This revolution advanced the industry to mass production, where the production process is divided into stages, benefitting from the extended experience of labor gained from the repeated work. The second industrial revolution responded to the increased market demand and witnessed the birth of the industrial conveyor which was used to transfer products between machines automatically. The third revolution, known by the automation era, emerged as the result of integrating programmable logic controllers, which were invented during the 1970s, in the manufacturing systems. Such an integration facilitated the automation of industrial production and minimized the efforts needed by the labor. Recently, computer systems are developed and integrated into the industry. This utilization is advanced by the IoT, CPS, and Big-Data setting up new industrial opportunities that are agreed to be known as Industry 4.0 (Keller et al., 2014; Qin et al., 2016; Scheer, 2013).

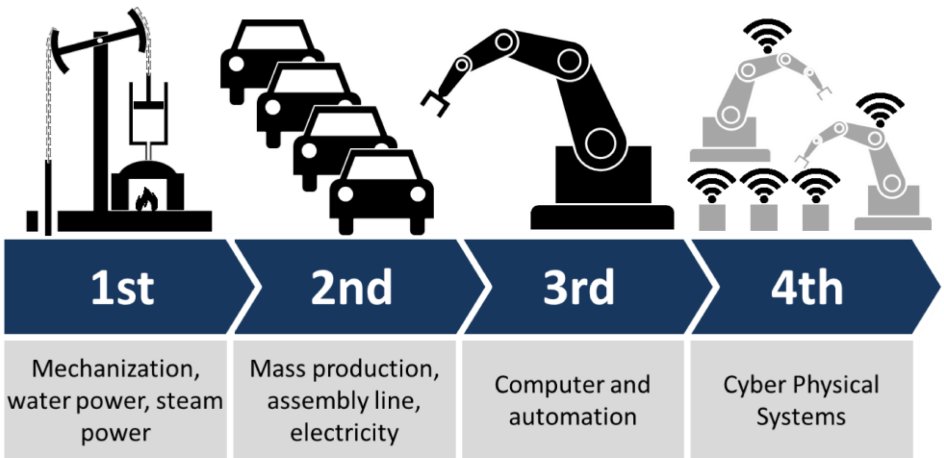


Fig. 2.1. Illustration of Industry 4.0 showing the four industrial revolutions (Roser, 2017)

Industry 4.0 is characterized by the ability to transfer the real world to the virtual level where it is optimized and improved and then executed again in the real world. Such a transferee is being possible by utilizing IoT and CPS technologies. New levels of manufacturing are evolved such as flexible production systems and individualized products. Moreover, Industry 4.0 enabled the integration of business stakeholders and end-customer in the production value chain (Federal Ministry of Education and Research, 2014). An Industry 4.0 paradigm resulted in what is now called smart factory, smart machine, and smart products (Devezas et al., 2017).

The need for Industry 4.0 is founded since 17% of the gross domestic product (GDP) generated in European countries is accumulated from the industrial sector which offers about 32 million jobs annually. However, this large economical sector in Europe is being challenged by the aging community of the EU countries and the accelerating development of other competing developing industrial economies such as China and Asia (Qin et al., 2016). Therefore, Industry 4.0 was innovated and supported by the German Government in order to maintain the leading position of Germany in the industrial sector (MacDougall, 2013).

Similarly, Industry 4.0 is supported by the new development of smart IT solutions including data gathering tools (sensors) and intelligent analysis systems (software). Such support provided the ability to analyze Big-Data that is being generated and gathered from manufacturing processes as well as during the whole production value chain. The developed analysis techniques, such as AI and machine learning, enabled the transformation of the Big-Data to a user-friendly knowledge, illustrated on the computer dashboards. Such a presentation replaced the traditional monitoring tools and provided a key enabler for industrial effectiveness and efficiency. Hence, a bedrock for Industry 4.0 development. (Blanchet, Rinn, 2015; Keller et al., 2014; Qin et al., 2016, Zezulka et al., 2016; Zhou et al., 2016)

Additionally, Industry 4.0 came because of the increasing demand for innovative solutions in production and logistics, producers are focusing on creating greater value for customers, who are becoming more aware and demanding more advanced, reliable, personalized and high-quality products (Witkowski, 2017). Similarly, industrial firms are seeking a more competitive position through acquiring flexible production lines, zero inventory, efficient resources allocation, a high responsiveness to market demand, lower logistics and labor costs, and to acquire more competitive advantages above other competitors (Rennung et al., 2016; Wang et al., 2017).

Industry 4.0 swapped the production from a centralized to a de-centralized manufacturing system, made it possible to advance the production from the traditional machining process to a more interactive and complex process where the product communicates with the machine, telling it what to do (MacDougall, 2013). Additionally, the utilization of intelligent Cyber-Physical Systems catered the ability of the machine to gather data, analyze, learn, and decide independently (J. Lee et al., 2015). This feature paved the way to offer a new generation of industry, where factories are intelligent enough, having the ability to self-plan and self-adapt to provide more customized products and fulfill customers' expectations autonomously (Witkowski, 2017).

In the meanwhile, the production strategy depending currently on mass production to minimize the production cost-per-unit, and to fulfill the expanding market demand of a product (economies of scale). However, in the recent decade, customers are increasingly demanding more than ever before, looking for more customized and detailed products that differ from each other (Keller et al., 2014; Wang et al., 2017). Industry 4.0 opened the door for more customized products, preserving mass production, and fulfilling advanced customers' requirements at the same time.

However, Industry 4.0 is still a new phenomenon that is not implemented widely, while several industries are in the testing and development stage. Thus, Industry 4.0 requires further research on several areas to identify its impact on manufacturing, human resources, products, and economies (Ibarra et al., 2018). Additionally, industry 4.0 still has some ambiguities in terms of security, safety, and connectivity issues. Such problems in addition to the lack of expertise that is needed to run the utilized technologies effectively can cause significant damages when occurring. Failure during production entails expensive costs and could be harmful to human beings (Mrugalskam Wyrwicka, 2017).

2.1.1. Industry 4.0 features

Industry 4.0 is characterized by three key features; Interconnection, Integration, and Big-Data:
Interconnection: is the core feature of Industry 4.0, where all kinds of machines doing various jobs are interconnected together, forming an intelligent digitized value chain, where the product can hold readable information (RFID) that can be understood by machines, thus, the machines can process the product, and when it is needed, it can re-adjust, diagnose, and repair production tactics until achieving an optimal situation (Zhou et al., 2016). The basis of Industry 4.0 is the ability to exchange data and information among the value chain in real-time, all instances involved in the value chain are connected and data is accumulated (Husti et al., 2017).
Integration is the ability of Industry 4.0 to perform vertical, horizontal, and end-to-end integration. As illustrated in Fig. 2.2, vertical Integration refers to the networked smart business units; smart factory, smart logistics, smart marketing, and services (Mrugalska, Wyrwicka, 2017), where manufacturing units are coordinating and communicating smoothly. Horizontal Integration over the value chain refers to the forward to backward (customer to supplier) integration. Horizontal Integration enabled the manufacturing environment to become collaborative during the stages from the development of the product till production, resulting in more efficient, reliable and effective manufacturing. End-to-End integration is the overall integration of the entire production regime, performing a decentralized system where all participating entities have real-time access to information, and control is distributed among the production floor instantly (Keller et al., 2014).

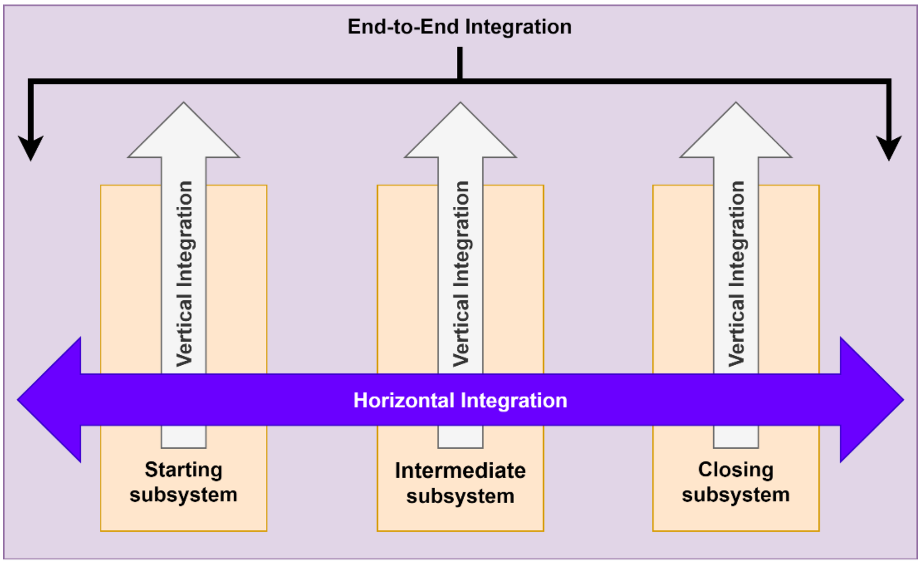


Fig. 2.2. Simplified illustration of the three types of integrations (Husti, Daróczi, Sader, 2017)

Big-Data: The rapid development of internet and networking, produced a large volume of information that requires innovative methods and tools to handle (Blanchet, Rinn, 2015). Big-Data is a data management and distribution system, which is very necessary for achieving self-aware and self-learning machines (J. Lee et al., 2014). Big-Data consists of four dimensions: Volume, Variety, Velocity, and Value. These so-called (4Vs) refers to the characteristics which allow Big-Data to analyze data at a more advanced level than traditional tools. Volume refers to the ability to collect, store, manage, and analyze the huge size of data that can’t be handled by ordinary tools. Variety; is the variety of data sources such as transactional systems, social networks, or internet, this data is highly dynamic and changes in a very short time, variety is also referring to the type of data such as images, videos, text, etc. Velocity; is the speed of data generation and analysis, which occurs in real-time, and should be analyzed on an ongoing basis despite its different changes. Value; is the ability to isolate important and highest value data that represent the actual situation in real-time (Witkowski, 2017).

Based on these features, Industry 4.0 is expected to lever the following capabilities of a production system:

- Ability to improve communication and collaboration among the value chain of a production system from customers' end to suppliers and vice-versa.
- Creating a responsive production system that fulfills market demand quantitatively and qualitatively in a very responsive manner. The new Industry 4.0 production systems can respond to customer’s expectations and technical requirements and improve products simultaneously (Wang et al., 2017).
- Achieving higher effectiveness and efficiency of production systems; improved resource allocation, selective human intervention, automatically optimized production planning, and improved supply chain management (Witkowski, 2017).
- Advanced quality assurance, introducing modern “intelligent quality control systems”, early failure prediction system, cost-effective quality monitoring techniques (Kuo et al., 2017).
- Optimized lean production systems, where all kinds of waste including time, materials, human power, and inventory levels are in their optimum values (Mrugalska, Wyrwicka, 2017).
- Transparent production system, where every activity is clearly rendered, monitored, recorded, and assessed in real-time.

These abilities, as summarized in Fig. 2.3, are key enablers for business excellence and directly reflect an improvement on quality principles. The above-described features enabled Industry 4.0 to provide solutions for different fields in the industry, advanced monitoring and analysis techniques, process and functional optimization, decision-supporting systems at different organizational levels, moving from a centralized to a decentralized model of management and upgraded the management approach from the traditional popular model to a modern one at several sides.

Such an advancement came synchronized with the recent global trends in business, where the world is becoming more connected; global business models are expanding, and customers are more open to online shopping, demanding innovative products, with more personalized specifications. Moreover, new emerging economies are coming as key players at the global industrial stage, leading industrialized economies are experiencing key challenges, such as aging communities, the open competition with Asian economies of scale. All these challenges became the justification of adopting Industry 4.0 technologies (Blanchet, Rinn, 2015; Federal Ministry of Education and Research, 2014).

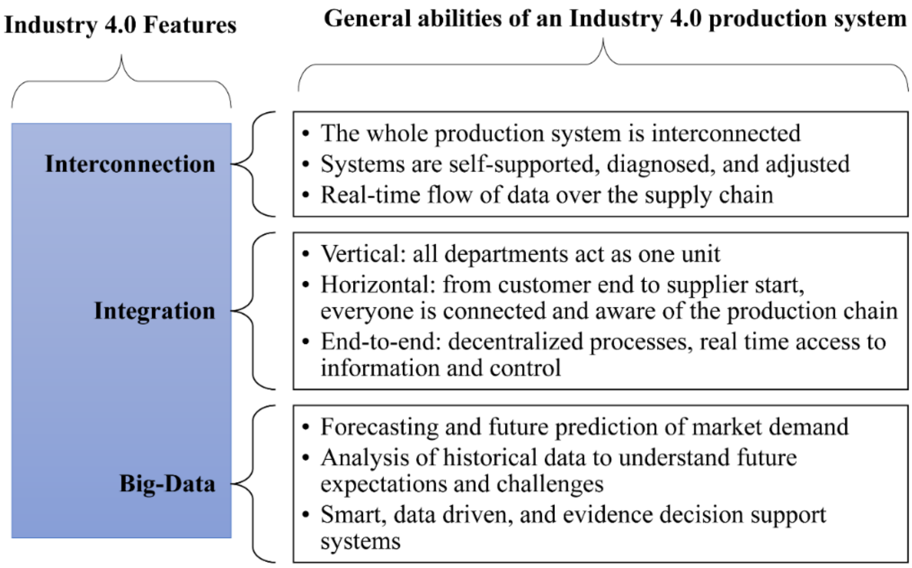


Fig. 2.3. Abilities of an Industry 4.0 production system

2.1.2.Industry 4.0 key technologies

According to literature, these are the key technologies that support the advancement of Industry to reach the outstanding level of Industry 4.0:

Cyber-Physical Systems (CPS): Gilchrist (2016) defined CPS as the integration of computation, networking, and physical processes. The embedded computers and networks monitor the physical process, feedback is returned continuously after computational processes are made. In industry, IT systems will be working jointly with machines, warehouses, and suppliers to adhere a defined standard and offer real-time control over the value chain, using these technologies will enable highly efficient manufacturing in which production process can be handled at a short notice and minimum downtime (Blanchet, Rinn, 2015).

Cloud Computing: The National Institute of Standards and Technology in the United States, defined cloud computing as "*a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction*". Data handling and processing became more reliable and efficient by using minimum resources to store and handle the data processing activities (Mell, Grance, 2011). Cloud computing owns several advantages, it can offer infinite computing resources on-demand, eliminate up-front commitment, pay for resources consumption only, applicable economies of scale strategies, and the simplicity of operation and resources utilization (Armbrust et al., 2010).

Internet of Things (Industrial Internet of Things): is the ability of real-world objects to communicate in different ways and to perform jobs more responsively and collaboratively with the ability of self-learning (Trappey et al., 2016). IoT connect adapters and devices in the form of a social network, where every element is connected to a control and management layer through a gateway to becoming ubiquitous throughout the Smart Factory and supply chain (Husti et al., 2017).

Artificial Intelligence (AI) is radically developing nowadays in many different fields, empowered by the development of computer and telecom technologies such as Big-Data and supercomputers which are able to analyze large volumes of data at a super-fast speed (Duan et al., 2019). Machine Learning (ML) is one of the AI technologies, it is used in many fields of our lives, based basically on extracting knowledge from Big-Data, trying to detect patterns or predict future behaviors (K. M. Lee et al., 2019). ML is being widely used by large scale businesses such as Google. Microsoft, and Facebook benefiting from the massive amounts of data accumulated through the usage of their services (Guyon et al., 2019). Currently, ML is being used at other sectors such as health (Faes et al., 2019), finance (Sadgali et al., 2019), and in many business management fields such as logistics and workflow optimization (Lyutov et al., 2019), customer care (Arora et al., 2009) and more. There are many ML tools and platforms, some examples are Google TensorFlow, Scikit-learn, Google's Cloud AutoML, Microsoft, etc. (K. M. Lee et al., 2019; B. Liu, 2018).

2.1.3. Impact of Industry 4.0 on several fields

Industry 4.0 elevated the automation of production to a new advanced level, where machines can collaborate to attain higher efficiency in production systems, enhancing productivity, and more customization ability of products. The era of Industry 4.0 is characterized by the use of the Internet to connect machines together like in a social network. Cyber-Physical Systems and Artificial Intelligence extended the ability of the production systems to reallocate and reorganize itself virtually and instantly to respond to any prompt changes requested by stakeholders in the value chain.

In addition to the industry itself, Industry 4.0 had many significant consequences on several other socio-economic fields, such as developing new businesses and services models, generation of new types of complex, smart services and products, modern business management systems, collaborative and interactive work environment, which in total led to major changes in the required human skills, as well as in the demographic and social life (Pereira, Romero, 2017).

Industry 4.0 aims to obtain a flexible and automatic adaption of the value chain, to offer the ability to customize products and maintain mass production at the same time, and to facilitate communication among all production elements; products, machines, humans, and resources. Furthermore, it aims to optimize production and to provide an advanced level of interaction and coordination between different resources (Blanchet, Rinn, 2015).

Witkowski (2017) examined the impact of utilizing Industry 4.0 techniques, including Big-Data and the Internet of Things, as innovative approaches to supply chain management. The author concluded that Industry 4.0 created opportunities to develop logistics and supply chain management, hence, meeting customers' needs and improve lead time and service delivery.

Mrugalska, Wyrwicka (2017) examined the impact of Industry 4.0 on lean production techniques. These techniques were successfully challenged in an Industry 4.0 integrated mass production environment. Industry 4.0 helped to eliminate waste during production, eliminating everything that does not add any value to the product.

Kuo et al. (2017) utilized sensors, simulation, and artificial intelligence techniques to design and implement an automatic machine status prediction model, that predicts machine status and diagnose any quality defects due to machining failures. This approach resulted in a cost-effective solution for monitoring the production process to improve the quality of products using Industry 4.0 technologies.

Moreover, Albers et al. (2016) suggested a three-phase procedure for identifying and running an Industry 4.0 intelligent quality control system, within which a single production process was analyzed to identify quality-related production issues that shall be addressed with an intelligent condition monitoring based quality control system. This procedure aided industries to move forward in developing industry 4.0 based quality control systems. Moreover, the authors summarized the influence of Industry 4.0 on the industry from a quality perspective. For example, the study reported 50% increased productivity and 80% increased efficiency, while 45% of the surveyed companies believed that Industry 4.0 improved customer satisfaction due to eliminated defective products.

Industry 4.0 became the umbrella for several innovative technologies such as Cyber-Physical Systems, Internet of Things, Big-Data, and Cloud Computing. As a result of integrating these technologies in the industry, new capabilities and possibilities reinforced the traditional quality techniques and improved the effectiveness and efficiency of production systems. Industry 4.0 had a significant impact on several managerial fields. Therefore, it is important to address its impact on quality management which is the scope of this study.

2.2. Total quality management

Total quality management (TQM) is a managerial approach that leads an organization to achieve a world-class position by ensuring that its products and services satisfy customers, meeting their requirements and expectations (Yusof, Aspinwall, 2000).

The term “total quality management” was first suggested and led by the American scientist “William Edwards Deming” (1900-1993), who traveled from the United States of America to Japan to help the Japanese industrial firms to recover from the World War II. During his work, he implemented the statistical quality control and process control, as tools to trace production errors and to identify the source of products’ defects (G. K. Kanji, 1990). Later, he met with “Joseph M. Juran” (1904-2008), who was stressing to focus on customers’ satisfaction through producing fit-to-use products that fulfill the customers’ needs. Shortly, both Deming and Juan successfully caught the attention of the markets all over the world, their innovative ideas increased the production rates in Japan and contributed very strongly to the Japanese well-known successful industrial miracle (Kanji, 1990).

Since then, the philosophy of TQM has been enhanced and expanded, several TQM principles were identified to guide the good implementation of TQM at organizations. The goal was to extend the scope of quality management from micro to macro level by benefitting business stakeholders, where everyone at the organization as well as the business processes are cooperating to produce value-for-money products and services. This cooperation fulfills and positively exceeds the customers’ expectations (Dale, 2015). Researchers found that TQM has improved organizational effectiveness, flexibility, competitiveness, excellence, created positive attitudes, and was a source of creating continuous improvement culture at the organization (Anil, K.P., 2016).

2.2.1. Approaches to total quality management

TQM is a general philosophy that can be achieved by several approaches. Historically, TQM was first introduced by the two quality experts William Deming and Joseph Juran. Later, other experts followed and contributed to further approaches and tools to quality management such as Philip Crosby, Feigenbaum, Kaoru Ishikawa, and others. Every one of those experts contributed to the development of TQM as a powerful technique to achieve business excellence. Later, during the 1980s to 1990s, several quality organizations introduced models such as international standard organization (ISO) and national quality award (NQA). These models were used as guiding roles and principles to apply TQM (Neyestani, 2017). Moreover, some literature summarized and proposed different approaches and methods to successfully implement TQM, some of the literature works are also summarized here. In conclusion, this study suggests three general approaches to quality management, these are illustrated in Fig. 2.4.

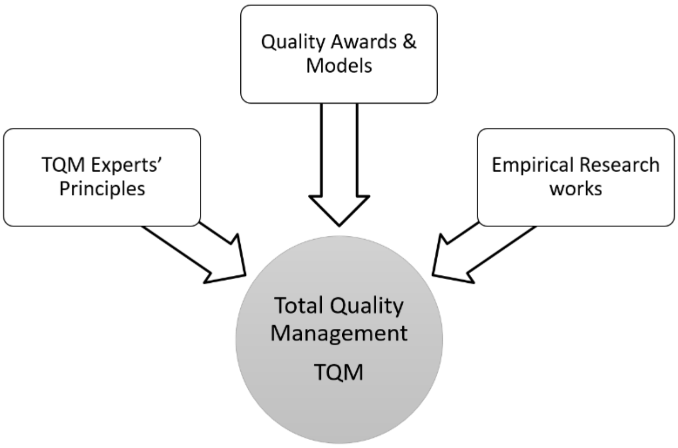


Fig. 2.4. Three general approaches to TQM

At first, TQM practices as suggested by quality experts. Such practices were developed based on the actual experience of quality experts as they were involved in many manufacturing and business firms. For example, William Deming (1900-1993) suggested his approach to continuous improvement by the well-known strategy called Plan-Do-Check-Act which became later the core of most quality management policies such as DMAIC, DMADV for Six-Sigma, and RADAR. All these concepts represent the continuous improvement of processes' quality (Sokovic et al., 2010). Moreover. He suggested the 14 points for quality management, and seven deadly diseases (Walton, 1988). These points are very popular quality principles and used as successful transformation strategies for any company toward achieving excellence.

Joseph M. Juran (1904-2008) known as "the father of quality management" for his contribution to quality management, especially by the "quality trilogy" and his philosophy of continuous improvement through planning, controlling, and improvement (Petersen, 1999). Moreover, Juran focused on statistical process control using Pareto charts, the quality triangle as a system involving three important corners; customers, processes, and suppliers (Neyestani, 2017).

There are also other quality experts such as Kaoru Ishikawa (1915 – 1985), Philip Crosby (1926 – 2001), and Armand V. Feigenbaum (1920-2014). Ishikawa is known for his cause-and-effect diagram (Scouse, 1985), which is a very successful tool for analyzing information related to a problem to detect its potential causes (Sartal, Vázquez, 2017). Crosby suggested his 14 steps for quality improvement, these steps intersect with other suggested approaches, for example, the importance of management commitment, the existence of quality management team, employee involvement and training, and continuous improvement (Kanji, 1990). Feigenbaum was the first quality expert who suggested the implementation of total quality control (TQC) concept. He defined TQC as a comprehensive system that integrates quality management activities such as quality development, improvement and quality maintenance with the other managerial functions such as product design, marketing, and service, in order to reach full customer satisfaction (Neyestani, 2017).

The second source of TQM practices is as suggested by quality models and quality awards that are suggested by many quality leading institutions. The Japanese Union of Scientists and Engineers (JUSE) created the "Deming Prize" in 1950, the prize is awarded according to an evaluation criterion consisting of 10 elements relevant to quality management. Moreover, the Malcolm Baldrige National Quality Award is the American model created in 1987 by the government in order to recognize firms that excel in quality according to seven categories namely *"leadership, strategy, customer and market focus, information and analysis, human resources focus, process management, and business results*" (Ghicajanu et al., 2015, p. 450).

European Foundation for Quality Management model, launched in 1991, is designed to help the European enterprises in increasingly global competition through encouraging collaboration, innovation, and cooperation (European Foundation for Quality Management, 2013). The model consists of nine criteria grouped in two main categories: enablers and results. Enablers consisting of leadership, strategy, people, partnerships, processes Results consist of customer results, people results, society results, and business performance results (Porter, Tanner, 2004).

International Standard Organization (ISO 9000) standards family, was firstly suggested in 1987 when the first version was released. The latest version in the ISO 9000:2015 which was approved on the basis of ISO 9001:2008 version. The benefits of implementing this system are the ability to provide high-quality products and services that fulfills customers' requirements, continuously enhance their satisfaction, addressing the risks and opportunities associated with the organization's context and objectives, and conformity to specified quality management system requirements. ISO 9000:2015 consisted of seven quality management principles namely customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision making, and relationship management (ISO, 2015a).

Thirdly, TQM practices as suggested by research works: which at the same time influenced by the previous two approaches. For example, (Saraph et al., 1989) concluded a set of eight quality management practices for both manufacturing and services companies. These practices defined the role of the leadership at the organization, the importance of creating a quality management department, continuous training, involvement of all departments at a company in the process of product/service design and development, focusing on suppliers, process management, data analysis to support decision-making, and finally the involvement of company's employees in the quality works. This paper is important as it concluded the most common practices of previous quality experts and then examined these practices through a survey study.

Kanji, Asher (1996) suggested 100 methods for implementing TQM, these methods are grouped into four main methods' categories depending on its purpose or scope; (1) The management methods are used at a managerial level to define the quality goals and objectives such as the Deming wheel. (2) The analytical methods such as failure mode and effect analysis. (3) Ideas generation methods such as brainstorming. And finally, (4) the data acquisition, analysis, and presentation methods such as tally charts, histograms, and pie charts. This work is important for its technical know-how presentation, every method of the 100 is explained by meaning, purpose, when and how to use, its advantages, and aligned with practical examples.

Porter, Parker (1993) concluded eight factors that are critical to the success of TQM, these factors are influenced by the quality experts' literature or TQM implementation success stories at very known companies. The importance of the study comes from its approach to reviewing the literature, conclude success factors, and then examine the reliability and importance ranking of these factors in real implementation. The authors suggested that management attitude is the most critical factor for a successful TQM implementation. A broad strategy for implementing TQM comes as the second importance, structured organization, communication, training and education, employee involvement, process management, and using the up-to-date quality-related technologies.

2.2.2. The selected approach to TQM in this research work

As explained in the previous discussion, there is no specific universal approach to implement TQM (Anil, K.P., 2016). However, Yusof, Aspinwall (1999) agreed that TQM critical success factors are those "*must be practiced in order to achieve an effective quality management system*". Accordingly, after an extensive literature review for the most known TQM experts (such as Juran, Crosby, Deming, Ishikawa, and Feigenbaum), Quality Awards (such as the American Malcolm Baldrige National Quality Award, European Quality (EFQM) Award, and Deming Prize), and empirical researches, Anil & K.P. (2016) concluded 30 critical success factors, and shortened later to 18 representing the most critical factors for successful TQM implementation. The authors suggested the comprehensive list in Table 2.1.

Table 2.1. TQM Critical success factors (Anil & Satish, 2016)

1. Leadership and top management commitment	10. Quality assurance
2. Education and training	11. Employees empowerment
3. Continuous improvement	12. Quality citizenship
4. Strategic management	13. Quality culture
5. Supplier quality management	14. Process management
6. Statistical process control	15. Benchmarking
7. Customer focus	16. Product innovation
8. Quality information analysis	17. Process and product design
9. Employees involvement	18. Knowledge management

Accordingly, to make this research more specific, the requirements of the ISO 9000:2015 quality management system (QMS) are critically analyzed. Opportunities and challenges of TQM practices as in ISO 9000:2015 in the context of Industry 4.0 are highlighted. These general principles are chosen in this research work as the baseline of total quality management as they can exhibit the majority of the success factors that are listed in Table 2.1. For example, as shown in

Table 2.2 the ISO 9000:2015 principle which is "process approach" can also refer to process management, statistical process control, and quality assurance. This can be confirmed based on the interpretation of each item as explained in the ISO 9000:2015 fundamentals and vocabulary document (ISO, 2015c). Moreover, the hierarchy of the ISO quality management system principles and its link to TQM implementation is illustrated in Fig. 2.5.

Table 2.2. ISO 9000:2015 TQM principles VS. 18 principles as in Anu P. Anil & Satish (2016)

ISO 9001:2015 TQM principles	18^{th} Principles as in Table
Customer focus	- Customer focus
Leadership	- Leadership and top management commitment - Strategic management - Quality citizenship
Engagement of people	- Employees empowerment - Employees involvement - Education and training - Quality culture
Process approach	- Process management - Statistical process control - Quality assurance
Improvement	- Process and product design - Continuous improvement - Benchmarking - Product innovation
Evidence-based decision making	- Knowledge management - Quality information analysis
Relationship management	- Supplier quality management

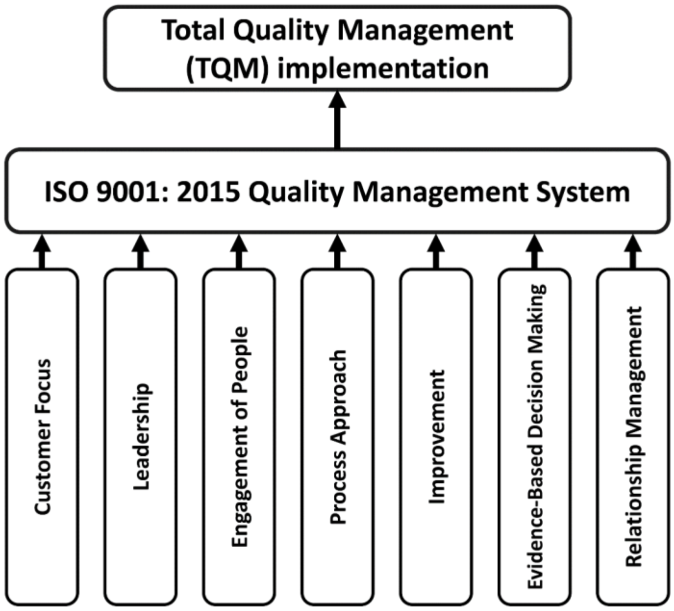


Fig. 2.5. ISO 9001:2015 principles and TQM implementation

Moreover, it is important to discuss “quality control” and “quality assurance” as each of them represents an effective tool of a quality management system. In conclusion, the ultimate objective of all the approaches is to implement TQM which finally aims to satisfy customers and realize business excellence through effectiveness and efficiency. The ISO 9000:2015 principles are defined by (ISO, 2015c) as follows:

Customer focus: is the main driver for quality, meeting customers’ requirements and strive to exceed their expectations. Such a goal is achieved by understanding the organization’s customers, grouping and communicating with them, aligning the organization’s objectives to customers’ needs and expectations. Other supporting activities to this goal are to measure and monitor customer satisfaction and take proper actions and modify products when needed. It is also important to maintain sustainable relationships with customers. The outcomes of these goals are measured by several indicators such as customers’ loyalty, satisfaction, growth of customers’ base, the improved reputation of the organization, and increased market share.

Leadership: the role of leadership is important to ensure unity of purpose between all leadership levels toward achieving the organization’s quality goals. This implies that the leadership is responsible to communicate the organization’s vision, mission, strategies, and policies to all managerial levels. It is also important to encourage an organizational-wide commitment to quality principles, which means that every member of the organization including leaders shares the same believes and habits. Additionally, it is important to train people at the organization and to delegate authorities and responsibilities to them. This needs proper training and clear accountability policy.Engagement of people: it is important to engage people of the organization in achieving the organization’s quality objectives. Empowerment, recognition, enhancement of competences, support personal development, and encouraging initiatives, all will contribute to the excellence of the organization, improve business activities, building a creative, motivating, and trust environment. It will improve the satisfaction of employees and will support and promote the organizational values among all people.

Process approach: activities and processes of the organization should be understood, consistent, managed and coherent with the entire system of the organization. It is necessary to identify the system objectives to understand the necessary processes to achieve them. Managing processes needs authorities, responsibilities, and accountability policies to be identified. It is important to understand the interdependencies of processes and the interrelations to achieve the quality objectives of the organization effectively and efficiently. Performance monitoring, analysis, transparency is important to evaluate processes and take corrective actions or optimize processes when needed. Risks affecting the system should be addressed to avoid downtime and emergency maintenance.

Continuous improvement: is essential for organization development, it will maintain its innovative position among competitors, continuously enhancing processes' performance, supporting organizational capability, and customers' satisfaction. Continuous improvement will enhance the organization's ability to avoid risks and react to opportunities. Improvements include the development of new products and services as well as processes. Successful organizations support the culture of continuous improvement by admiring innovators and recognize improvements.

Evidence-based decision-making: measuring, analyzing, monitoring of key performance indicators will support the process of decision making. Decisions are taken based on transparent, accurate, secure, reliable, and balanced information that will provide effective, efficient, and factual decisions that prove their correctness in the future.

Relationship management: identifying stakeholders of the organization and their relationships will enhance the organization's production supply chain. Suppliers, partners, customers, investors, employees, etc. relations should be managed in a collaborative manner in order to unify the efforts of the organization toward its goals.

Quality Control: is defined by the American Society of Quality in (ASQ, 2019) as the "*part of quality management focused on fulfilling quality requirements*". It aims at measuring products, ensuring there are no significant variations from the control limits, and take corrective actions whenever is needed (Dora et al., 2013). Moreover, quality control aims to ensure that all products and services delivered by the company meet the specifications which were defined to fulfill customers' needs. Quality control involves tools such as product inspection (Goetsch, Davis, 2014), statistical quality control where statistical techniques are used to evaluate the overall population of production (Scouse, 1985), different kinds of charts such as Pareto chart, cause and effect diagram (Fishbone Diagram) and control charts (Neyestani, 2017). Quality control is implemented during production for monitoring both processes and products (Jiang et al., 2014), or at the supplier (Scouse, 1985). Quality control tools including statistical quality control (SQC) and statistical process control (SPC) (Montgomery, 2009). Statistical quality control was first used in the 1930s when control charts and sampling were used to ensure the quality of mass production products (Juran, 1995). Another modern approach to quality control is six-sigma (Dahlgaard et al., 2007).

Quality Assurance: is a process-oriented quality approach, developed in the 1950s -1960s, to ensure that processes and procedures developed to deliver products or services are standardized, documented, and maintained, in order to maintain the same level of quality of products and services at every time (Dahlgaard et al., 2007). Quality assurance is also defined by the (ASQ) as the process to ensure that "*all the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality*" (ASQ, 2019). In other words, it is the process of ensuring that the quality system is functioning, and all quality requirements are successfully met.

The difference between quality assurance and quality control is that quality assurance is focusing on the quality system by ensuring that all manufacturing processes are producing high-quality products. On the other hand, quality control is focusing on the product itself, by inspection or examination. However, both quality assurance and quality control are complementing each other, while the ASQ defines quality assurance as more comprehensive than quality control.

2.3. Failure mode and effects analysis

Failure mode and effects analysis (FMEA) is a proactive analytical technique for identifying, tracking and mitigating product and process potential failures in a systematic way by determining its potential occurrence, root causes, consequences, and impact (Cicek, Celik, 2013). FMEA provides a quantitative score to evaluate failures where every failure is transformed into a numerical value that is called risk priority number (RPN). RPN is the result of multiplying three parameters namely severity, occurrence, and detectability. Every element is evaluated on a scale from 1 to 10 where the meaning of every scale value from 1 to 10 is elaborated in detail in (Chang et al., 1999; Chin et al., 2008). Severity is the risk or damage that may affect the machine, product, next operator, or the end-user. On the other hand, occurrence is the likelihood of this failure that may occur again. Finally, detectability is the degree to which this failure could be detected (Arabian-Hoseynabadi et al., 2010; Chang et al., 1999; Yang et al., 2015). Higher RPN value represents a higher priority of risk (H. Liu et al., 2019). Appropriate corrective actions are usually determined based on the RPN threshold value which is identified according to the quality policy of the manufacturer. If this threshold is reached, a risk mitigation procedure is applied accordingly (Keskin, Özkan, 2009). Moreover, RPN value is used as a tool for optimal resource allocation by giving focus on risks that have the highest RPN or the most critical issues (Chang et al., 1999; Pillay, Wang, 2003).

FMEA was firstly developed by NASA in 1963 to enhance the performance of the devices that are used in the aerospace industry (Yang et al., 2018). Later, FMEA was adopted and promoted by Ford Motors in 1977 (Chang et al., 1999). Currently, FMEA is being used in the automotive industry to ensure the quality and reliability of production systems (Chin et al., 2008). Daimler Chrysler, Ford, and General Motors have developed an international standard called SAE J1739_200006 as general guidance for implementing FMEA techniques to avoid failures and enhance system reliability and safety (Xu et al., 2002).

FMEA documents are classified into two types namely design FMEA, and process FMEA (Hassan et al., 2010). Design FMEA is constructed during product design to define product weaknesses, critical components, and their respective potential failure modes, root causes, and effects (Cicek & Celik, 2013). Meanwhile, process FMEA focuses on potential failures that may occur during the manufacturing process and incurred risks at each process step (Chang et al., 1999).

FMEA is a robust tool for quality improvement in both manufacturing and services industries. It can be used at the design stage of the product and during its implementation (Chin et al., 2008). The aim of this is to avoid the end-user from experiencing unfavorable defects that may affect the reputation of the company negatively (Chang et al., 1999). FMEA is classified as a quality management analytical method that aims at preventing failures occurrence at product and process levels (Kanji, Asher, 1996).

Moreover, FMEA is also used as a process improvement technique to ensure consistency, reliability, and avoid deviations. Moreover, it is also used to define and mitigate risks (Ayber & Erginel, 2020). On the other hand, FMEA is used to improve maintenance management by analyzing the maintenance requirements of the product and developing the maintenance plans that would be used to ensure that the system is doing what it is meant to do when it is created. Finally, FMEA is used to improve safety by conducting hazards analysis of components that have critical hazards on lives, property, or other losses that are identified and mitigated (Pillay & Wang, 2003). However, FMEA is criticized for many conceptual aspects. The most popular disadvantage of this method is the narrative and qualitative nature of its structure. For every product or process, FEMA documents are developed by engineers and experts using linguistic terms that are based on personal evaluation. The RPN parameters' values are determined by engineers and experts which may include uncertainty and vagueness (Ayber, Erginel, 2020). Moreover, the parameters that are used in FMEA are represented by (1-10) crisp scale which is an unreliable representation of real-application cases (Haktanır, Kahraman, 2020; H. Liu et al., 2019).

Additionally, Chang et al. (1999) have criticized the RPN estimation by the inhomogeneous morphologic correlations between the three parameters. This criticism is based on the fact that each of these parameters is obtained and linearly multiplied by the other with an identical scale. This process is done despite the actual impact of every independent parameter and the different qualitative interpretation of the scale. For example, a high severity value should result in an extremely high RPN value due to the critical hazard on the operator or the machine. In other words, once there is a risk on human, the other parameters shouldn’t downgrade the overall value of RPN even if they are low. Thus, in order to overcome this ambiguity, researchers proposed several approaches to improve the application of FMEA and the development of RPN. Several fuzzy techniques were examined to develop a new risk assessment approach to overcome the weaknesses of FMEA.

Haktanır, Kahraman (2020) have summarized several fuzzy techniques and grey theory and proposed interval-valued neutrosophic (IVN) sets based FMEA to eliminate the inaccuracy of human decisions and evaluations. Additionally, Ayber, Erginel (2020) have proposed single-valued neutrosophic (SVN) Fuzzy FMEA as a new risk analysis tool to overcome the ambiguity of the linguistic terms. In the meanwhile, Al-Khafaji et al. (2019) have proposed a fuzzy multicriteria decision-making model aligned with FMEA principles to obtain an efficient criterion for maintenance management.

Moreover, H. Liu et al. (2019) have used cloud model theory and hierarchical TOPSIS method to enhance FMEA effectiveness, overcoming bias probability of human judgment, and to facilitate the transformation of qualitative terms to quantitative values.

In the meanwhile, Yang et al. (2015) have utilized a data mining-based method for isolating faults based on FMEA parameters in order to enhance predictive maintenance by using historical Big-Data to create data-driven models, by which future failure can be predicted efficiently and accordingly avoid failures at a very critical operational item. Additionally, Keskin, Özkan (2009) have applied fuzzy adaptive resonance theory (ART) method for FMEA modeling in order to improve the classical methodology of calculating the RPN, which in total minimized cost and efforts needed to respond to corrective actions alerts.

In the aforementioned research, the interpretation of FMEA documents was well addressed and resolved. However, the weakness of FMEA and RPN is not limited to the ambiguity of the FMEA textual description nor its quantitative representation, but it also extends to the importance of being proactive and responsive to failures. The flow of information once a failure is detected until the time it is ranked and resolved is important as well to guarantee minimum impact and limited implications. Another shortcoming of the conventional FMEA technique comes from the fact that its documents are prepared during the product or process design stages, which makes these documents obsolete after production starts ahead. Therefore, these documents need to be dynamically validated and updated on a continuous basis. Hence, utilizing new technologies is very vital to overcome these weaknesses and keep these documents updated and responsive (Yang et al., 2015). Here comes the role of Industry 4.0 technologies and features.

In the era of Industry 4.0, connectivity offered instant communication and collaboration among the value chain. Artificial intelligence (AI), the internet of things (IoT), Big-Data, and cyber-physical systems (CPS) made a great leap in automation and optimization at all levels of manufacturing. Here, automation is not limited to machines and processes, but also to management information systems such as enterprise resources planning (ERP), customer relationship management (CRM) and quality management systems (QMS) (S. M. Lee et al., 2019).

Additionally, the real-time flow of data among the value chain, which is instantly analyzed and transformed to user-friendly information, thanks here to the advanced supercomputing and analyzing power (Duan et al., 2019), resulted in new paradigms of manufacturing systems which are being called nowadays by the smart factory, smart machine, smart product and augmented operator (Keller et al., 2014). These pillars changed the production systems from being reactive to be proactive and levered the human intervention from doing the work to supervise it while it is being done. Sensors, 3D cameras, RFID, and Wi-Fi made monitoring processes more precise and accurate. Unseen defects or deviation of products or processes can be detected as soon as it is occurring. Defect elimination and processes re-adjustment are made autonomously at the micro and macro levels (Gilchrist, 2016; S. M. Lee et al., 2019; MacDougall, 2013).

All these technologies, alongside the increased complexity of products and their manufacturing systems, generated a large volume of data, at a high velocity, variety, and value. The analysis of such Big-Data requires advanced resources and techniques to classify data and detect patterns that cannot be detected using traditional analytical tools.

2.4. Auto-machine learning technologies

Automated machine learning (AutoML) is a cloud computing-based tools that automate the process of machine learning workflow, offering the same capabilities of regular machine learning, without explicit knowledge of programming (K. M. Lee et al., 2019). AutoML aims at reducing human intervention in data pre-processing, feature selection, and algorithm selection so as to make machine learning automated (B. Liu, 2018).

Google AutoML is a cloud machine learning platform that automates supervised machine learning in a very efficient way. It handles the tasks of data pre-processing, feature extraction, feature engineering, feature selection, algorithm selection, and hyperparameter optimization (AI Multiple, 2020). Google AutoML automatically develops models based on neural architecture search (NAS). It follows the try and error strategy by developing the model based on a random set of hyperparameters, then evaluate the performance of the model which is resulted by using this set of hyperparameters and finally concludes the most accurate model (AI Multiple, 2020; Gangele, 2018).

AutoML is increasingly used in scientific research areas. Faes et al. (2019) have evaluated the performance of AutoML hosted by google cloud platform against other machine learning methods and algorithms. It is claimed that AutoML has higher accuracy in medical image classification and can be used by people who are less experienced in coding and algorithms. Similarly, Hayashi et al. (2019) utilized Google AutoML to identify pest aphid species and improving crop protection effectiveness. The authors concluded that such a tool provided an accuracy of 0.96 which allowed them to consider the AutoML as a useful and effective tool.

Additionally, Li et al. (2019) have used AutoML to automate customer service activities by analyzing different customers' information and respond to their inquiries based on historical frequent inquiries. According to the authors, the solution provided improved responsiveness and minimized the cost of customer service management. Moreover, Galitsky et al. (2009) proposed a novel approach to automate customer complaints processing and classification by training a machine learning algorithm on analyzing dialogues recorded between customers and company-agents. Google AutoML is being discussed here as it is the tool that will be used in developing the novel approach to improve the FEMA method and the generation of its associate value of RPN.

2.5. Previous literature joining quality management and Industry 4.0

In this section, a comprehensive literature review is made for all literature that is linking quality management and Industry 4.0. Resources such as Scopus, Web of Science, and Google scholar are searched to conclude all research works that are produced linking at least one of the quality practices as in previous literature to Industry 4.0. The aim is to explore previous works in the field of the study and to show the importance of this research work.

Accordingly, the gathered literature is divided into two groups, first which included articles that mentioned quality in an Industry 4.0 focused article or mentioned Industry 4.0 in quality management focused article. This group reviewed articles that discussed the impact of Industry 4.0 on quality or vice versa roughly. Therefore, the group is called "broad studies". The second group discussed the relationship deeply and therefore will be named "focused studies".

2.5.1. Broad studies

Studies that mentioned the impact of Industry 4.0 in a very broad perspective, the term quality was mentioned in a general context without further analysis.

Vaidya et al. (2018) discussed Industry 4.0 technologies and features, and the impact in several fields. They highlighted the advantages of using simulation techniques as an Industry 4.0 tool to improved productivity and minimize machine downtime due to setup or failure. Moreover, simulation could help to support decision-making quality, and the deployment of CPS in manufacturing aids the planning and optimization of processes and manufacturing systems.

Lu (2017) analyzed the Industry 4.0 technologies and applications. The author highlighted the impact of utilizing CPS in manufacturing. He suggested that such utilization will result in higher-quality products with minimum cost. Thanks to the efficient combination of information and materials. Moreover, the author suggested increased productivity, growth, production flexibility, and workforce performance. Additionally, the author highlighted the integration of the production value chain with customers' needs which enhanced customer satisfaction.

Gerbert et al. (2015) discussed the impact of Industry 4.0 on productivity and growth in manufacturing industries. They highlighted the impact of utilizing different Industry 4.0 tools such as data gathering tools, Big-Data analysis, and IT systems to achieve higher productivity, performance, flexibility, and quality products at lower costs. Moreover, Big-Data analysis and simulation optimized production quality and resulted in higher effectiveness in terms of resources consumption and equipment service. However, the authors concluded that the integration of Industry 4.0 technologies should be subjected to the real needs assessment and clear objectives definition.

Bittencourt et al. (2019) addressed lean thinking in the context of Industry 4.0 the authors explored the impact of Industry 4.0 on realizing the main objectives of lean thinking. A leaner production can be achieved efficiently by adapting Industry 4.0.

Costa et al. (2017) utilized RFID technology to improve logistics and visibility of the supply chain. Their project in partnership with a manufacturing company in Portugal analyzed the supply chain problems and proposed a smart internal supply chain. The proposed solution indirectly reduced quality-related problems which may result in products' call back or customers' complaints.

Erol et al. (2016) suggested "a scenario-based Industry 4.0 learning factory concept" which aims at implementing an Industry 4.0 integrated factory in Austria. The authors suggested an example of an intelligent quality assurance system that connecting assembly lines to the information system and quality management.

Rojko (2017) presented a detailed description of Industry 4.0 including its impact at different levels. He concluded that quality was a major driver behind the development of Industry 4.0 and is now utilized by large industrial countries like China to reform its current mass-low-cost production strategy to high-quality products. The author suggested that an Industry 4.0 integrated factory could result in a decreased quality cost by 10-20%, logistics, and production costs of 10-30% each in arrow. Additionally, the author suggested that the advantages of Industry 4.0 integration are improved customer and market responsiveness, maintaining the mass production systems aligned with higher-quality and lower cost, and better working environment as well as efficient consumption of resources.

Keller et al. (2014) returned the need for Industry 4.0 from the fact that German companies have to endure the competition of large developing countries which can offer similar quality and cheaper prices. The authors concluded that customers are not willing to pay more money for similar quality features. Therefore, the German factories focused on products' differentiation by offering customized products with a competitive price and minimum time to market. Industry 4.0 enabled these factories to provide high-quality products with the same production cost and higher responsiveness. Moreover, the authors focused on the opportunities generated by the implementation of manufacturing smart products through which mass information can be collected regarding the performance of the product in the field and therefore, enhance new generations of the product.

Oztemel, Gursev (2018) suggested that the new complex business models in very volatile markets require high technological production systems in order to compete and survive. The authors explored the impact of integrating Industry 4.0 technologies on quality, productivity, effectiveness, efficiency, flexibility, and performance. For example, the impact of interconnecting the value chain and IT system, and the power of data analysis to predict failure and self-adapt to preserve production and avoid downtime. Moreover, the authors discussed new quality tools such as product traceability, through which data is being collected and analyzed about product performance in order to improve future product editions.

2.5.2. Focused studies

Wright (2016) discussed the impact of Industry 4.0 on quality assurance. The author concluded that Industry 4.0 enhanced quality assurance in different ways. For example, the use of Big-Data offers capabilities such as predictive modeling, establishing correlations between different unseen performance factors, and suppliers' performance analysis. Additionally, the enhanced possibilities of accurate measurement, self-calibration, and distance customer service which innovated new business models and new kinds of smart products which all, in turn, require further measurement and quality assurance systems from design to manufacturing and after-sale. Such opportunities will endorse more market growth and more complex systems to handle.

Foidl, Felderer (2016) explored the impact of integration as an Industry 4.0 feature on quality management practices, specifically its impact on process optimization. The authors concluded that vertical integration influences quality control from being a single shop floor activity to become every management level's activity, given its integration with the ERP system which optimizes the entire value chain. Further, new advanced techniques for backward error tracing are used in addition to early failure prediction techniques. On the other hand, horizontal integration can improve customers' experience by making them contributors to the production stage instead of being only receivers. From the other end, suppliers are also integrated with the value chain. Quality issues related to suppliers are instantly transferred to suppliers. Moreover, the smart machine can be more interactive, either by downloading functioning data from the manufacturer cloud system or by offering maintenance recommendations to operators. Finally, the authors concluded that end-to-end integration enabled the value chain to cover all aspects of production to manufacture individual customer's products with optimum utilization of resources and quality.

Oliff, Liu (2017) focused on data-mining applications to improve product and process quality. They proposed a case study where open source and free software are utilized along with data-collection hardware on data-collection points to provide feedback that can enhance manufacturing processes and products' quality. Such a process can help small and medium companies to use these technologies which do not need large investments as in large business companies.

Shin et al. (2018) proposed an Industry 4.0 integrated quality scorecard (QSC) in which qualitative measures can evaluate the quality aspects of the new Industry 4.0 era organization. The proposed framework proposed 15, 30, and 60 for simple, generic, and detailed potential measures to assess the cost of quality. These measures represent three categories namely prevention, appraisal, and result measures. The development of the QSC was inspired by the balanced scorecard. The authors contended that Industry 4.0 contribution to the QSC is the ability to combine diverse approaches as joint or composite. They argued that such integration will lead to better business competitiveness and excellence.

Hanifa et al. (2018) discussed the opportunities and challenges of Industry 4.0 on quality management in the Malaysian industry through three dimensions strategy, operations, and environment, and people. In terms of opportunities and advantages, they concluded that the main contribution it can improve the strategy by offering new opportunities for business effectiveness. This could be achieved by utilizing future predictions of customers and business needs, effective interaction with customers, evidence-based decision making, and improved efficiency. Moreover, they concluded that enhanced operations can be achieved by integrating technologies in operations management. Additionally, the article explored the implications of Industry 4.0 features such as horizontal, vertical, and end-to-end integration on quality management since data gathering and analysis offers better process monitoring and production error handling. Additionally, customers can monitor and contribute to the production as well as suppliers who are integrated into the value chain.

Tracy (2018) argued that although Industry 4.0 changed the way how things are managed, quality traditional tools such as the plan-do-check-act strategy will never be obsolete. The author focused on the challenges of quality in the era of industry 4.0. Such challenges are related to the cost of investment and the return period, data security and privacy protection issues, system reliability and management, and the data talent which is suffering shortage at this stage. However, these challenges are the same challenges of Industry 4.0 but can cause a severe impact on quality management if not evaluated and mitigated successfully. Finally, the author concluded that competition requires the companies to follow the change, otherwise, to be left behind.

Albers et al. (2016) suggested an intelligent quality control system and a supportive procedure that integrates Industry 4.0 technologies and tools with quality control practices such as products and process control. Accordingly, three phases of execution are introduced to conclude the intelligent quality control system. The initialization phase aims at understanding the company’s needs, documentation of the current product-related quality specifications. The second aims at defining the current state of quality control practices. The third aims at defining the development objectives and the technical requirements, constraints, boundaries, and relationships with stakeholders. The suggested approach may help small and medium-sized companies to conduct their own Industry 4.0 transformation strategy, by defining their specific needs and therefore, their transformation plan. Moreover, in their experiment, the authors successfully integrated two parties in single machine health, the machine manufacturer/supplier, for the purpose of future development and optimization, and the machine applier/user, for quality monitoring in terms of product and process.

Gunasekaran et al. (2019) summarized the potential of quality management in the era of Industry 4.0 from five general aspects namely economical, decision models, business models, human aspects, and technological aspects. In terms of the economic aspects, the authors suggested an enhanced economic performance due to improved and joint monitoring activities for process and product quality and less sampling costs. Further, the authors summarized the impact on decision models in terms of better inventory management, enhanced inspection strategies, enhanced failure mode and effects analysis (FMEA) techniques which will improve risks assessment and ranking, and improved analysis and decision-making regarding supply chain issues.

Závadská, Závadský (2018) assessed the expectation of quality managers toward the new smart technologies related to Industry 4.0 from a quality perspective. The paper concluded that there is a potential growth of technologies and their respective experiences needed in the future. Similarly, the automotive industry was leading in utilizing such technologies. The future potential for growth is for smart devices such as smart glasses and smart gloves for quality applications. RFID, barcodes, QR, autonomous vehicles and drones for logistics management, transportation, and tracking. 3D printing will be utilized in pre-manufacturing processes, robots in manufacturing, and finally, utilizing simulation and virtual reality applications to improve manufacturing quality issues.

Durana et al. (2019) utilized a survey tool to evaluate the quality culture and its impact on Industry 4.0 transformation at Slovak companies. They figured out that although quality culture is vital to ensure successful adaptation of Industry 4.0, such culture is insufficient in the Slovak enterprises. Therefore, the authors recommended elaborating quality principles from a cultural perspective, hence, preventing defect from occurring is a culture at any firm, and also is a typical quality management approach. Moreover, the authors recommended utilizing information technology and tools of Industry 4.0 to ensure the effective implementation of quality management.

Jayaram (2016) suggested a model where Industry 4.0 technologies and industrial internet of things (IIoT) are integrated with lean six-sigma strategies to enhance global supply chain management effectiveness. The proposed model suggested that in addition to intelligent monitoring of supply chain, real-time connectivity offers the ability to visualize data and optimize logistics. On the other hand, data-mining and critical analysis of data generated from the IIoT can provide rich knowledge and hyper levels of management skills such as predictive analysis and automation.

Stojanovic et al. (2016) developed a Big-Data-driven approach to enhance anomaly detection and quality control practices. The authors used Big-Data handling platforms to store and analyze data generated from quality control inspection to detect any anomaly behavior or pattern. The authors argued that traditional quality management techniques are no longer useful to cope with new production regimes and quality control techniques such as automatic 3D scanning, especially the huge volume of data resulted. In addition to the volume of data, the authors added the multi-parameters, and complex causalities resulted because of that. Moreover, the newly deployed Big-Data system requires objective analysis more than the traditional subjective analysis which is handled by highly specialized and experienced people. The proposed approach consisted of six layers: data storage, data processing, data analytics, user interface, integration, and security layers. Additionally, the proposed approach used clustering procedure where similar objects or instances are grouped together, accordingly, normal behavior groups are known and defined, any anomaly is easy to be detected and isolated.

Illés et al. (2017) described the new challenges that emerged to quality assurance in manufacturing facilities due to the emergence and application of Industry 4.0. The authors concluded that Industry 4.0 will achieve higher production systems efficiency due to minimized processes, decreased failures, optimized planning, and effective communication between machines, equipment, people, and products. However, the integration is based on Big-Data gathering and analysis, which raises questions such as what data to collect and how it should be utilized. Therefore, the authors suggested several data types and data collection tools, along with their respective utilization opportunities.

Park et al. (2017) discussed the impact of Industry 4.0 on quality management cultural creation.

In this research work, the authors claimed that Industry 4.0 changed the focus of quality from product to "*design, safety, service quality, and brand quality*". Therefore, the quality goals should be extended to respond to this fast change, a new multiway flow for quality management is suggested based on new Industry 4.0 technologies such as AI, Big-Data, and Internet of Things. In conclusion, the authors recommended that quality experts should be side-by-side to data experts to successfully integrate the new Industry 4.0 technologies into the quality management system. Odubiyi et al. (2019) discussed the challenges of implementing quality management in the era of Industry 4.0 in the construction industry. These challenges are related to processes, people, and technology. Therefore, the authors suggested deploying a virtual quality management system where construction activities can be simulated before real implementation to conclude its weaknesses and avoid failure wastes. Accordingly, the authors suggested using Industry 4.0 technologies and platforms to apply the proposed system to improve competitiveness, optimization, and achieve customer satisfaction.

2.6. Timeline of the previous researches

Tables 2.3. and 2.4. summarizes the previous relevant literature which addressed the topic of TQM in the context of Industry 4.0 generally or precisely.

Table 2.3. Summary and timeline of broad studies

Authors	Year	Highlight	Scope	Approach
Keller et al.	2014	Assessed the impact of Industry 4.0 on manufacturing landscape and proposed some transition recommendations	Impact analysis	Theoretical
Gerbert et al.	2015	The impact of Industry 4.0 on productivity and growth in manufacturing industries	Impact analysis	Theoretical
Erol et al.	2016	Suggested "a scenario-based Industry 4.0 learning factory concept"	Conception	Theoretical
Costa et al.	2017	Utilized RFID technology to improve logistics and visibility of the supply chain.	Application	Experimental
Lu	2017	Advantages of utilizing CPS on improving efficiency and effectiveness	Application	Theoretical
Rojko	2017	Presented detailed description on Industry 4.0 including its impact at different levels.	Conception	Theoretical
Vaidya et al.	2018	Advantages of using AI techniques in different fields such as quality	Application	Theoretical
Oztemel, Gursev	2018	Explored the impact of integrating Industry 4.0 technologies on quality, productivity, effectiveness, efficiency, flexibility, and performance	Impact analysis	Theoretical
Bittencourt et al.	2019	Focused on lean thinking in the context of Industry 4.0	Conception	Theoretical

Table 2.4. Summary and timeline of focused studies

Authors	Year	Highlight	Scope	Approach
Albers et al.	2016	Suggested a transformation strategy toward an intelligent quality control system. The strategy is examined at a manufacturing company, where a spring machine is selected.	Application	Experimental
Jayaram	2016	Developed a combined lean six-sigma, Industry 4.0, and IIoT model to enhance the performance of global supply chain management	Application	Theoretical
Stojanovic et al.	2016	Examined data mining tools and techniques to differentiate between normal and anomaly patterns detection	Application	Experimental
Wright.I	2016	The impact of Industry 4.0 on quality assurance practices including measurement, calibration and the resulted new customer service models	Impact analysis	Theoretical
Foidl, Felderer	2016	Impact of vertical, horizontal, and end-to-end integration on quality control, discussed the challenges and suggested future research topics	Impact analysis	Theoretical
Illés et al.	2017	Explored the new challenges of quality assurance practices in manufacturing due to Industry 4.0 technologies	Challenges	Theoretical
Hyun Park et al.	2017	Discussed the impact of Industry 4.0 on quality management cultural creation	Challenges	Theoretical
Oliff. Liu	2017	focused on data-mining applications to improve product and process quality	Application	Experimental
Shin et al.	2018	Proposed an Industry 4.0 integrated quality scorecard (QSC) in which qualitative measures can evaluate the quality aspects of the new Industry 4.0 era organization.	Application	Theoretical
Hanifa et al.	2018	The impact of Industry 4.0 on quality management in terms of strategy, operations, environment, and people	Impact analysis	Theoretical
Tracy	2018	Challenges of quality management and Industry 4.0 implementation which may	Challenges	Theoretical

		cause severe impact if not assessed and mitigated successfully.		
Závadská, Závadský	2018	Assessed the expectation of quality managers toward the new smart technologies related to Industry 4.0 from a quality perspective	Impact analysis	Theoretical with survey
Gunasekaran et al.	2019	Summarized the potential of quality management in the era of Industry 4.0 from five general aspects namely economical, decision models, business models, human aspects, and technological aspects.	Impact analysis	Theoretical
Odubiyi et al.	2019	Discussed the challenges of implementing quality management in the era of Industry 4.0 at construction industry	Challenges	Theoretical
Durana et al.	2019	Assessed the quality culture and its impact on Industry 4.0 transformation at Slovak companies	Impact analysis	Theoretical with survey

2.7. Challenges of TQM in the context of Industry 4.0

Although this research work highlighted the opportunities offered by industry 4.0 to quality management, which obviously is the main course here, it is important to highlight the other ambiguous zones (threats and challenges) within the same context (quality management in the context of Industry 4.0) where quality management can't sufficiently be served by Industry 4.0 features, due to Industry 4.0 own challenges and difficulties such as: "scientific, technological, economic, social and political challenges" (Zhou et al., 2016), or due to barriers to achieving the full advantage of Industry 4.0 in TQM practices.

As a matter of fact, there are always barriers to applying new technologies in the industry, Albers et al. (2016) summarized few studies which highlighted difficulties of applying Industry 4.0 and related technologies at small and medium companies in Germany. These difficulties were due to knowledge (know-how) and organizational barriers. As a result of such studies, Albers et al. (2016) suggested a procedure to lead the change to an intelligent QMS by defining quality objectives based on analyzing the current state of quality and defining the intended targets for the quality management and stakeholders. Moreover, although automation will enhance the connectivity between customers and organization but there are some tasks that are irreplaceable due to the fact that these jobs need face-to-face interaction (Arntz et al., 2016). Hence, dealing with customers before, during and after-sale could be one of such tasks. This implies that although industry 4.0 will support some "customer focus" activities, some other activities are difficult to substitute.

This disadvantage can also be generalized to other QM activities, such as leadership, process approach, and decision-making, where human cumulative experience is needed to conclude from the rich information and data analysis flowing from smart technologies. However, the quality of skills and tasks required to handle such development is also changing to a higher level of experience (Acemoglu, Autor, 2011), where higher-skilled people are required at more advanced job positions, and new learning and training qualities are intended to fill the gap of demanded skills and expertise (Autor, 2015).

In addition to the abovementioned challenges, cyber-security and data protection are also important challenges to Industry 4.0 (Blanchet, Rinn, 2015; Pereira, Romero, 2017). Lu (2017) highlighted the limitations of customers' involvement in decision making related to products' customization and quality needs (which is more dependent on IoT and Industry 4.0 technologies), resulting from security threats and complexity of human-to-machine interaction. These challenges should also be considered in the ongoing context (TQM and Industry 4.0). What will be the impact of data privacy and security on quality issues? And how to maintain the flow of information related to quality management avoiding the data loss or inaccuracy? Therefore, mitigation plans should be developed to deal with such threats and challenges.

Finally, it is also important to define a set of specific quantitative measures as evidence to describe the actual impact of Industry 4.0 on TQM practices. For instance, what is the resulted quantitative change when applying Industry 4.0 at an industrial company in terms of customer satisfaction, improvement of products and processes, cost of quality, efficiency and effectiveness of processes and leadership, decision-making process, and after all the improvement of the overall business results? Such changes require further analytical studies which could be the focus of research in the next years.

2.8. Summary of literature review evaluation

As concluded from the literature review, and the summery in Tables 2.3. and 2.4, the earlier research works relating total quality management and Industry 4.0 are focusing mainly on the theoretical approach. Most of the studies have been carried out recently which shows that the topic of this study is important, recent, and trending. Basically, all studies focused on three major aspects; impact analysis, applications, and challenges. However, there is no comprehensive approach to identify the impact of Industry 4.0 on TQM in a detailed and comprehensive method although all studies agreed that quality management is positively affected by the application of Industry 4.0. Similarly, some works highlighted the challenges of this application. Moreover, most researches utilized theoretical approaches to address the topic, which implies a lack of experimental works to show real applications from the industry and real evidence that represent the impact of Industry 4.0 on quality management in practice.

Additionally, most of the experimental research works focused on AI applications including machine learning, and Big-Data analysis as Industry 4.0 tools. Although this is supporting the study and application being addressed here, other fields are required to be examined.

Therefore, this study is focused on TQM in the context of Industry 4.0 in a comprehensive theoretical and experimental approaches. The novelty of the study is coming from:

- The theoretical approach in identifying the interaction interface that integrates Industry 4.0 technologies and features with TQM practices.
- The identification of key performance indicators to measure and evaluate the impact of Industry 4.0 on TQM practices.

- The development of a basic Industry 4.0 - Quality Management based system, where Industry 4.0 features and technologies are integrated into the basic QMS as in ISO 9001:2015 standard.
- The utilization of AI technologies to develop a novel approach to enhance FMEA as one of the quality practices and the optimization of its associated element namely risk priority number (RPN).
- The utilization of a cloud computing service namely Google AutoML, which is able to integrate with the partner company's ERP system
- The development of a special platform through which the evaluation of the FMEA can be made through a friendly interface which is integrated with the machine learning platform.

3. MATERIALS AND METHODS

The aim of this study is to analyze the impact of Industry 4.0 on TQM practices. Therefore, two approaches are followed. The first is theoretical, in which the main practices of TQM are intensively analyzed and discussed in the context of Industry 4.0, and the second approach which is experimental by showing a real application of one of the industry 4.0 features to improve a single quality management process which is failure mode and effects analysis (FMEA).

In this chapter, the used materials and methods for theoretical analysis and experimental investigation are discussed concerning TQM practices jointly with Industry 4.0 features and technologies. Industrial cooperation is made with an industrial company in Hungary to apply machine learning methods including data collection, pre-processing, analysis, and machine learning modeling.

3.1. Research methodology

The theoretical approach of this study discusses the impact of Industry 4.0 on TQM, including the set of indicators and their measurement tools from Industry 4.0, and suggesting a theoretical Industry 4.0 - QM based system that describes the implementation of Industry 4.0 features and technologies to improve quality management practices.

The experimental approach examines one of the Industry 4.0 technologies namely machine learning. In this work, a machine learning technique is applied for data modeling and developing four machine learning models that can evaluate the process and product failure automatically based on analyzing textual, categorical and numeric data generated from the failure reports received from further manufacturing processes. The quality checklists at the shop floor level are dynamically connected to the machine learning platform so as to be updated as soon as a new failure is reported. In this process, human intervention in such an important process is replaced with machine learning models.

3.1.1. The methodology of the theoretical approach

As illustrated in Fig. 3.1. the theoretical approach of this research work is realized as follows:

- Firstly, an intensive theoretical analysis of the impact of Industry 4.0 on the TQM principle, quality assurance, and quality control is made. This analysis explored the capabilities of Industry 4.0 to support TQM activities and principles.
- Such an impact is important to be assessed through a set of key performance indicators along with suggested measurement means. Therefore, the set of key performance indicators is suggested aligned with measurement methods respectively.
- As a further step, a combined Industry 4.0 - quality management-based system is suggested, where every element of the quality management system is supported by one or more features provided by the Industry 4.0.

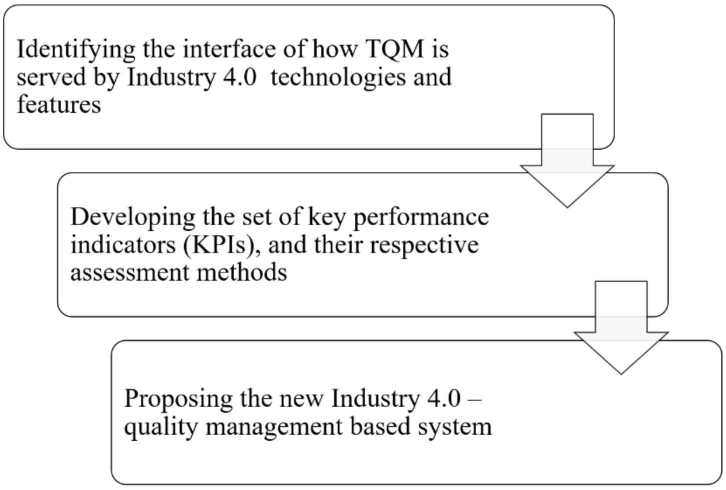


Fig. 3.1. Theoretical approach methodology

3.1.2. The methodology of the experimental approach

As illustrated in Fig. 3.2 the experimental approach of this research work is realized as follows:

- Establishing a research partnership with an industrial company in Hungary, finding an opportunity where such a theoretical model can be examined.
- Gather and prepare data for machine learning and train four machine learning models that can be deployed to enhance FMEA which is conducted by the quality management at the partner company
- Deploy the proposed system for testing at the company and evaluate the results accordingly and suggest further development of the models and the experimental approach.

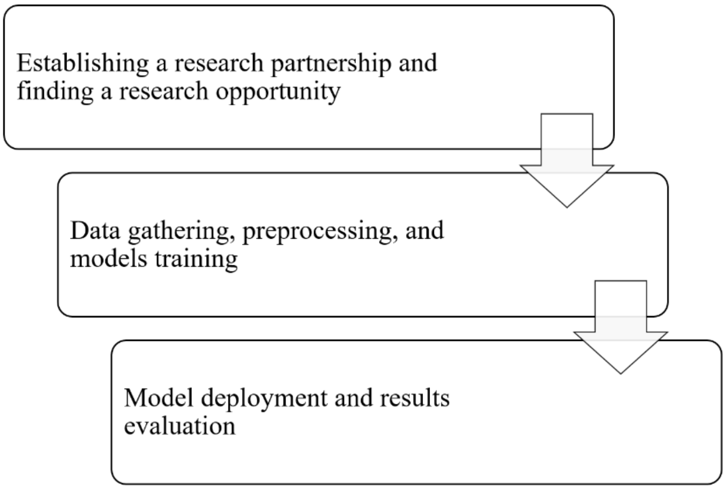


Fig. 3.2. Experimental approach methodology

3.2. The theoretical approach

As illustrated in Fig. 3.3 the following section is the first step of the theoretical approach; analyzing the interface where Industry 4.0 and TQM principles intersect. In this section, the features of Industry 4.0 are discussed as tools that can support quality management practices. After that, the key performance indicators for evaluating such integration are suggested, and accordingly, an integrated Industry 4.0 - QM based system is suggested.

3.2.1. Total quality management in the context of Industry 4.0

Based on the literature review and the identification of the TQM principles according to ISO 9000: 2015 standards, this section aims at finding the baseline where Industry 4.0 can serve the optimum implementation of the TQM principles, quality control, and quality assurance. The following analysis establishes the connection between TQM and Industry 4.0 based on aligning ISO 9001:2015 requirements and Industry 4.0 features and technologies. The analysis suggesting a balanced view where opportunities and challenges are brought together to the table and discussed from an ideal point of view. The following discussion suggests the means of support that Industry 4.0 can afford to TQM implementation practices.

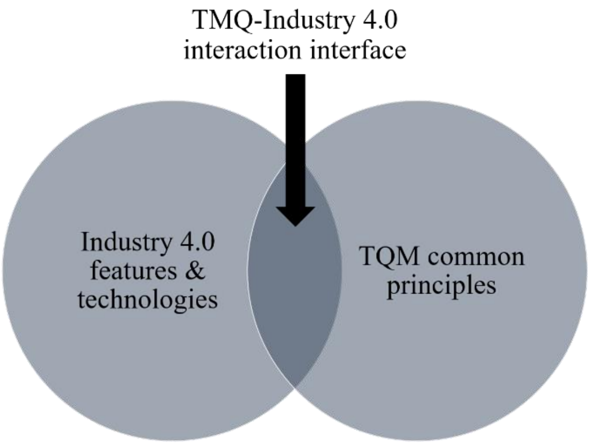


Fig. 3.3. An interface where Industry 4.0 can serve the successful implementation of TQM principles

Industry 4.0 offered many capabilities for quality management practices, the technological advancement provided new techniques to ensure the quality of the products, new inspection tools, new early failure detection and prediction methods, and self-adaptation and self-adjustment possibilities. These techniques enabled the production facility to re-adjust its production plans to respond to customers' requirements, fluctuating demand, or to avoid machine failure or downtime.

Interconnectivity provided the ability to the production system to be more flexible, as the entire system is interconnected, every unit of the production system is aware of what is happening at the other units at the micro or macro levels. Moreover, the real-time flow of information from machines, facilities, and labor to and from the factory management made the decision-making process more effective, reliable and prompt. Connecting all parties of the production value chain including people, products, devices, and processes with other business management solutions such as ERP and the quality management system. People can use smart devices to transmit and receive information that can support their roles at their respective locations. Products can store data that is generated during production on technologies such as RFID. Stored data is about what processes or machines the product went through beside other manufacturing specifications. The introduction of Internet Protocol version 6 (IPv6) in addition to the improved network infrastructure extended the space to connect more devices online. Furthermore, products can provide information about their performance in the field for further product improvement. Such information includes defects, operating environment, failure circumstances, and customer feedback. This information can be compared with other data flowing from other devices, processes, and ERP systems, leading to a causal explanation of the defects and root cause analysis (Jacob, 2017; Ngo, Schmitt, 2016; Radziwill, 2018).

Collaboration technologies such as social media platforms can contribute to the development of quality by creating collaborative channels with customers, between employees, and across business units. Another technology is the blockchain which is now used by many industrial companies to track product history, especially when supply chains are deep and versatile; where did this product came from, what were the involved production line, machines, and even operators (Jacob, 2017). Moreover, collaboration in the context of Industry 4.0 is multiple way collaboration, customers are more involved in quality activities through social media platforms, they can contribute to the advancement of products during development and production stages. Feedback is advanced using technologies such as deep learning where content such as comments and reactions are gathered, analyzed, and automatically directed to relevant responsible parties. Bots are now responding at an almost zero-time delay to customers inquires coming from online messengers. Hashtags are being traced and processed by deep learning technologies such as natural language processing.

Horizontal, vertical, and end-to-end integration of departments and business units elevate businesses to act internally and externally as one integrated unit including suppliers and customers. Information from the customer end to the supplier is transmitted smoothly. Orders of customers are transferred instantly among the value chain, notifying involved parties about it, customers are able to monitor their product being made in real-time and they can provide further customization when needed. Integration among different managerial and operational departments enhanced the coordination and resulted in a dynamic and effective working environment.

Big-Data that is the data being gathered from ERP systems, tracking and monitoring sensors, statistics, and social media. Such a large volume of data is processed and modeled using AI techniques such as machine learning and deep learning in order to provide enough and useful visual information that can be used for several quality purposes. For instance, historical data about customers' behavior could be used to improve production schemes to handle fluctuating demand and make a balance with other production schemes. Moreover, Big-Data can be used to develop AI models to provide the ability to make an instant decision on the production floor, it could alert operators to make recommended actions such as predictive maintenance or better production arrangements.

New production systems increased the data generation among the digital value chain exponentially. The use of generated data in a proper manner can result in an improvement in quality management practices. Therefore, data-based quality regulation is vital to maximizing rewards from error analysis and remediation methods (Ngo & Schmitt, 2016). Gathering data in real-time became possible using Big-Data. All data can be combined and compared to find relationships or patterns. However, quality is not only about simple or advanced data gathering and analysis. It is the ability to find hidden relationships or patterns of different variables that can't be found using traditional data analysis tools. Here come the new data science tools such as AI, machine learning, and deep learning which is a higher level of programming by IT professionals. Using such tools will enable quality experts to discover un-seen related factors affecting quality.

Accordingly, the above discussion is summarized in Table 3.1. below. Where TQM principles, quality control, and quality assurance objectives are defined along with their relevant Industry 4.0 contributions.

Table 3.1. TQM and Industry 4.0 interaction summary

TQM principles	Quality Objectives	Industry 4.0 contributions
Customer Focus	• Improved customer satisfaction & loyalty, • growth in customers' base, • improved organization's reputation.	• Improved responsiveness due to collaboration technologies and the integration of different service units. Moreover, utilizing Big-Data analysis using AI techniques such as ML and robotics, • customized product/customer due to dynamic individualized production systems and integration, • smart prediction of market demand due to prediction techniques of Big-Data analysis.
Leadership	• Unity of purpose among the organization, • aligned strategies, policies, processes and resources, • effective communication between all administrative levels.	• Smart allocation of resources using CPS, • high coordination among all levels of the organization due to integration feature, • effective evaluation for results due to Big-Data analysis and integration among the value chain.
Engagement of people	• Increase the motivation of people, • increasing innovative ideas, • enhanced people satisfaction, • self-evaluation and self-improvement culture.	• Improved communication and collaboration due to connectivity and collaboration features, • facilitating innovation and sharing of ideas due to future predictions by Big-Data analysis.
Process approach	• Identify key processes and points of improvements, • optimized performance and effective process management, • manage processes, and interrelations, as well as dependencies.	• Transparent, interconnected, dynamic processes due to utilization and integration of smart prediction and analysis tools, • self-learning and early failure prediction due to AI prediction-based systems,

		• less downtime, early maintenance prediction due to AI and ML applications.
Improvement	• Responsive systems to customer requirements, • enhanced ability to react to the development of processes, products and market needs, • support drivers for innovation.	• Active interaction with dynamic market requirements due to collaboration and integration features, • instant re-configuration of production processes to respond to improvement requests due to the utilization of CPS, • motivating for change environment due to instant Big-Data analysis.
Evidence-based decision making	• Clear and agreed decision-making process, • data availability and clarity, • effective past decisions, • analyze and evaluate data using suitable methods and tools.	• Rich information and analytics dashboards about production, machines, and markets due to Big-Data analysis. • early evidence detection to correct or support decisions due to AI and ML applications, • factual decision making based on Big-Data analysis, AI, and ML techniques.
Relationship management	• Stakeholders are identified and suitable communication tools to each are known, • stakeholders are satisfied, and their feedback is considered, • suppliers are responding to materials requests on time and at the required quality, • the supply chain is stable and no downtime due to lack of supply.	• Easy identification and communication tools due to integration features and collaboration technologies, • the ability to hire segmentation of stakeholders based on priorities by using Big-Data analysis and AI techniques, • stronger collaboration with providers and partners to encourage continuous improvements.
Quality control	• Ensuring high-quality products free of defects and conformed to design, • the fulfillment of customers. needs, • utilizing inspection and statistical quality control tools.	• Real-time quality control activities including inspection and defected products exclusion by using smart monitoring and analysis tools such as sensors, 3D cameras, and deep learning techniques,

		• instant product quality inspection by using smart monitoring and analysis tools such as sensors, 3D cameras, and deep learning techniques, • lower cost of quality due to less defective production and instant process adjustment using CPS.
Quality assurance	• Standardized processes and production procedures, • ensure process quality in order to produce quality products, • minimize process variation and deviations.	• Process monitoring and early deviation prediction by using smart monitoring and analysis tools such as sensors, 3D cameras, and deep learning techniques, • self-process adaption and self-adjustment by utilizing CPS, • overall integration with other stakeholders such as suppliers and maintenance management by utilizing collaboration and interconnectivity features.

3.2.2. Developing the relevant key performance indicators

The impact of Industry 4.0 on TQM practices can be measured and evaluated by comparing the performance results of the quality management system before and after the implementation of Industry 4.0. For example, enhancing customer satisfaction is a quality objective. Accordingly, the impact of implementing Industry 4.0 technologies and features in the production value chain is expected to enhance the customers' satisfaction. The question is: what improvement is resulted in customer satisfaction because of the implementation of Industry 4.0 features and technologies? i.e. the customer satisfaction is increased by (x%).

Therefore, in order to assess the effectiveness and efficiency of integrating Industry 4.0 on TQM principles, a set of key performance indicators is suggested for every TQM principle or practice. Moreover, it is important to select suitable assessment tools by which data is being gathered, and effective data analysis and evaluation methods. Moreover, it is important how the results will be presented to relevant people at their respective locations.

In this context, Industry 4.0 improved data gathering and analysis tools; real-time inspection of produced items can be made without the need to make statistical sampling in most of the production processes. In fact, 3D scanners and infrared sensors are able to measure products' variance in dimensions and colors. Moreover, process deviation is easy to detect using instant sensors and evaluation at the machine or process levels. However, in some cases, it is more efficient to practice quality control techniques in traditional ways such as statistical sampling.

A few years ago, the high cost of utilizing nowadays technologies such as sophisticated sensors, connectivity tools, data storage, and high computing power, made the implementation of such technologies avoided. Nowadays, these technologies became cheaper and so it is being widely used. Moreover, companies are increasingly establishing their IT backbone for a production-integrated quality engine that connects, monitors, and analyses all data relevant to operators, machines, products, and tools in real-time in terms of process control (Nyendick, 2017).

Smart devices are now spread everywhere including mobiles, tablets, and smart screens. Traditional communication tools such as telephone, fax, and computers are now replaced with a single view device called the smartphone (Radziwill, 2018). Augmented reality technology is now used to enrich the normal video feeds with objected information over it. Mobile apps are providing a better user experience and a higher level of participation, collaboration, and efficiency (Jacob, 2017). Such tools will help to display information in a friendly, easy to understand format.

Additionally, intelligent support systems, which proactively and efficiently support the workers in their work, changing the employees' role from machine operators to decision-makers (Nyendick, 2017). More smart devices and screens can be located at the shop floor displaying rich information to operators and seniors, showing rich animation and colored alerts and instructions.

In conclusion, key performance indicators are important to assess the impact of Industry 4.0 on TQM. Such indicators require more advanced measurement methods and sophisticated analysis that transform data into user-friendly knowledge. Hence, the suggested KPIs to assess the impact of Industry 4.0 on TQM practices are presented in section 4.2. The identification of the KPIs is subjected to the seven TQM practices, quality assurance, and quality control.

3.2.3. Developing an integrated Industry 4.0 - quality management-based system

A quality management system is a formalized system that aims to document processes, procedures, and responsibilities to maintain the continuous improvement of customer satisfaction and improving its effectiveness and efficiency (Nanda, 2007). A QMS provides the basis of coordination and direction of an organization to achieving quality policies and objectives.

There are several approaches to obtain and implement a QMS, the most prominent is the ISO 9001:2015 based quality management system which is described by (Abildgaard, 2018; ISO, 2015b) and illustrated in Fig. 3.4. A QMS contains the most important activities and stakeholders. In this research work, this system is used as the basis for developing the Industry 4.0 - QM-based system, which will be presented in the results chapter.

The development of the proposed system is carried out by integrating the Industry 4.0 features and technologies with all the functions of the QMS. For example, integrating Industry 4.0 collaboration feature in gathering customers' requirements through different channels, and translate these requirements into working orders which are managed by the QMS.

Plan-do-check-act (PDCA) cycle is also backed by Industry 4.0 technologies. For example, an optimum production including efficient processes and operations planning is reached by utilizing CPS (Plan). Where new production scenarios are translated into actual production plans (Do). The performance of the system is measured and evaluated (check) using data gathering and analysis techniques such as Big-Data and AI. Further enhancement and system adjustment are suggested and re-planned by CPS (Act).

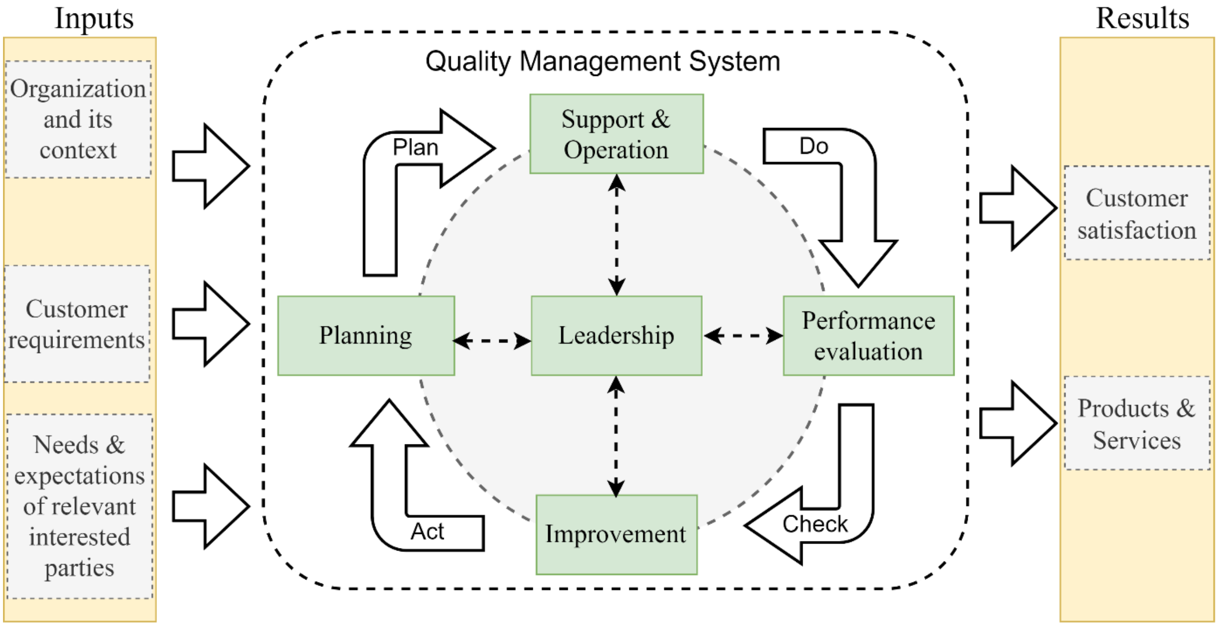


Fig. 3.4. Standard Quality Management System for further development (adopted from Abildgaard, 2018; ISO, 2015b)

3.3. The experimental approach

In order to conduct the experimental side of this research work, a partnership was sought with an industrial company in Hungary to test and implement the suggested Industry 4.0 - QM based system. For this purpose, CLH was contacted in order to find a cooperation opportunity to examine the experimental part of the work and to share experience, given that the company has already implemented a successful quality management system. The main goal of such a cooperation is to examine the proposed Industry 4.0 - QM based system in a real application. However, the experimental work can’t examine all parts of the QMS. Therefore, a single quality management activity is selected based on a careful overview of current quality management practices and the discussion with the partner company to find a mutual interest in such a single activity.

CLH was established in 1997 in Hungary, as a subsidiary company of CLAAS Group in Germany. Since establishment, CLH expanded from 350 workers and eight hectares plant to more than 700 workers working on a 14-hectare plant and became a center of excellence for combine harvester tables and trolley carts production. CLH manufactures supplementary devices such as combine harvester tables, cutting heads, and trolley carts, as shown in Fig 3.5. Fig. These devices are shipped from Hungary either to the mother company that is located in Germany or directly to the end-customers for final assembly with the machine which can be a combine harvester or a tractor. The cost of a single failure is tremendously high, not only due to the machine cost itself but also due to the entailed logistics and the re-work cost.

The main activity of CLH today is the production of various types of feeding houses, cutting bars, maize, and sunflower adapters, development and production of cutting bars trailers, and the development of new agricultural and other machinery equipment.

Fig. 3.5. Sample of devices manufactured at the subsidiary company subject of this study
Source: (https://www.claashungaria.hu/)

(The first communication with CLH in this research work was initiated during the 17th CLH symposium organized at Szent István University in Godollo on May 18, 2017. A short meeting with the head of quality management at CLH Mr. Csombordi Róbert resulted in a short introductory visit by Professor István Husti and Sami Sader (the research student) to the company location in Törökszentmiklós. This short visit resulted in a longer study visit to the company where the researcher was able to testify the quality practices at CLH and after constructive discussions with the quality management team, a clear vision for the future research work was drawn. Therefore, at the end of the visit, the researcher along with his supervisors (Professor István Husti and Dr. Miklós Daróczi) and Mr. Róbert Csombordi, agreed to proceed with the implementation of the research work. Over two years of cooperation, several meetings and visits were carried out and a conclusion presentation is delivered to the company to show the results of the cooperation.)

3.3.1. Quality management practices at CLH

As illustrated in Fig. 3.6, the quality management office at CLH consists of four divisions handling the daily quality tasks. The office is led by a manager, the divisions are the measurement room, the shop floor quality, product development and planning management, and supplier quality management.

The task of the measurement room team is to check the technical and geometrical specifications of the products and items according to design sheets and drawings. The measurement room consists of different measurement devices including smart physical characteristics testing devices.

The shop floor quality control division consists of three main quality activities, quality gates, test cabins, and product audit. Additionally, the quality management team is responsible to handle claims and feedback coming from the customers and other service units.

The product development and planning management is responsible to evaluate and assess the risks related to newly developed products, it includes project risk analysis, product risk analysis, functional safety, legal and safety risk analysis, and production safety analysis.

The supplier quality management is responsible to ensure the quality of items that are supplied from external suppliers. During the exploratory visit, the research had the opportunity to witness problem-solving techniques and the systematic approaches being used in order to handle quality deficiencies on many occasions.

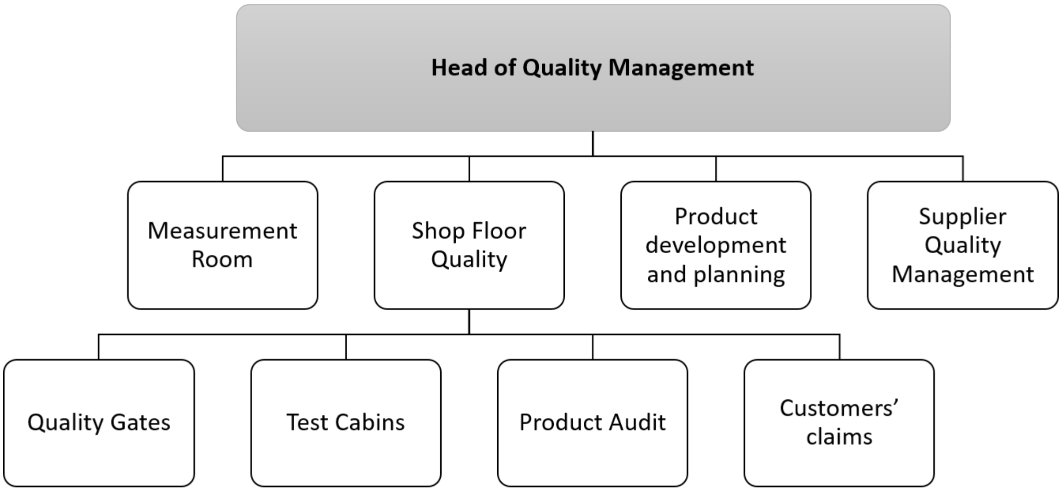


Fig. 3.6. Quality management Hierarchy at CLAAS Hungária Kft

In the shop floor quality division, the quality activities are practiced daily at five quality levels which are illustrated in Fig. 3.7.

First, at the lowest level of the quality hierarchy, comes the self-check, where quality is being practiced as a routine activity by the workers who work at the shop floor level. In other words, every labor or employee is responsible to ensure the quality of his work to ensure there is no internal missing parts or wrong manufacturing process during the production. It depends on the workers' commitment to produce high-quality products.

At the end of every production process, there are the quality gates, where the products are checked based on the quality checklists which are developed by the quality management based on design requirements, issues reported from the field (customers or service engineers), or due to recurring defects discovered during other quality auditing processes.

In the testing cabins, every produced product is connected to an in-house testing simulator. For example, the harvesting head. Once this product is manufactured it goes into the testing cabins, where it is connected to a simulated combine harvester as in the field. The test includes operating the device for a few minutes during which hydraulic, mechanical, and electrical systems are checked, adjustments are made if needed, and accordingly, a test report is generated including any failure results in addition to any missing parts detected.

In the product audit division, a selected device such as a harvesting head is connected to an actual combine harvester and checked in the field as in real operation. During this auditing, further evaluation metrics are evaluated, and a final quality report is issued.

End of line check**,** where the harvesting head is being checked for the last time, re-adjusted and packaged for shipping. A final check for the customer specification is done at this stage. In case of any issues, the product is sent to the re-work area, where it is re-adjusted to ensure the quality of the product.

The company utilizes the most recent technologies in gathering and analyzing data and information about its products during production and after-sale. An effective ERP system is used to monitor all management processes during the whole chain of production and later. CLH integrates its value chain with about 300 qualified suppliers, which enhanced the company's responsiveness and the quality of products.

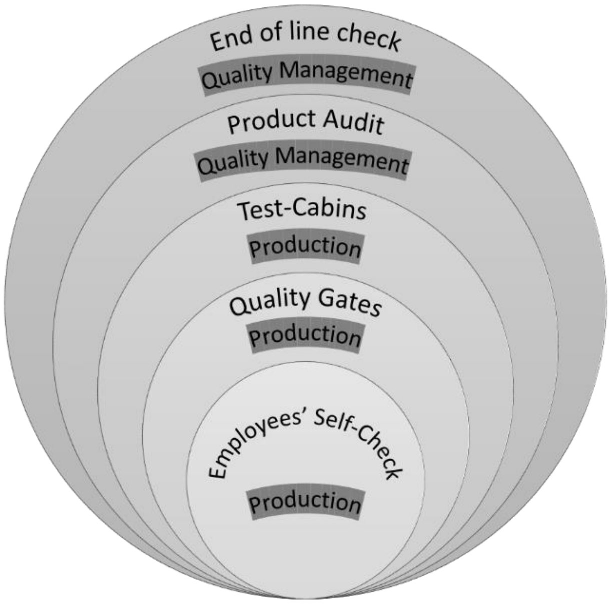


Fig. 3.7. Quality management layers at CLH

Based on the above information and background on the quality management system at the company, the quality management system which is implemented at the company is demonstrated in Fig. 3.8. As illustrated in the figure, quality management is responsible to ensure the quality of production at all stages. The continuous improvement process receives customer requirements, claims, and feedback about technical issues, revers it to the research and development unit (R&D) and to the quality team in order to figure it out and communicate related issues to the relevant party. Quality management is responsible to monitor the quality during planning, production, checking, and final product auditing.

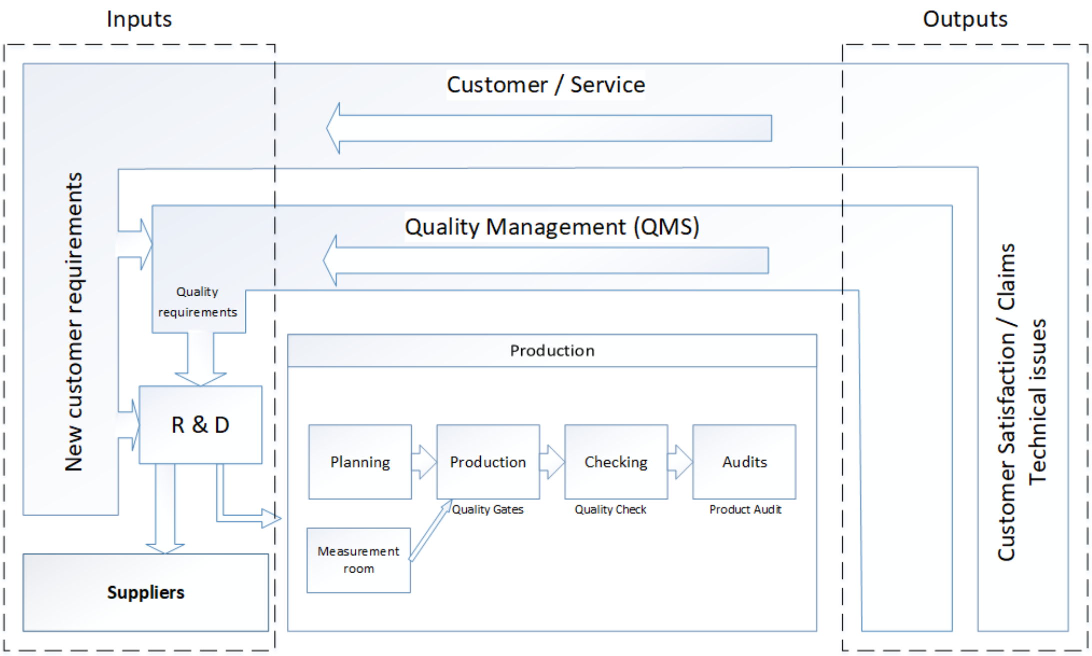


Fig. 3.8. Quality management system at CLH

3.3.2. Cooperation objectives: study background

CLH's staff has developed dedicated "Quality Checklists" for every product, process, or manufacturing phase. These quality checklists are developed based on the FMEA documents and are being used at the quality gates on the shop floor in order to ensure that common failure causes are avoided. Moreover, this process aims to ensure that critical device components are installed and configured at the optimal conformance to design. However, as mentioned earlier, FMEA documents are prepared during the product design phase and can be changed once the serial production is initiated. Meanwhile, further failures can be detected at the final assembly phase. Therefore, these quality checklists are needed to be dynamic, updatable, and responsive to critical quality issues that are reported during or after the production. The chosen experimental subject in this research is selected after discussion with the industrial partner to highlight priorities and the availability of data for analysis and implementation.

This research activity is focusing on a single device that consists of the combine harvester feeder house as shown in Fig. 3.9. The feeder house is a device that is attached to the combine harvester to facilitate the control of the cutting head and the flow of crops from the cutting head to the combine harvester. The device consists of several complex systems such as mechanical, hydraulic, electrical, and electronic systems. This device is wholly manufactured in the subsidiary company in Hungary and dispatched to be assembled to the combine harvester at the mother company in Germany.

Failures or defects which are observed during assembly or reported by end-users are gathered daily through the global ERP system of the company. After that, this information is extracted, manually reviewed, and evaluated by an experienced quality management team. This evaluation process aims at analyzing the failure root cause(s) and consequently taking the needed correction actions in order to maintain profitability and high-quality production. The company uses an internally customized FMEA technique to evaluate reported claims by obtaining RPN for every claim according to FMEA documents. The method which is used here aims at generating an RPN value for every claim on a scale from 1 to 300 points, where 300 is the highest priority number.

Fig. 3.9. CLAAS combine harvester feeding house
Source: (https://www.claashungaria.hu/)

RPN in CLAAS Hungária Kft. is obtained based on three major factors namely severity, occurrence, and impact. The relationship between these three elements is illustrated in Fig. 3.10. Severity, or gravity as named by the company's internal manuals, represents the risk consequences of the claim on the final customer/ operator (F1.1). It also includes the safety impact on the internal operator at further manufacturing processes (F1.2) and the cost of resolving this issue (F1.3). The weight of this factor ranges from 1 to 10 points, where 1 is the lowest severity, and 10 is the highest. In the meanwhile, occurrence represents the number of incidents a specific claim has been witnessed in a specific period (F2.1). The weighting scale of this factor is also 1-10, where 10 is the highest. Impact is weighted by a scale of 3 points from 1 to 3. Impact represents the repair efforts, time (F3.1), the overall impact of the claim on the reputation and image of the company (F3.2), and repetition of the same work (F3.3).

Equation 3.1 shows the multiplication of the three factors values that result in an RPN value between 1 and 300 points. An RPN value above 160 points is classified at a very high priority, while, a value between 100 and 160 points is classified as a high priority. Medium priority is noted if the RPN value is in the range of 35-100, while low priority is noted if the RPN value is less than 35.

$$RPN = Severity \times Occurrence \times Impact. \tag{3.1}$$

According to the RPN value of every claim, the quality team decides the next handling steps. Further steps could be tracing root cause(s) and ensuring the elimination of such cause(s) and/or updating the quality checklists to ensure further failures will not repeat in the future. Time and experience play a crucial role in this regime. It is important to improve the process of evaluating claims and lever the current experience.

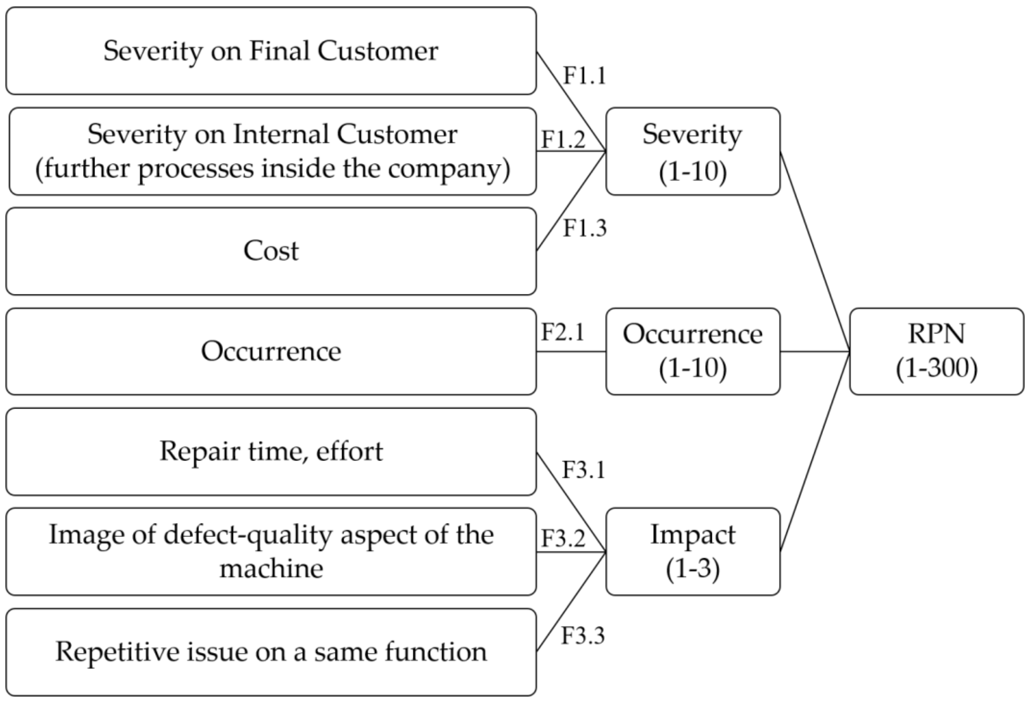


Fig. 3.10. Factors affecting claim ranking and the weight of every factor

The evaluation and ranking process requires highly experienced people who are fully aware of the FMEA documents and their applications. The volume, velocity, and veracity of claims reported, and their processing time is very critical from a quality management perspective. It is essential in such a high-cost industry to resolve issues as soon as they are reported. Early and fast processing of quality issues is translated to a lower quality cost and will positively enhance the general business performance. Moreover, standardization of the evaluation process and consistency of the process is vital to guarantee consistent RPN results every time.

The accumulated experience, time of processing, consistency of the evaluation process can be attained through the proposed solution in this research work; utilizing automated machine learning to classify and analyze claims data. Machine learning capabilities provide the capacity to analyze several input features (columns) at one dimension, aligned with a large volume of data (rows) at the other dimension. This helps in discovering and analyzing unseen factors, considering that the best quality practices focus on the claim root cause analysis. Additionally, utilizing technology whenever possible is very promising in the industry, because of its availability at any time (24/7) under any conditions and its ability to go deeper in analysis beyond human capacity. Delegating such tasks to machines will let human intelligence focus on higher strategic issues and to reach a higher level of efficiency and effectiveness.

In this experimental work, it is suggested to utilize supervised machine learning technology to replace human intervention in processing, evaluating, and categorizing claims. The current flow of claims from involved parties is illustrated in Fig. 3.11. In this figure, claims from internal company quality product audit (Product audit claims) and issues that were detected during assembly (Cross company claims) are pipelined in the company's ERP system and human intervention is important at one point to evaluate claims manually. Every claim is evaluated and assigned an RPN value from 1 to 300 points. According to the RPN value, further actions are made. For instance, if the RPN value is above 160 points it means that the issue is very critical and therefore, it is transferred to the 8 disciplines of problem-solving techniques (8D method) in which the root cause of the defect is traced, resolved, and prevented from re-occurrence. If the RPN is less, a simpler procedure is followed by updating the shop floor quality checklists in order to ensure the quality of next produced devices. Otherwise, this reported issue is just as it is an accidental incident and occupies a very low RPN value.

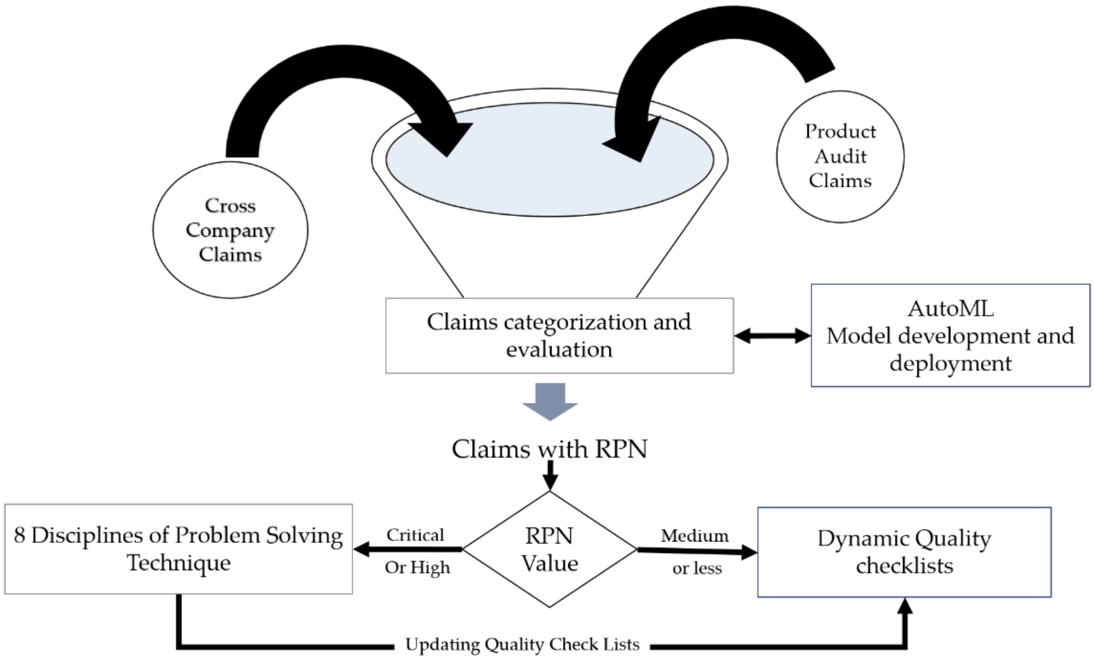


Fig. 3.11. The flow of internal quality audit and cross-company claims to quality management

Accordingly, a dataset that contains one-year data of claims is extracted from the ERP system of the company. This data is concerning the selected device only (the feeder house is shown in Fig. 3.9). Firstly, to ensure the accuracy of the developed models, the data was prepared and validated manually by experienced quality engineers to obtain the three RPN elements (severity, occurrence, and impact) and to define the root cause and the source manufacturing process (such as cutting, bending, welding, painting, assembly, etc.) of every claim. The evaluation process depends on the experience of the quality team and based on the internal FMEA procedure for every failure mode. After that, the updated dataset is used for models' training and to develop four machine learning models that are deployed to predict an RPN value for future failures claims and classify its root cause instantly without further human intervention.

3.3.3. Data preparation platform

Data preparation for the purpose of developing machine learning models is made in two stages, the first is made manually for the raw data received from the industrial partner in order to review, validate, evaluate, and assign an accurate RPN value for every un-evaluated claim. While the second is made at the machine learning platform and consisting of regular data pre-processing including; feature extraction, and hyper-parameter selection techniques. Both stages are different in procedure and techniques. The first is developed by regular programming code, and the process is made manually, while the second is implemented automatically by the help of the auto-machine learning platform. However, the overall objective of this research/industry cooperation is to replace the manual evaluation of RPN by a machine learning-based system that can evaluate and automatically assign an RPN value in addition to categorizing it.

The excel sheet included 1532 claims reports which are extracted from the company's ERP system. The data was recorded for over one year and related only to the selected product in Fig. 3.9. However, the data which is extracted suffered some lack of information and is not evaluated based on the RPN criteria. Hence, there are no assigned values for severity, occurrence, and impact.

Further, the claims are not categorized according to the manufacturing process that is probably responsible for this specific failure. Therefore, a data preparation process is needed, where every claim is manually explored, evaluated, and assigned the proper RPN elements' values. However, reviewing the claims manually and one by one is a very exhausting task if it is made manually or directly to the excel sheet. Therefore, a special data platform is developed using the Microsoft SQL database and Active Server Pages (ASP) programming language in order to provide a user-friendly interface that facilitates the process of evaluation.

The data platform displays the data from the SQL database and facilitates the process of reviewing all reported claims. The basic and simple analysis of raw data by the developed platform detected an overall overlapping of claims by 40%. This means that 40% of the overall dataset is similar and the effort of evaluation can be reduced by such value. The developed platform guarantees such reduction is obtained. Accordingly, the details of every claim are displayed as shown in Fig. 3.12 below.

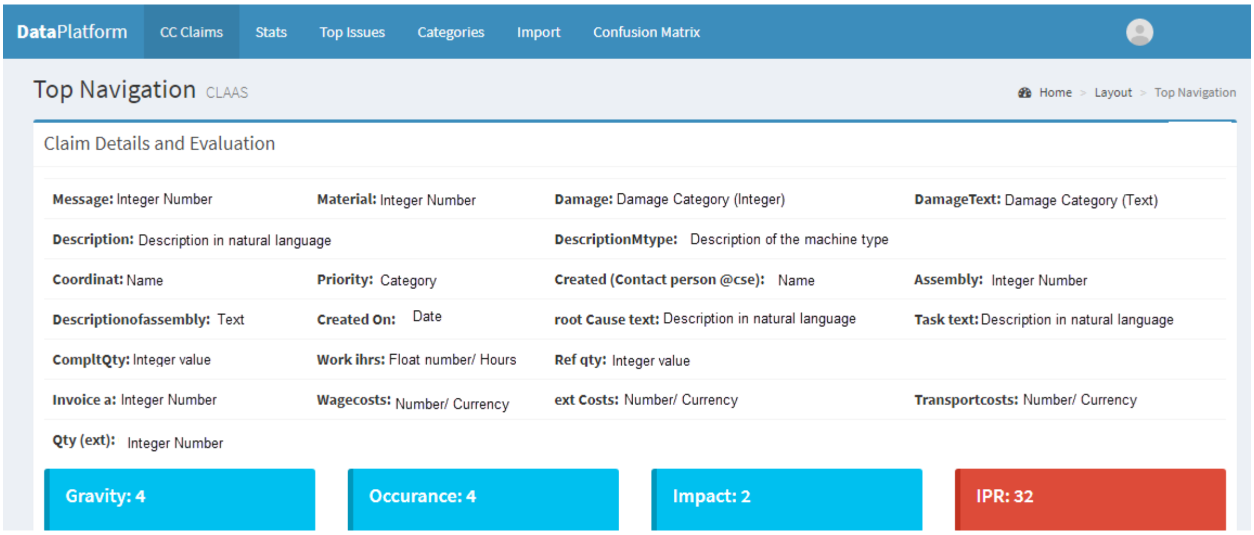


Fig. 3.12. Claim details as shown in the developed platform

The dataset is imported to the SQL database as a first step expanded by adding four more columns for severity, occurrence, impact, and category. The users are able to modify every claim manually from the screen shown in Fig. 3.13. In the back end, the system is developed so once the first failure is evaluated, the system uses this evaluated claim for learning and accumulating its knowledge base according to the filed data just similar to a snowball. After that, when evaluating the second claim and claims coming ahead, the system will first check if the new claim is similar to a one which is already evaluated before, if yes, the same evaluation is suggested. The knowledge of the developed system is expanding as more claims are evaluated.

In the evaluation process, every claim is assigned three values; Severity, Occurrence, and Impact. Moreover, the claim is categorized to classify the manufacturing process which is responsible for the root cause of such a claim. Once these values are assigned, the system will automatically calculate the RPN value for this claim. In addition to the evaluation process, the platform offered the possibility for users to edit the text of every claim. Some words were miss-spelled, or two words are connected without a space between them, therefore, fixing typo issues is possible. Moreover, the platform offered the ability to select one or more keyword that represents useful knowledge about the claim, therefore, the system will construct a bag of keywords along with their weights in order to make future learning more efficient. A screenshot of the evaluation screen is presented in Fig. 3.13.

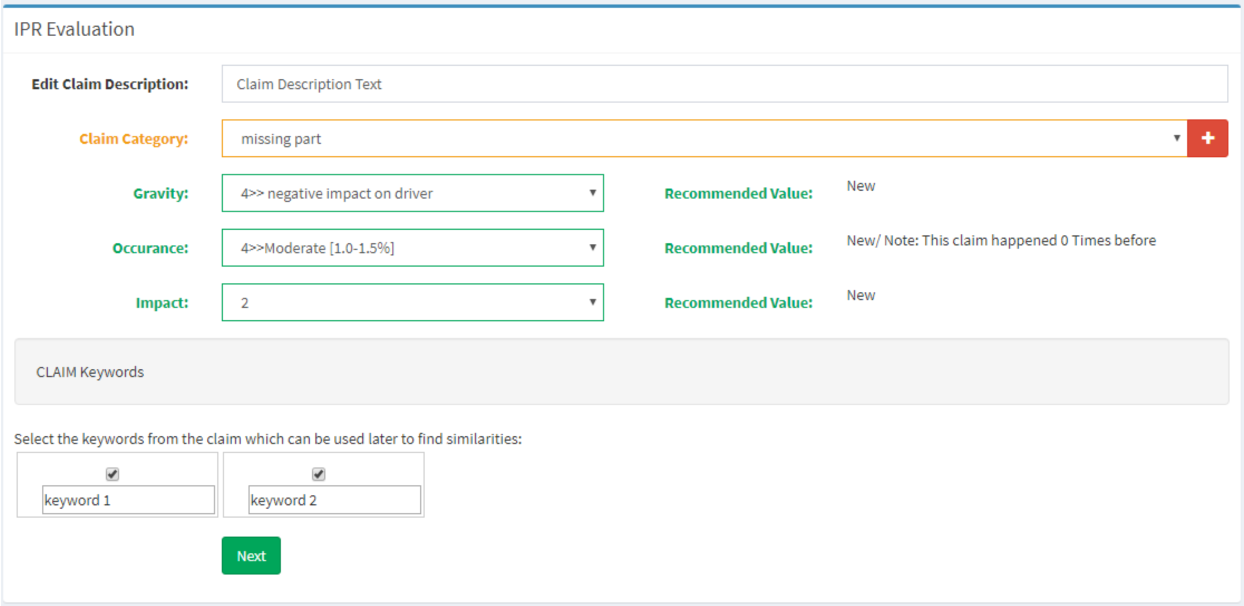


Fig. 3.13. Claim evaluation screen

The developed platform used a structured methodology to analyze the content of every claim in order to find similarities with other claims. This similarity check algorithm function as shown in Fig. 3.14 detects similar previously evaluated claims, or similar un-evaluated claims to assist to evaluate them. Once a similarity is detected, the function will highlight it in a different color.

```
Function matchfinder(input1,input2)
    sInput1 = replace(trim(input1),",","," ")
    sInput2 = replace(trim(input2),",","," ")
    if sInput1 > "" and sInput2 > "" then
        sInput1 = replace(trim(input1)," ", ",")
        sInput2 = replace(trim(input2)," ", ",")
        arrPaging1 = split(sInput1, ",")
        For j = 0 To UBound(arrPaging1)
        if InArray(sInput2,arrPaging1(j)) = True then
            txtnew = txtnew & "<span class='label label-success'>" & arrPaging1(j) & " </span>"
        Else
            txtnew = txtnew & " " & arrPaging1(j)
        End if
        next
    End if
    matchfinder = txtnew
End Function
```

Fig. 3.14. Similarity check function

Every claim textual data including claim description, root cause description, and actions taken is analyzed by dividing every line of text of every input data to an independent entity containing one word. Every word is used to inquire the evaluated claims to find similar words among other claims, once a similar entity is detected, the system will compare the other words. If the whole sentence is partially or totally similar, the system will check the other textual fields to find similarities following the same routine. Such an activity helps the user to find the closest claim(s) to the evaluated one. After evaluating the claim, the same methodology is used to detect similar un-evaluated claims and then to suggest the same RPN value.

For example, suppose the user is evaluating the claim (1), namely $claim_1$ and consisting of (n) words. The claim is selected from the entire set of claims containing (m) number of claims as in Fig. 3.15.

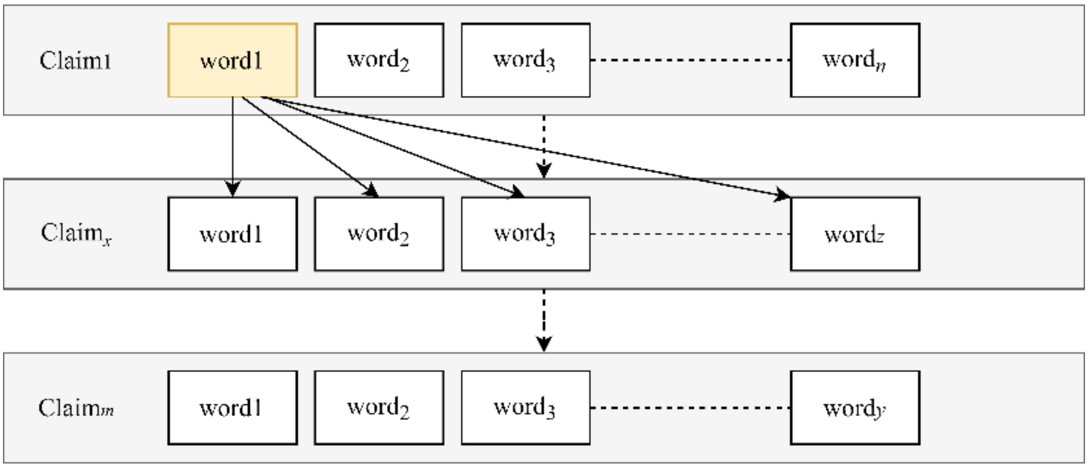


Fig. 3.15. Similarity detection process

The following is the SQL query which is used to extract similar claims from the database:

SQL Query for $claim_1$ *=(Select from DB where* $claim_x$ *Contains (*$word_1$*, or* $word_2$*, or* $word_3$*, ...or* $word_n$*).*

The system will search in the database for (n) times to detect any evaluated claims that have at least one similarity. Once a similarity is detected, the count will start by 1 and will count the number of similar words between both claims. Finally, the similarity strength is estimated by eq. 3.2:

$$similarity\ strength = \left(\frac{\#\ of\ similar\ words\ detected\ between\ claim1\ and\ claim\ x}{\#\ of\ words\ in\ claim1 + \#\ of\ words\ in\ claim\ x}\right) \times 100\%. \quad (3.2)$$

Once the similarity strength is obtained, it will be proposed on the portal interface, the user can decide if the evaluation is correct. In case of no actual similarity or no similarity at all, a manual modification can be made to achieve higher accuracy.

After that, once a claim is evaluated, the system will check the un-evaluated set of claims in the database. The system is able to catch all similar un-evaluated claims and will suggest assigning the same ranking which is given to the already evaluated one. The user decides whether to apply the same evaluation values or to restart evaluation for a new claim Fig. 3.16 elaborates on the process.

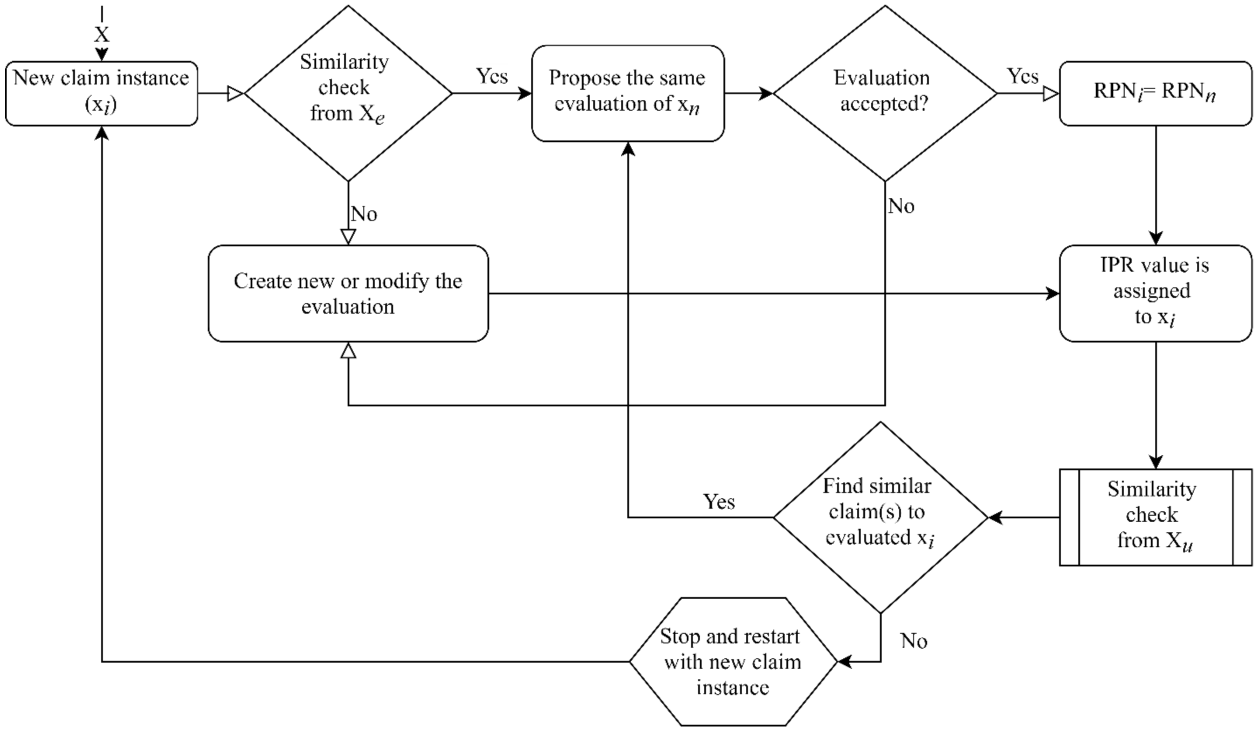


Fig. 3.16. The evaluation process in details

The markings shown in the figure are as follows:

X: The set of all claims

X_e: Evaluated set of claims

X_u: Un-evaluated set of claims

x_i: New failure claim instance

x_n: An evaluated claim from X_e

RPN_i: risk priority number for instance (*i*)

RPN_n: risk priority number for instance (*n*)

After the first data preparation stage is made, the data is ready for the second stage; applying machine learning techniques, including data pre-processing for machine learning, feature extraction, and hyper-parameters selection.

3.3.4. Machine learning and models development

In this research, Google AutoML is selected for three reasons: first, its effectiveness, as Google AutoML is a cloud service that utilizes the latest ML technology developed by Google brain team and the hardware of Google platform. Second, its ease of use, which is very important to ensure the sustainability of the project results after the research cooperation ends, keeping in mind that people who are working at the partner company are less experienced with coding and modeling. Therefore, such a friendly system will ensure that the partner company can deal with the work after the end of the project with the least knowledge of coding and data processing. Third, its ability to integrate. It is agreed with the partner company to integrate the developed models in the company's ERP system. Google AutoML offers the ability to deploy and integrate the resulted models by application programming interface (API).

Supervised machine learning is used to improve the failure claims processing process. Claims are reported by engineers at the assembly location in Germany or from service centers to the quality management office through the company's ERP system. Claims are analyzed, categorized and ranked by the quality management team based on FMEA documents. Accordingly, failures are ranked and prioritized based on their importance and critical impact.

The proposed solution aims at developing an automatic claim ranking system to replace human intervention based on developing four machine learning models that can read, analyze, evaluate, and assign relevant ranking values for every processed claim. In order to do so, the dataset which is evaluated in the first stage is used to train the model. Afterward, the model will be deployed to evaluate new claims based on the experience gained by the training data. Fig 3.17 elaborates on the process of models' development, inputs, and outputs. The first step in models' training is to pre-process the input data, feature selection, and data types. The auto machine learning tool resulted in four models that will be able to predict four independent values by which three of them will be multiplied to calculate an RPN value (as in eq. 3.1). The fourth decides the source manufacturing process of the same claim.

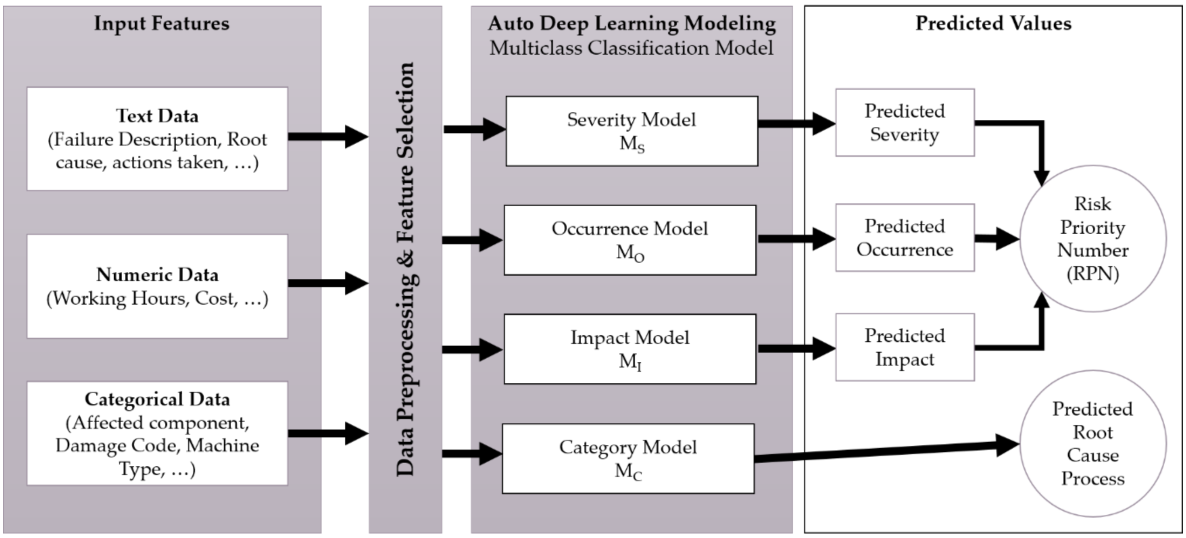


Fig. 3.17. Development of a machine learning model

3.3.5. Machine learning data pre-processing

After the dataset was manually reviewed by the engineers of the partner company, and every claim was assigned its proper evaluation elements, which in total resulted in an updated RPN value, the second stage of data modeling and processing is started. The data was extracted again from the SQL database, where every row in the dataset contains the details of a single incident and described by 23 different input features (columns) that help the quality engineers to recognize the failure mode and therefore, refer to the FMEA documents to assign the proper RPN value that fits this failure mode. For example, suppose a single failure is claimed from the assembly line in Germany where the engineers reported an incident of "an insufficiently tightened screws at one component in the device", along with this reported failure, further information is provided such as the serial number of the device, the code number of the component as in the design, further description written in textual format by the labor who solved the issue including his opinion on the issue and its criticality, the damage code as picked from the list of options in the input screen, the expected root cause of the problem is explained in textual format, the time consumed to fix the problem, and cost involved for rework, and the final conclusion. Table 3.2 summarizes the input features types and roles in the models. Whereas this dataset is used to develop the machine learning models. The first step is to prepare the data for the AutoML platform. This includes ensuring that all features of the dataset are organized, and data types are well defined.

Table 3.2. Dataset input features for the machine learning model

Data Type	Number of inputs	Labels	Brief summary
Textual Text	5	Claim description, root cause, machine type, and description, and remediation action made	This data is written in natural language by the labors or engineers at the German company, explains the failure, its root cause, the part involved, and the remediation action made It will help to recognize the failure mode, its root cause, and its technical solution
Categorial Data	10	Machine code and name, damage name and code, initial criticality assessment, component type, and reporter information	Contains data about the device affected, the damage category, and its criticality It will help to identify reoccurrence of similar failure, evaluate its importance, and define the location at which it was detected
Numeric Data	7	Different costs data, number of affected devices	This data will help to evaluate the consequences of this failure in terms of labor cost, transportation, material cost, and any extra costs
Timestamp	1	Date and time of the report	This data shows the frequency of a similar claim in a specific period

Furthermore, 46 cases are excluded from the training process because of missing critical details such as claim textual description and the root cause input. Moreover, scales (8-10) in Severity and (7-10) in occurrence had an insufficient number of claims (less than 50 cases) for every element, these records are excluded too, as shown in Table 3.3 The reason behind that, AutoML platform cannot run the training with less than 50 cases per class. Therefore, the dataset is copied three times, and classes with less than 50 readings are eliminated. Finally, 1343, 1269, 1355, and 1309 claims are used for models training of severity, occurrence, impact, and category respectively. 141, 156, 131, and 134 claims are used as validation samples for every developed model for severity, occurrence, impact, and category respectively. The data plot is shown in Fig. 3.18 where the distribution of the data is illustrated.

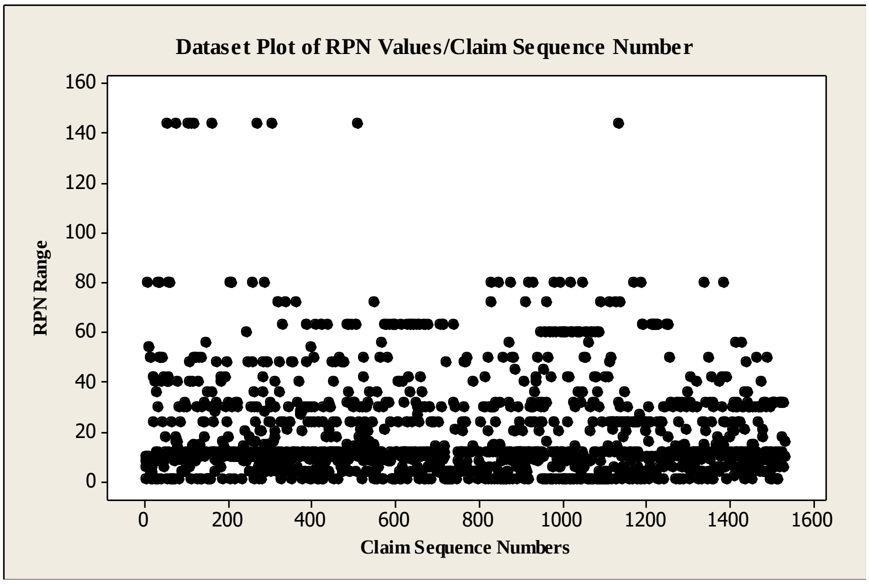


Fig. 3.18. Dataset plot of all claims based on RPN value

In addition to RPN evaluation, the research work includes classification of claims according to the respective manufacturing process which is described to be the root cause process of the defect. The names of processes are masked in Table 3.4 where the process could be any of the known machining processes such as cutting, pending, weddinged, assembly, etc. Processes with lower than 50 cases are excluded as well.

Table 3.3. Summary of dataset included in the modeling for FMEA elements

Scale #	Number of Records Severity	Occurrence	Impact
1	182	267	866
2	454	199	511
3	167	424	109
4	291	204	
5	218	128	
6	81	203	
7	91	28	
8	0	10	
9	2	0	
10	0	23	
Total cases	1486	1486	1486

Eliminated cases	2	61	0
Dataset cases	1484	1425	1486
Training cases	1343	1269	1355
Evaluation samples	141	156	131

Table 3.4. Summary of dataset included in the modeling for claim category

Process Category	Number of Records
Category A	89
Category B	104
Category C	464
Category D	123
Category E	206
Category F	86
Category G	303
Category H	68
Others	43
Total	1486
Dataset cases	1486-43 = 1443
Training cases	1443-134 = 1309
Evaluation samples	134

3.3.6.Data modeling

The AutoML platform analyses the dataset and constructs the models automatically. Such analysis including text processing is made by the Google AutoML in addition to the other categorical and numeric data.

Multiclass classification technique is applied to develop four machine learning models, while the suitable algorithm is automatically developed by Google AutoML. Google AutoML is developed to help researchers in handling large data and building high accuracy models with the least coding experience and resource consumption. The datasets are uploaded, the input features are defined, and targeted elements are selected. The prepared datasets are analyzed to obtain three independent models that can evaluate every claim to predict three independent values for severity, occurrence, and impact, from which an RPN can be calculated by applying eq. 3.1. Additionally, a fourth model (for category) is obtained to identify the manufacturing process which caused this failure to occur. The manufacturing process could be cutting, bending, welding, painting, assembly, packaging, and transportation. The aim of the fourth model could be extended in the future to include more specific processes such as welding machine 1, assembly line 2 and so on. Fig. 3.19. illustrates the four models obtained after training.

As the AutoML platform is a cloud system, then the consumption processing can be measured by node hour. The training process consumed 0.944, 1.105, 0.86, and 1.111 node hours for severity, occurrence, impact, and category respectively. Every node hour includes the use of 92 n1-standard-4 equivalent machines in parallel, where a single n1-standard-4 machine operates 4 virtual CPUs and 16 GB of RAM memory.

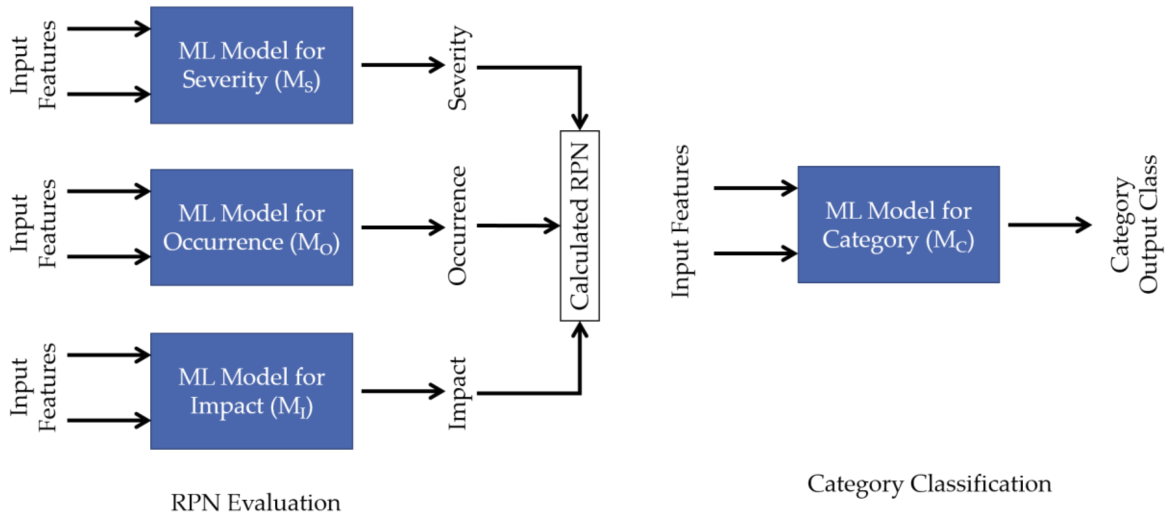


Fig. 3.19. RPN evaluation and Category Classification models

3.3.7. Models evaluation

In this research activity, models are evaluated by three methods; the first, by examining models' accuracy using standard classification metrics such as precision, recall, F1 score, and confusion matrices using the testing dataset which is truncated from the original dataset. The second, by applying the machine learning models on the entire training dataset in order to obtain predicted values for it. After that, compare the two results, predicted RPN values against the actual ones. The comparison can be made using regular error measurement indicators such as mean squared error (MSE) and the mean absolute error (MAE). The third, by extracting a new dataset containing new 361 records from the ERP system of the company which has never been used or evaluated before, evaluate it in the traditional way, then apply the resulted machine learning models and compare the two results again.

In the first approach, the models' evaluation metrics are precision, recall, and F1 score. Further evaluation metrics are adopted here such as area under curve (AUC) and the confusion matrices. The goal of these metrics is to evaluate the accuracy of every model of the four resulted models using classification metrics. The data used in this approach is the testing dataset which was truncated from the original training dataset before the modeling was initiated.

For instance, precision is the percentage of true positive predictions compared to all actual positive predictions (true positive and false positive). In the meanwhile, recall is the percentage of true positive predictions among all testing dataset (true positive and false negative). While F1 score is a balanced evaluation between precision and recall, and it is used especially when the data in the datasets are not equally distributed over classes.

The area under the precision-recall curve (AUC-PR) and the area under the receiver operating characteristic curve (AUC-ROC) are used to visualize the performance of the models. AUC-PR shows the trade-off between precision and recall for the model. AUC-ROC shows the trade-off between true positive rate and false-positive rate.

In the confusion matrices, the predicted values for every class are compared against the actual value from the validation sample. This technique helps to evaluate the models more precisely at the class level. In other words, precision, recall, F1 score, and AUC are metrics that evaluate the overall performance of the model. In the meanwhile, confusion matrices provide precise evaluation for every class in the classes used for validation. It can help to find where the model performs better.

In the second approach, the whole dataset is used to predict the three elements of RPN, at first, the resulted values are used to calculate the RPN according to eq. 3.1. After that, the resulted values are compared to the original values using regular statistical methods such as MSE and MAE.

In the third approach, the company extracted a new dataset from its ERP system which was never used or evaluated before. The quality engineers are asked to evaluate manually this set of new data, after which the models are applied to the same data. The statistical accuracy measures are applied to compare the manually evaluated data against the predicted RPN values using MSE and MAE.

In fact, the accuracy of the models is affected by the type of every element, the number of cases that are used for training, the accuracy of details provided per row, and the scale of every element (or the number of classes per element). It is important here to recall the objective of this work which is to provide a proof-of-concept that machine learning is an effective technique to enhance FMEA and the development of RPN value.

3.3.8. Models deployment and system implementation

After the development of the four machine learning models, the models are deployed. Deployment means that every machine learning model is transferred from its training mode to the application mode. This research work is a cooperation between academia and industry, therefore, having such a cooperation entails that the developed solution should be tested and utilized at the industrial partner in a real-life application.

Accordingly, as mentioned earlier, the advantages of the selected AutoML platform is its ability to be deployed to application mode through its API single line of code. The models are deployed from the AutoML platform, a line of code is resulted to be integrated into the ERP system of the partner company. However, as the ERP system used at the partner company is difficult to upgrade at this stage, therefore, the integration is implemented on the data platform which is developed earlier to manually review the dataset.

As shown in Fig 3.20, the machine learning models are integrated into the platform using the API offered by the AutoML platform. Therefore, the system is able to utilize the developed model on the Google cloud platform to evaluate new claims which are extracted as an excel file from the ERP system of the company.

Accordingly, the file containing a new set of claims is uploaded to the developed platform. Once the file is uploaded, the platform will transfer the claims as records to the SQL database. After that, the platform will read every single claim and connect to the AutoML platform through the API. The AutoML on Google cloud platform will evaluate the claim independently based on the deployed machine learning models and will return its relevant predicted severity, occurrence, impact, and category values through the API again. Once these four predicted values are returned from the AutoML platform, the developed platform will obtain the RPN value and will categorize the claims in their respective process.

At this stage, as shown in Fig. 3.21. the system will work as guidance for the quality experts to help in evaluating new claims. However, as mentioned earlier, this proposed solution can be integrated into the current ERP system of the company. Therefore, further implementation and integration steps can be made whenever is needed.

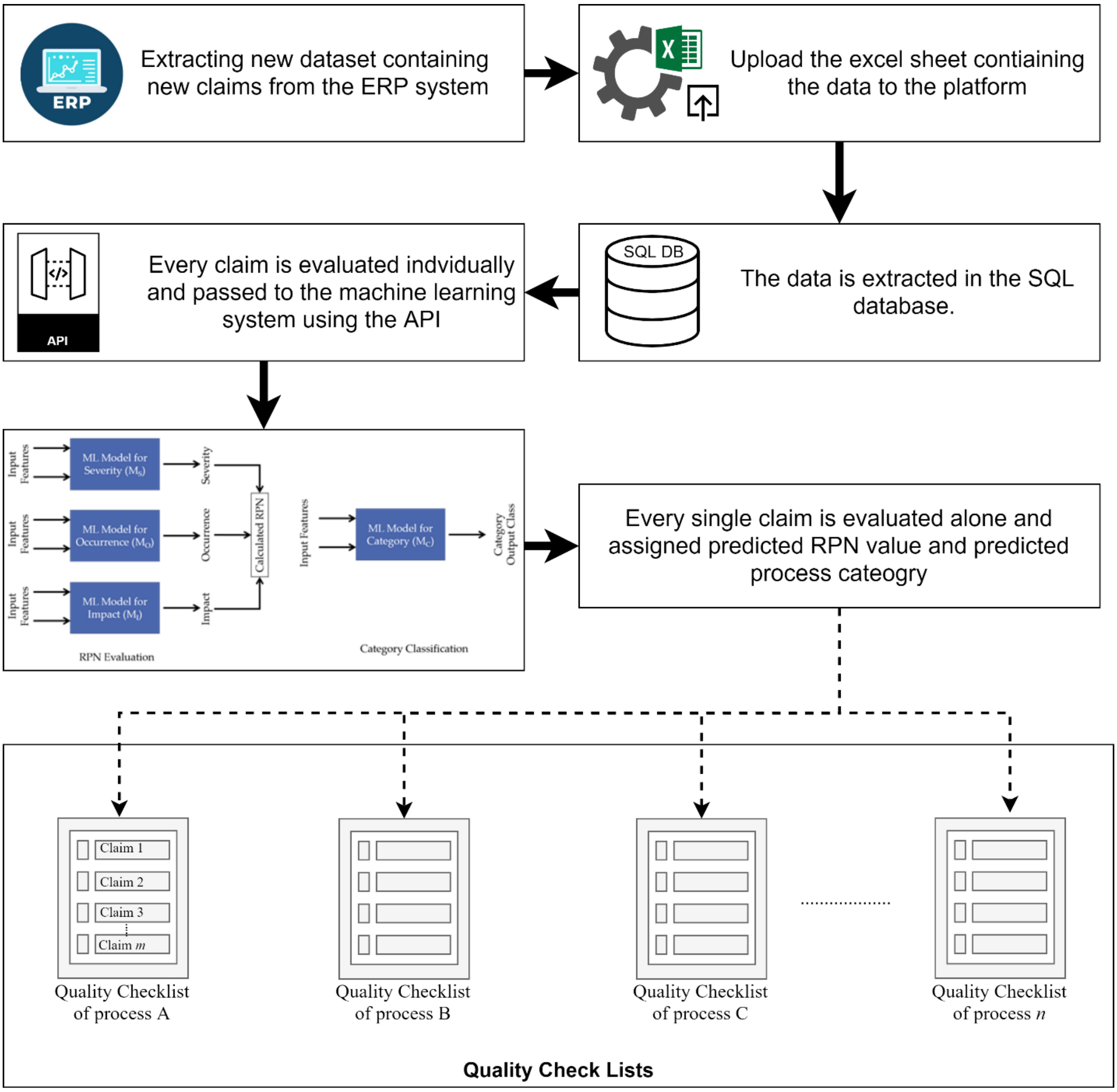


Fig. 3.20. ML Models deployment and implementation

Furthermore, a new screen is developed for the system containing the dynamic quality checklists which will be dynamically connected to the shop floor of the company. Every checklist will be diverted to its respective manufacturing process or phase. The quality checklists will also be shared with the quality gates to ensure the top issues are resolved and no further defects or failure have resulted.

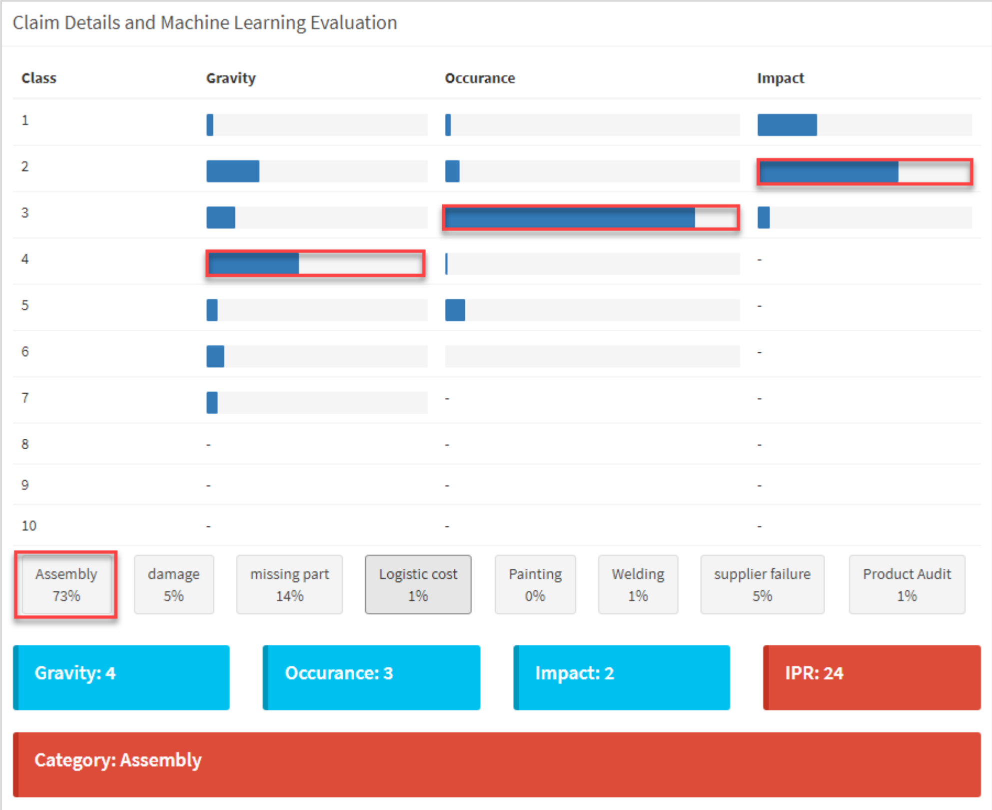


Fig. 3.21. Machine learning models deployment as a guide for evaluators

This proposed system is effectively closing the quality loop (plan-do-check-act). Once a failure is reported it will be handled automatically and quality checklists are updated. All the process is handled in a very efficient and effective way. Therefore, this project is successfully implemented and validated.

4. RESULTS

In this chapter, the results of the research work are presented. Given the two approaches of this research, the theoretical and the experimental, the results cover both approaches and fulfill the research goals and objectives as identified in section 1.2.

4.1. Total quality management – Industry 4.0 interface

As concluded in the previous discussions, Industry 4.0 can serve the successful implementation of the seven TQM principles as in ISO 9000:2015 standards family. Therefore, the first result of this research work is to define the interface where the impact of Industry 4.0 can be assessed and improved. The following points define this interface according to ISO 9000:2015 standards family and conclude the interaction points in Fig. 4.1.

4.1.1. Customer focus

As per the ISO 9000:2015 fundamentals and vocabulary (ISO, 2015c), Customer focus as an approach to TQM aims to show the commitment of the organization leadership to fulfill and to strive to exceed customers' needs and expectations. Moreover, ensuring consistency with regulatory requirements and statutory, identifying risks and opportunities that can affect customers' conformity of use and customer satisfaction. Finally, ensuring that the customer focus approach is sustained and continuously maintained.

Accordingly, Industry 4.0 will enable organizations to improve their customers' satisfaction through improving the quality of the delivered products and services, due to intensive quality control and quality assurance practices. Additionally, Industry 4.0 will enable companies to produce and deliver "individual customized" products and services at a regular time, away from the complexity of amending the mass production regimes. Therefore, customers will be served on an individual basis, which will consequently improve customers' satisfaction and conforming their quality expectations.

Moreover, Industry 4.0 connectivity features will involve customers in the production process by providing means of communication before, during, and after the production process, allowing them to be part of the production process, rather than only being the recipient of it. Other features like Big-Data analysis will boost the ability of the company to early predict market demand and consumption trends and changes, thus, increasing responsiveness by providing proper products at the proper time.

4.1.2. Leadership

Leadership aims at establishing a unity of purpose where people inside a firm are involved in achieving the quality objectives of the company. This will enable the company to align strategies, policies, processes, and resources to realize the quality objectives (ISO, 2015c). Industry 4.0 features such as "Vertical, Horizontal, and End-to-End integrations", Enterprise Resources Planning (ERP) systems, Big-Data analysis, and high connectivity technologies, facilitated leadership tasks by enhancing coordination and collaboration among different leadership levels, which in total improved the capability of the company to deliver distinctive quality results.

Evidence showed that Industry 4.0 had a great impact on information flow over the production chain, integrating the business processes and supporting the ERP systems to optimize manufacturing management (J. Lee et al., 2014). Industry 4.0 provided transparent production processes, thus, supported the leadership capabilities to align and optimize resources such as labor and machines to fulfill demand efficiently and effectively.

4.1.3. Engagement of people

A successful quality management system (QMS) encompasses that people at all levels inside the organization are engaged and participating in boosting the organization's capabilities to create and deliver value to customers (ISO, 2015c).

Within such context, Industry 4.0 will support the communication and collaboration among all people inside the organization providing different means of people engagement and human resources management benefiting from connectivity features and social networking. Moreover, Industry 4.0 will stimulate innovation, by encouraging individual contribution to the development of the organization.

Utilizing Industry 4.0 tools such as Big-Data analysis, ERP systems, Artificial Intelligence, and instant interpretation of data to knowledge and information will help people at their respective positions to use this knowledge to avoid risks and suggest virtually developed and tested solutions, hence, be more initiative and creative.

Moreover, Industry 4.0 changed the role of workers from being "machine operators" to a higher position by supervising the work while it is being done by the machine (which is called now the "augmented operator"). It is important to mention the Industry 4.0 does not mean a full replacement of people inside the organization. Keller et al. (2014) suggested that future work of labor will remain irreplaceable, but its content will be changed from the position of doing the work to a more coordinating position where workers must be more skilled in decision making and problem-solving especially in dealing with unforeseen problems.

4.1.4. Process approach

ISO (2015c) stated that effective and efficient business processes are achieved when activities are understood and managed as interrelated and consistent. Optimized system performance can be realized by defining the intended results and how they are produced.

Accordingly, Industry 4.0 will support the transparency of business and production processes, it will aid processes' optimization, improve efficiency, and resource allocation. Industry 4.0 will facilitate tracing production bottleneck, defects' sources, and minimize production cost. Additionally, it will improve the supply chain responsiveness, through total integration from market demand back to suppliers (Wang et al., 2017). \

Industry 4.0 will provide accurate information about processes (time, risks, resources, critical constraints) among all aspects of production. Thus, it will help the planning level of key-processes to maintain continuity and efficiency (Wang et al., 2017). Moreover, Cyber-Physical Systems will simulate the possible production scenarios according to production dynamic parameters, and then will operate at the optimum scenario. This will minimize the time required to design and test the production regime and will improve process flexibility.

Within an Industry 4.0 integrated QMS, quality objectives are defined and aligned with process objectives (supported by ERP systems, business integration, smooth flow of information between all managerial and production levels). This will provide a solid base to define and align authorities, responsibilities and accountability means needed to manage the processes.

4.1.5. Improvement

One of the objectives of a QMS is to ensure the commitment of the organization toward continuous improvement of its processes, products, and services to enhance customer satisfaction. This entails more focus on root cause analysis and to suggest prevention and remedy actions whenever is needed (ISO, 2015c).

Industry 4.0 will provide a basis for continuous improvements in the product, process, and business performance of an organization. A totally integrated production system will improve the value chain performance and the responsiveness of the entire system. Moreover, many industries (such as automobile industry) attaching smart devices that can send raw data from the vehicle to the companies' data center containing vehicle performance during operation, thus, reporting any operating issues and, thus, enhancing future products to overcome such issues.

Additionally, Industry 4.0 features such as AI and machine learning will enable the industrial system to detect or early predict machine failures or defective products at early stages and can provide instant root cause analysis as well as instant recommendations of proper remediation. Such an advantage will improve the use of learning for improvement and will enhance the ability to anticipate and react to different kinds of risks and opportunities. Such advantages are key benefits to maintain the process of continuous improvement and will open the door for further innovations.

4.1.6. Evidence-based decision-making

ISO 9000:2015 fundamentals and vocabulary document (2015c) stated that desired results are more likely to be reached by decisions taken based on accurate data and information.

Industry 4.0 and the linked IT solutions such as Big-Data, AI, and Cloud Computing, afforded great opportunity to improve the decision-making process, by providing accurate data and information with useful tools such as business dashboards, to support real-time monitoring, measuring, and determining the organization's performance.
Moreover, at the shop-floor level, machines are self-learned (supported by AI and machine learning technologies), connected to each other forming a collaborative community, collecting and analyzing data, providing the ability to make independent, self-optimized, autonomous, and instant decisions (Lu, 2017).
Experiments show that Industry 4.0 techniques could send earlier prognostics about machine health, reducing downtime, and afford maintenance on time. However, although new technologies minimized the need for people's competency in data analysis, the human experience will remain needed in order to make decisions balanced with experience and human intuition.

4.1.7. Relationship management

In a sustainable QMS, interested parties at any organization are key factors to obtain and retain success, where all interests (opportunities and constraints) are being shared and informed between parties (ISO, 2015a). The aim of managing partnerships as an approach to achieve TQM is to optimize the production supply chain and to guarantee a smooth and stable flow of products and services to customers. Thus, ensuring the highest coordination with production parties and stakeholders (such as suppliers, patterns, customers, investors).

Accordingly, Horizontal, Vertical, and End-to-End integration among the entire business units, plus the effective communication and collaboration tools between all stakeholders within an organization, and modern communication systems under the umbrella of Industry 4.0 provided a great advantage in terms of relationship management with business partners. Suppliers are instantly connected with production systems, promptly notified for the supply-demand, which in return resulted in a responsive supply chain that responds effectively to market needs and decreases the time to market, hence, enhancing customer satisfaction (Keller et al., 2014).

4.1.8. Quality control

Intelligent quality control systems are widely used nowadays, replacing traditional quality control techniques like statistical quality control and statistical sampling. Utilizing sensors and real-time inspection technologies enabled instant defective products' exclusion, not only for a sample of products but to the overall population of production. Furthermore, intelligent quality control systems are operating at every stage during the production, thus, the cost of quality is minimized as production defects will be early detected, and root causes will be early analyzed and resolved.

4.1.9. Quality assurance

An Industry 4.0 integrated production system will ensure that all requirements to produce high-quality products are fulfilled. The smart machine, smart factory, and augmented operator will define and eliminate the root causes of production defects and will make an instant early action to avoid defects and production failure.

Industry 4.0 will aid processes' optimization, improve efficiency and resource allocation, minimize the efforts needed for quality issues by using sensors at each production stage, and provide means to support quality activities which will result in minimizing rework and scrape (Foid, Felderer, 2016).

Big-Data analysis will collect real-time data generated during production, transform it into friendly useful information that is readable and accessible by different business units and levels. Such knowledge will be useful to enhance the production systems. Machines can send early notifications for predictive maintenance in advance, avoid downtime or system failure.

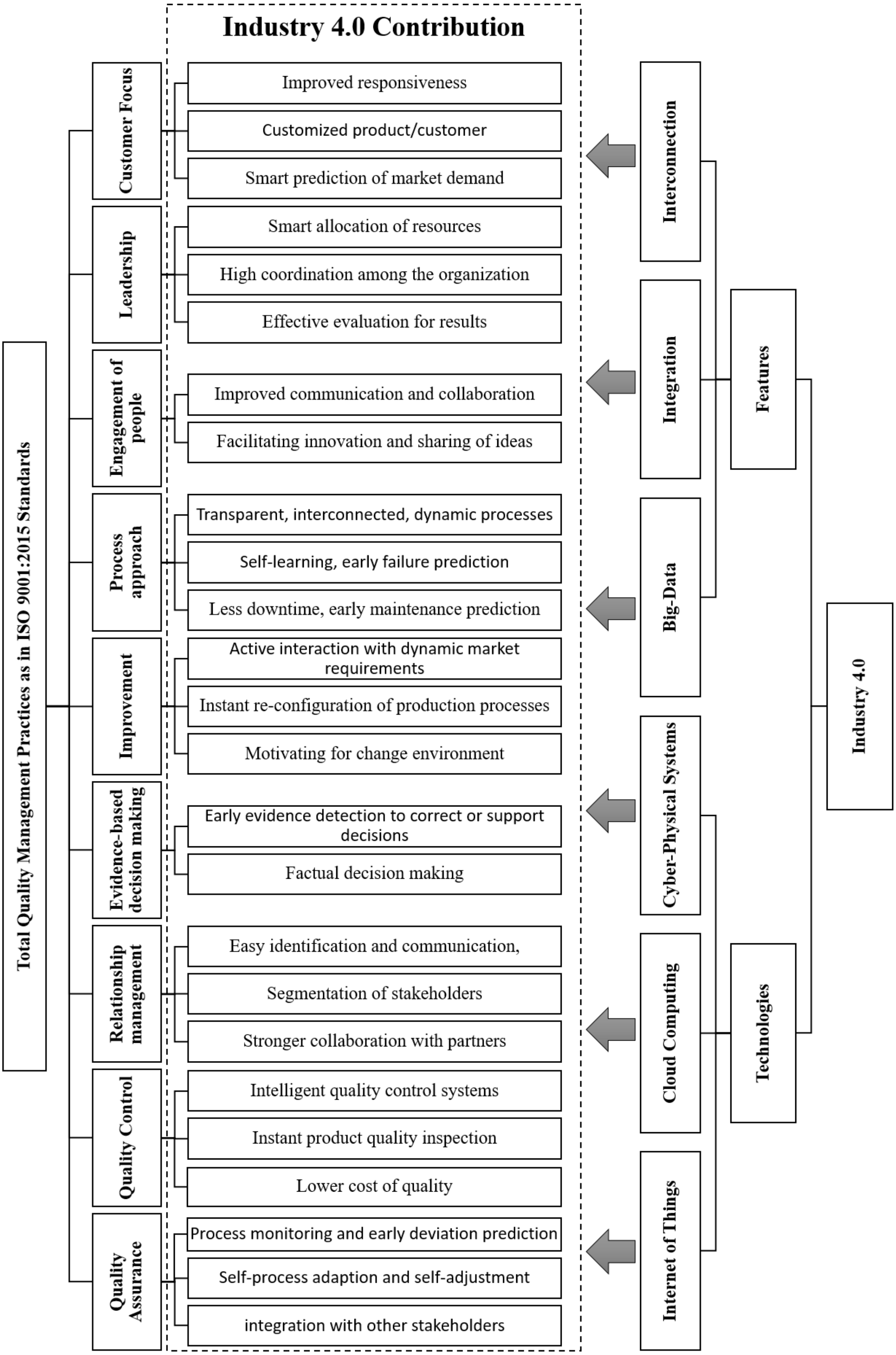


Fig. 4.1. Total quality management in the context of Industry 4.0

4.2. Identified sets of qualitative and quantitative measures

As the interface between TQM and Industry 4.0 is well defined, the impact of Industry 4.0 on the implementation of TQM shall be measured and evaluated. As mentioned earlier, the impact of Industry 4.0 on TQM practices can be assessed by comparing quality performance indicators before and after implementing Industry 4.0 technologies and features.

Therefore, Table 4.1 lists the set of indicators as identified by ISO 9000:2015 requirements document (ISO, 2015b) and as suggested by other literature such as (Coffey et al., 2011; Neyestani, Juanzon, 2016). The indicators are followed by their relevant suggested means of measurement which are suggested in the context of Industry 4.0.

Table 4.1. Set of indicators to measure Industry 4.0 impact on total quality management

TQM Principles	Indicators for measurement	Means of Measurement
Customer Focus	• Customer satisfaction, retention & loyalty, • Number of claims, • growth in market share, • improvement of organization reputation.	• IoT, Wi-Fi and Big-Data techniques as the data gathering and analyses tools, • social media, analysis of customers feedback using AI techniques, • CRM & ERP systems.
Leadership	• Effectiveness of meeting quality objectives, • coordination and collaboration efficiency among organization's units, • operational effectiveness.	• Real-time resources monitoring and automatic regulation and reallocation, • system monitoring dashboards, ERP systems.
Engagement of people	• Improvement in employees' satisfaction, • growth of innovative ideas, • Improvement of self-evaluation and self-improvement culture.	• HR management systems, • ERP system, • statistical data from production.
Process approach	• productivity increase, • improvement in lead time, • downtime due to poor process management, • improvement in production costs.	• ERP system (integrated with customers and suppliers), • sensors and actuators within the production process, • process-related Big-Data analysis, • Internet of Things (machines data), • maintenance management system.

Improvement	• Responsiveness to customer or market requirements/needs (time to react), • cost of poor quality, • defects rate.	• ERP system and CRM system, • Big-Data themes, • customers feedback.
Evidence-based decision making	• Clear and agreed decision-making process, • data availability and clarity, • past decisions effectiveness, • data-driven decisions.	• Big-Data analysis, • CRM system, • ERP system.
Relationship management	• Stakeholders satisfaction, • Suppliers' efficiency, • supply chain stability.	• ERP system (integrated with customers and suppliers), • sensors and actuators within the production process, • process-related Big-Data analysis, • Internet of Things (machines data).
Quality Control	• Cost of quality, • defective rates, • customer claims.	• CPS and ERP dashboards, • CRM systems.
Quality Assurance	• Cost of quality, • rework and scrap, • maintenance efficiency, • downtime and system failure.	• Smart maintenance management systems, • ERP system.

4.3. Development of a theoretical updated QMS in the context of Industry 4.0

Quality management has never been as smart as when utilizing Industry 4.0 features. Fig. 4.2. illustrates the integration of Industry 4.0 technologies in the manufacturing value chain. It represents the flow of information, data, and operational orders from and to the production level. Information is streamed from the customers and markets to the Big-Data, where it is analyzed by AI and machine learning technologies and transferred to the production systems as production orders containing instruction, specifications, and volumes. The production system transfers the received orders automatically from the ERP to the CPS to simulate and implement the optimum production schemes. At this point, process re-adjustment may occur based on the new production orders. During the production, sensors are transferring data via the necessary interface to the Big-Data and ERP systems, this data includes row-material requests, maintenance requests, and production analysis. Any unplanned changes occurring during the production are analyzed instantly, and responses are sent automatically to relevant stakeholders.

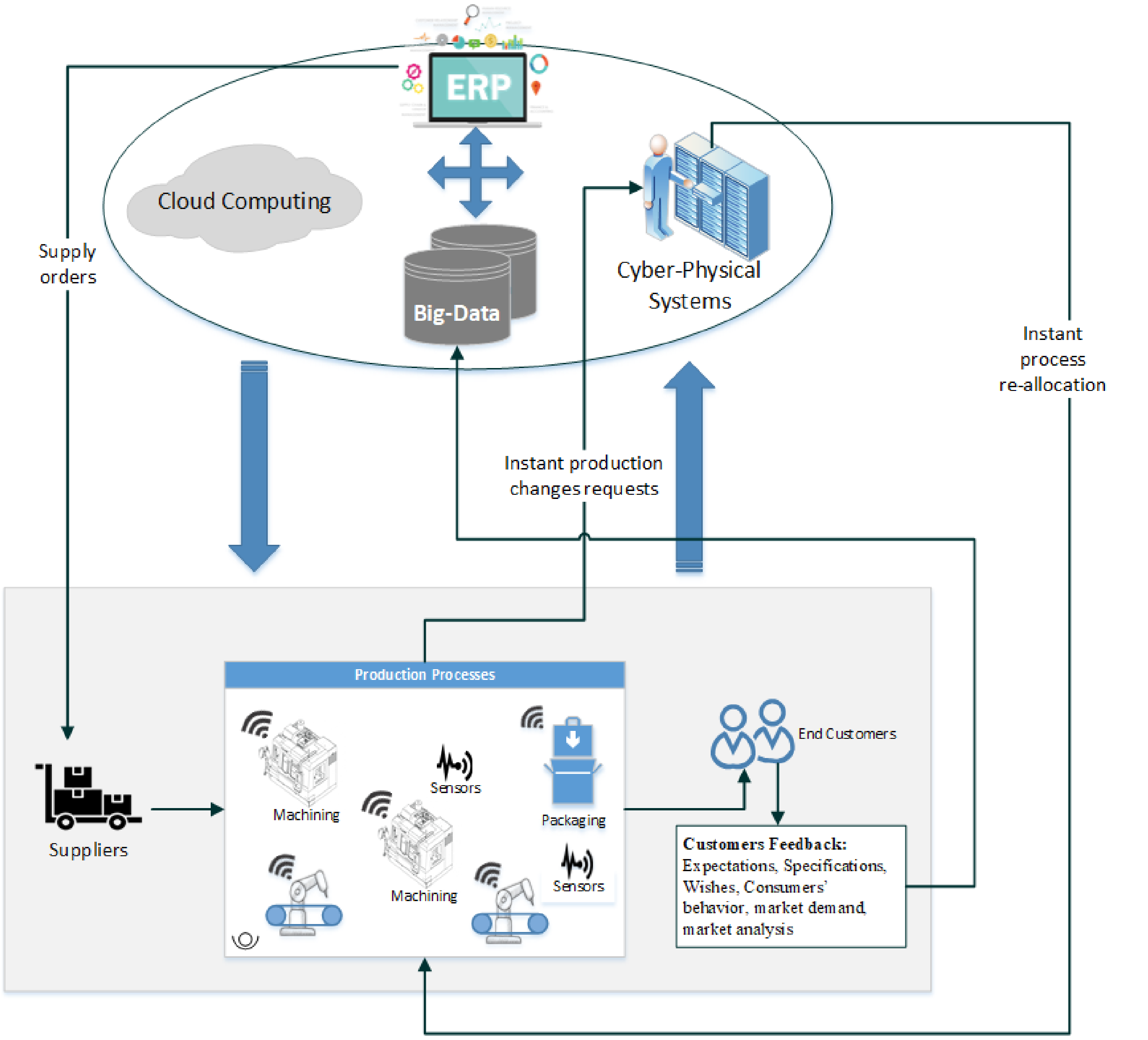


Fig. 4.2. Integration of Industry 4.0 technologies in the value chain

From a quality management perspective, sensors and in-process quality inspection devices are sending real-time data to the global Big-Data systems. Consequently, this data is processed locally at the machine smart system, which enables the machine to suggest or make decisions at the micro-level. Accordingly, the global Big-Data system analyses data at the macro level, making proper decisions to avoid defects, system failure, or downtime. Production is optimized by applying lean manufacturing, and supply chain management techniques.

The production system is managed by the ERP and CPS by analyzing the current production schemes, arrange production priorities, and allocate resources. The real-time quality inspection ensures that quality requirements are being fulfilled, and any causes of process deviation or production failures are avoided or eliminated.

An Industry 4.0 – QMS will enhance production and provide confidence that all quality requirements are fulfilled, and total quality management practices are all realized. Within such a system, the cost of quality is minimized, as defective products are early detected, and process deviations are corrected. Communication with the end customer is effective and the production system is responsive to market demand.

In conclusion, the general framework is developed. This general framework is used as a basic system for further development during the experimental part of this research. A quality management system is a general approach of how every company is progressing its daily processes and activities with the objective of maintaining and enhancing quality. Thus, each company has its customized quality management system.

A general theoretical model for integrating Industry 4.0 technologies and features with the quality management system is illustrated in Fig 4.3. In this suggested model, PDCA cycle and quality management system functions such as planning, support and operation, performance evaluation, improvement, and leadership are integrated with Industry 4.0 features. Industry 4.0 technologies are connected (connectivity) at every point of the quality management system starting by customers and closed by the main objective of quality management which is customer satisfaction (Integration). Customers’ requirements and feedback are gathered and analyzed using Big-Data and AI technologies using (Big-Data analysis) and translated to requirements and specifications (inputs). Such an activity could be made via cloud computing technologies to improve effectiveness and enhance performance.

In the meanwhile, the cyber-physical systems are controlling the physical manufacturing system according to the dynamic changes that are occurring from a quality management perspective. Failures in products or processes are reported directly and analyzed, decisions are made, and correction actions are executed. Fig. 4.2. illustrates an example of the integration of both Industry 4.0 technologies and features, along with the flow of information among different levels.

Within an integrated Industry 4.0 – QMS, customers’ expectations, market analysis, are directly communicated to the production systems, products’ quality is controlled and assured using smart sensors and failure investigation analysis. Machines are connected, smart, able to predict, plan, and operate under different circumstances. Production schemes are flexible and dynamic due to hiring cyber-physical systems, where customized products can be produced without production delay.

Suppliers are instantly notified about inventory consumption and can fulfill demand just in time. ERP systems can plan activities and handle orders and other business activities. Quality cost is at its minimum due to smart failure detection and early prediction. All the business units are performing as one integrated unit, where every business unit is aware and can participate positively in the entire system.

Within such scenarios, implications of Industry 4.0 are expected to reach an outstanding level of business excellence, effectiveness, and efficiency, and at the end a successful implementation of total quality management principles.

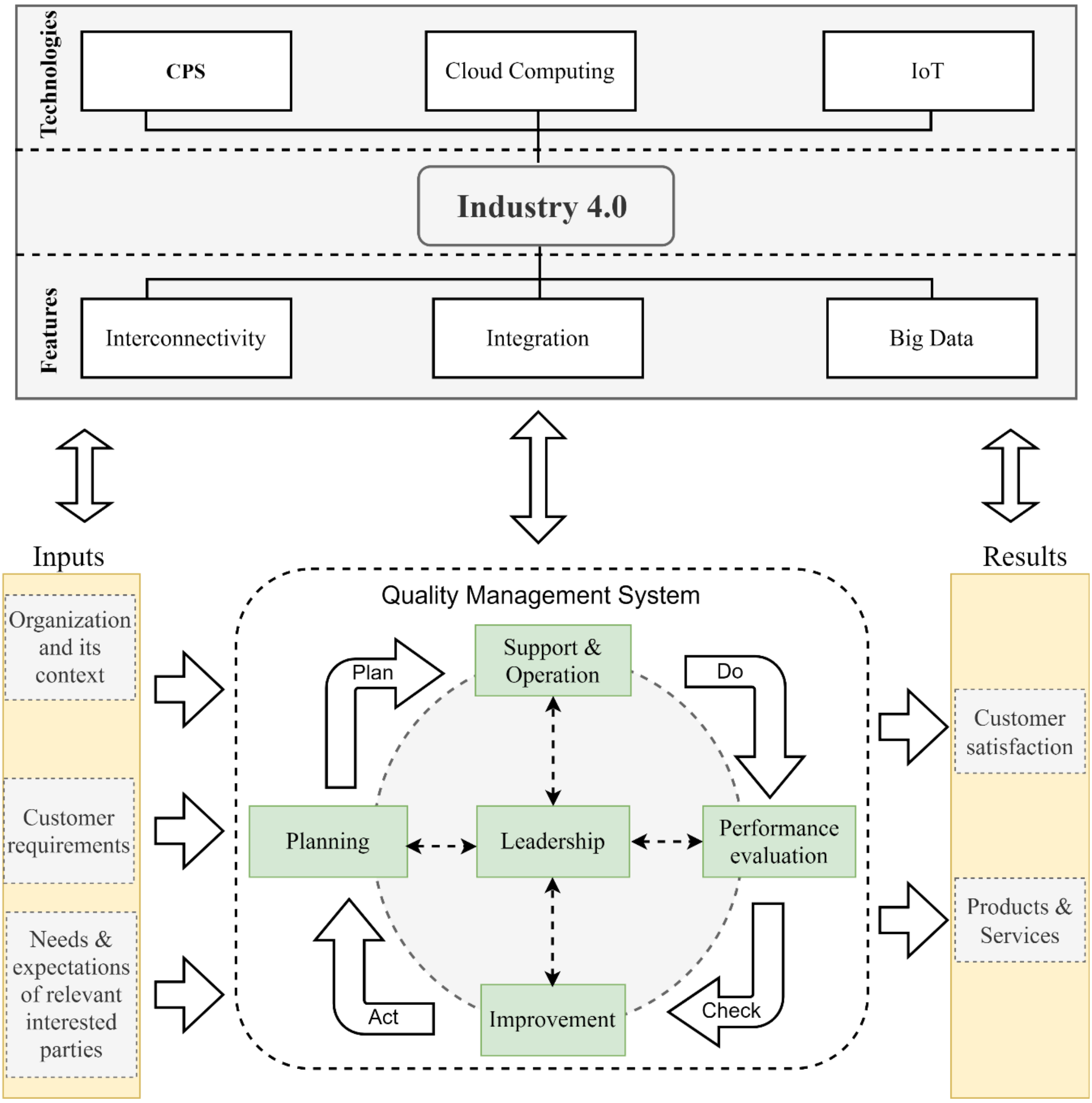


Fig 4.3. General QMS framework integrated with Industry 4.0 features and technologies (Upgraded from Abildgaard, 2018; ISO, 2015b)

4.4. Utilizing auto-machine learning to enhance FMEA

As discussed earlier, multiclass classification is used as an experimental method to develop a novel approach to enhance failure mode and effects analysis and the generation of RPN. This is done by developing four machine learning models using auto-machine learning. Failure mode and effects analysis is a technique that is used in the industry to identify possible failures that may occur and the effects of these failures on the system. Meanwhile, the risk priority number is a numeric value that is calculated by multiplying three associated parameters namely severity, occurrence and detectability. The value of risk priority number determines the next actions to be made.

A dataset that includes a one-year registry of 1532 failures with their description, severity, occurrence, and impact is used to develop four models to predict the values of severity, occurrence, and impact. In meanwhile, the resulted models are evaluated using 9.50%, 10.95%, 8.82%, and 9.29% of the dataset respectively. Evaluation results show that the proposed models have high accuracy whereas the average value of precision, recall, and F1 score are in the range of (86.6-93.2) %, (67.9-87.9) %, (0.892-0.765) respectively. The proposed work helps in carrying out FMEA in a more efficient way as compared to the conventional techniques.

Based on that, the aim of this research work is to examine a novel optimization approach applied to FMEA and RPN by classifying failures according to updated FMEA documents and generating the RPN automatically without human intervention. A successful FMEA is gained through optimized consistency, responsiveness, and accumulated experience. The suggested approach aims at solving the earlier-discussed FMEA weaknesses by two steps: first, reviewing and re-evaluating a dataset containing reported failures manually by experts to ensure accuracy. Secondly, conducting supervised automatic machine learning techniques on the updated data to develop four machine learning models that can be deployed to evaluate and classify newly reported failures automatically with minimum processing time and enhanced consistency.

As shown in Fig. 3.18 four machine learning models are developed, and a test sample is used for models' evaluation. The following sections discuss the evaluation and conclusion of the results.

4.4.1. Hyperparameters extraction

The auto machine learning platform suggested the most important input features in the machine learning models, hence, the hyperparameters of the models. All models shared the same training dataset and therefore, approximately the same hyperparameters have resulted.

As illustrated in Fig. 4.4., the most important hyperparameters are approximately the same for all models, given that for every input feature the importance is not exactly the same for every mode.

Moreover, the textual input features have the highest importance in the models' evaluation. Failure description, root cause description, damage code and text, and the correction action made are the most input features that have the highest impact on the models' accuracy. These fields are filed manually by the operator in the ERP system of the company, it was written in natural language, and therefore, natural language processing analysis by the AutoML platform is required.

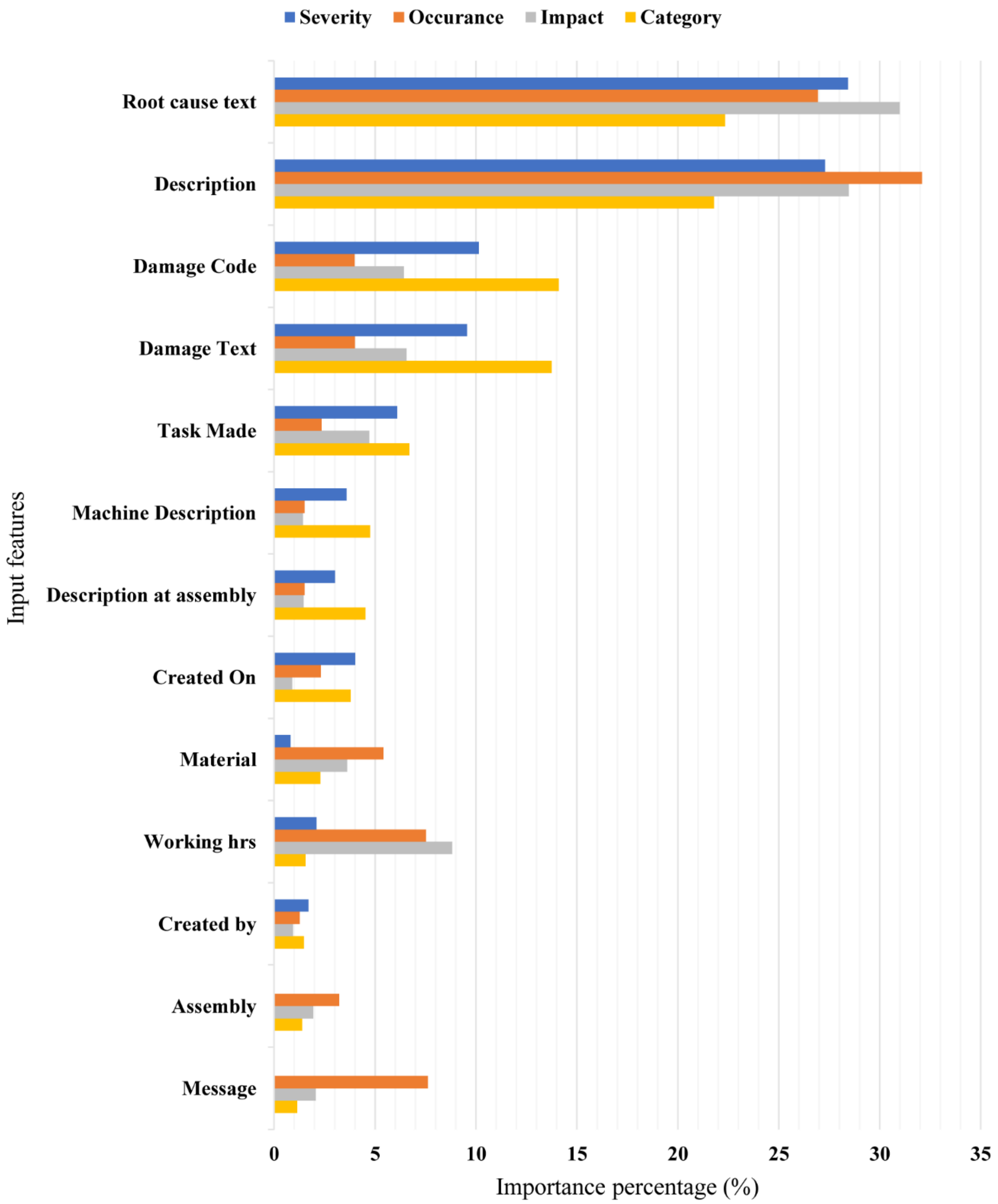


Fig. 4.4. Feature importance for all machine learning models

4.4.2. Evaluation of the results according to the proposed FMEA method

The resulted in trained models are evaluated according to evaluation metrics used in classification supervised machine learning techniques.

Table 4.2 summarizes the training evaluation results and accuracy metrics for four classification models of severity (M_s), occurrence (M_o), impact (M_i), and category (M_c). The evaluation sample was automatically truncated and tested by the AutoML platform. The evaluation metrics show relatively high-quality models, with different levels of precision for each model. The area under the precision-recall curve (AUC-PR) and the area under the receiver operating characteristic curve

(AUC-ROC) is close to 1, which indicates high-quality classification models.
Moreover, the models' precision rates which represent the correct predictions in the validate sample compared to the actual true values in the same sample are 93.2%, 87.6%, 89.9%, and 86.6% for M_s, M_o, M_i, and M_c respectively, which indicates that the models predicted correctly the classes of the validation sample for every model. The acceptance of such rates is accepted here given the size of the dataset and the quality of data. In a normal situation, the rates are evaluated based on the company's quality policy, the type of case being evaluated, and the identified quality objectives of the company.
Moreover, the true positive rates (recall) which represent the correct predictions of the validation sample compared to the total validation sample are 68.1%, 67.9%, 88.5%, and 76.9% for M_s, M_o, M_i, and M_c respectively. However, the F1 score values are 0.787, 0.765, 0.892, and 0.814 for M_s, M_o, M_i, and M_c respectively. Such values for the F1 score convey a balance between the precision and recall rates. For this problem, such values for precision, recall, and F1 score are acceptable and represent relatively high-quality machine learning models.
Table 4.2. Evaluation summary for the four models

Dataset targeted value	Validation Sample	Score threshold	Precision	TPR (Recall)	F1 score	AUC (PR)	AUC (ROC)
Severity (M_s)	141 test rows	0.5	93.2% (96/103)	68.1% (96/141)	0.787	0.895	0.970
Occurrence (M_o)	156 test rows	0.5	87.6% (106/121)	67.9% (106/156)	0.765	0.871	0.955
Impact (M_i)	131 test rows	0.5	89.9% (116/129)	88.5% (116/131)	0.892	0.954	0.973
Category (M_c)	134 test rows	0.5	86.6% (103/119)	76.9% (103/134)	0.814	0.877	0.972

The highest F1 score is recorded for M_i, where the precision and recall are very close to each other. 89.9% of all true values were truly predicted (precision), and 88.5% of the overall testing sample was truly predicted (recall). Given that in M_i, the full dataset is used for training, and the classification was only among the three classes (1, 2 or 3) while the training dataset for M_i contains 866, 511, 109 readings for every class from 1 to 3 respectively.

4.4.3. Models' evaluation according to confusion metrics

The evaluation metrics are not limited to the general metrics as in Table 4.2., detailed metrics are used in order to provide closer evaluation for the performance of the model. Every model is evaluated by applying the resulted models on the test set. As mentioned earlier, the test sets are approximately 10% of every dataset. Other useful metrics are discussed in detail as follows:
The confusion matrices in Tables 4.3 to 4.6 below show that the concentration of the true predictions is at the diagonal cells of all models. However, both models M_s and M_o show higher confusion for predicted labels against true labels, in contrast to M_i and M_c models where higher concentration is shown at the diagonal cells. This is highly connected with the data volume and will be improved when a larger volume of data is used for model upgrading. Moreover, Table 4.4 shows greater confusion in class 2 diagonal cells. The value 48% represents a shortcoming in predicting this class in the M_o model. An extended or an enhanced dataset could improve the

prediction of the model at this class and other classes in other tables.
However, predicting a higher value than the true one (negative true predictions in the confusion matrices) for the three models (M_s, M_o, and M_i) could be accepted, as higher prediction value for severity will increase the RPN value and therefore, the priority to resolve the failure is increased. However, this tolerance is not acceptable for M_c as it deals with a totally different interpretation, it describes the manufacturing process where the root cause of the failure is coming from. The model shouldn't predict a false manufacturing process instead of predicting a true one. In other words, a wrong prediction that a failure is caused by a process (X) is totally rejected if it is actually caused by another different process. However, such a disadvantage can be improved during the transition stage where the process of automatic claims evaluation is running in parallel with the manual traditional one so as to improve the next trained model after a larger dataset size is accumulated.

Table 4.3. Confusion matrix for the model of severity (M_s)

		Predicted labels						
	Class	1	2	3	4	5	6	7
True labels	1	95%	5%	-	-	-	-	-
	2	-	89%	7%	-	4%	-	-
	3	-	7%	60%	13%	13%	-	7%
	4	-	17%	3%	67%	3%	7%	3%
	5	-	20%	13%	-	60%	7%	-
	6	-	-	-	-	12%	88%	-
	7	-	-	22%	-	11%	-	67%

Table 4.4. Confusion matrix for the model of occurrence (M_o)

		Predicted labels					
	Class	1	2	3	4	5	6
True labels	1	81%	6%	3%	9%	-	-
	2	14%	48%	14%	10%	10%	5%
	3	-	7%	87%	4%	2%	-
	4	-	9%	9%	78%	4%	-
	5	-	-	13%	-	73%	13%
	6	-	-	5%	-	5%	90%

Table 4.5. Confusion matrix for the model of impact (M_i)

	Predicted labels			
	Class	1	2	3
True labels	1	97%	3%	-
	2	18%	80%	2%
	3	-	33%	67%

Table 4.6. Confusion matrix for the model of category prediction (M_c)

	Predicted labels								
	Class	A	B	C	D	E	F	G	H
True labels	A	95%	-	-	-	-	-	5%	-
	B	14%	86%	-	-	-	-	-	-
	C	-	-	71%	-	-	8%	13%	8%
	D	-	-	-	83%	-	-	17%	-
	E	-	-	-	-	86%	-	14%	-
	F	-	-	25%	-	-	63%	13%	-
	G	5%	10%	-	-	-	2%	83%	-
	H	-	-	-	-	-	-	-	100%

Labels' accuracy metrics for every model:

As shown in Tables 4.7 to 4.10, the accuracy metrics including F1 score, accuracy, precision, true positive rate (TPR), and false-positive rate (FPR) for every element of the RPN are presented. TPR represents the labels which are exactly or higher predicted compared to the true labels. In this case, the failure is given actual or higher priority which is generally acceptable. On the other hand, FPR represents under predicted values for true labels, which means that failure is underestimated. In conclusion, the data in the tables represent high accuracy for some labels and shortage for others. The accuracy is limited due to the quality of the training dataset and the size of the testing dataset. Table 4.7 suffers a shortage in labels 8, 9, and 10. The same for Table 4.8 (7, 8, 9, 10) and some labels in Table 4.10 this is because of the lack of data for the training dataset and therefore, these labels are skipped in this experiment. However, a larger dataset can solve such shortage and can improve the accuracy for labels where accuracy metrics are not of high value.

Table 4.7. Detailed evaluation metrics for the severity model (M_s)

Labels	Percentage of readings	F1 score	Accuracy	Precision	TPR (Recall)	FPR
Overall	100%	0.787		93.2%	68.1%	0.008
1	13.5%	0.973	99.3%	100.0%	94.7%	0.000
2	31.9%	0.884	92.9%	92.7%	84.4%	0.031
3	10.6%	0.545	92.9%	85.7%	40.0%	0.008
4	21.3%	0.667	89.4%	100.0%	50.0%	0.000
5	10.6%	0.692	94.3%	81.8%	60.0%	0.016
6	5.7%	0.857	98.6%	100.0%	75.0%	0.000
7	6.4%	0.571	95.7%	80.0%	44.4%	0.008
8	0	-	-	-	-	-
9	0	-	-	-	-	-
10	0	-	-	-	-	-

Table 4.8. Detailed evaluation metrics for the occurrence model (M_o)

Labels	Percentage of readings	F1 score	Accuracy	Precision	TPR (Recall)	FPR
Overall	100%	0.765		87.6%	67.9%	0.019
1	20.5%	0.881	95.5%	96.3%	81.3%	0.008
2	13.5%	0.545	90.4%	75.0%	42.9%	0.022
3	28.8%	0.769	88.5%	90.9%	66.7%	0.027
4	14.7%	0.750	93.6%	88.2%	65.2%	0.015
5	9.6%	0.593	92.9%	66.7%	53.3%	0.028
6	12.8%	0.900	97.4%	90.0%	90.0%	0.015
7	0	-	-	-	-	-
8	0	-	-	-	-	-
9	0	-	-	-	-	-
10	0	-	-	-	-	-

Table 4.9. Detailed evaluation metrics for the impact model (M_i)

Labels	Percentage of readings	F1 score	Accuracy	Precision	TPR (Recall)	FPR
Overall	100%	0.892		89.9%	88.5%	0.050
1	54.2%	0.932	92.4%	89.6%	97.2%	0.133
2	38.9%	0.854	89.3%	91.1%	80.4%	0.050
3	6.9%	0.750	96.9%	85.7%	66.7%	0.008

Table 4.10. Detailed evaluation metrics for the category model (M_c)

Labels	Percentage of readings	F1 score	Accuracy	Precision	TPR (Recall)	FPR
Overall	100%	0.814		86.6%	76.9%	0.017
Cutting	0%	-	-	-	-	-
Bending	0%	-	-	-	-	-
Welding	5.2%	0.833	98.5%	100.0%	71.4%	0.000
Painting	6%	0.533	94.8%	57.1%	50.0%	0.024
Assembly	31.3%	0.785	87.3%	83.8%	73.8%	0.065
Packaging	0%	-	-	-	-	-
Transportation	0%	-	-	-	-	-
Other	0%	-	-	-	-	-
Logistic cost	14.9%	0.952	98.5%	90.9%	100.0%	0.018
missing part	14.9%	0.905	97.0%	86.4%	95.0%	0.026
supplier failure	5.2%	0.857	98.5%	85.7%	85.7%	0.008
Cancelled	0%	-	-	-	-	-
General Damage	17.9	0.750	92.5%	93.8%	62.5%	0.009
Product Audit	4.5%	0.667	97.8%	100.0%	50.0%	0.000

Graphical representation of accuracy metrics:

The following charts Figures. 4.5 to 4.7 illustrate the AUC where true positive predictions are located under the curves for both precision and recall, given that the threshold value for this experiment is decided to be (0.5) such a presentation confirms the previous evaluation results which show high-quality models where most of the true positive predictions are located under the curves.

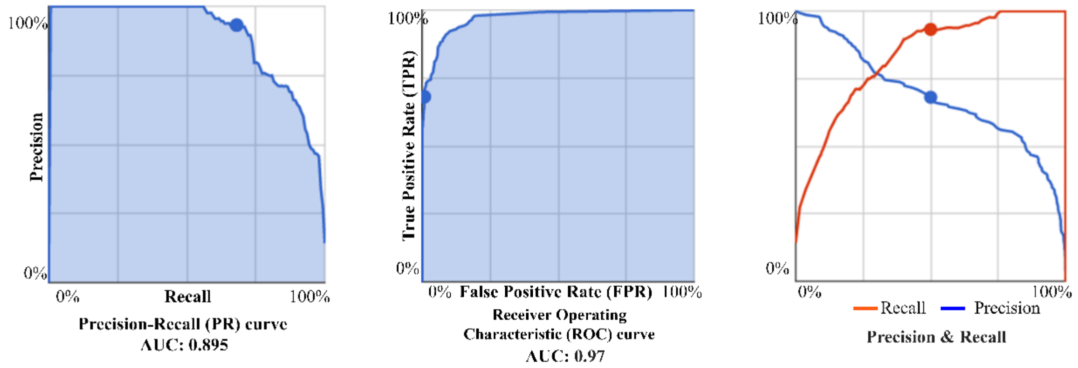


Fig. 4.5. Accuracy measures presentation of M_s

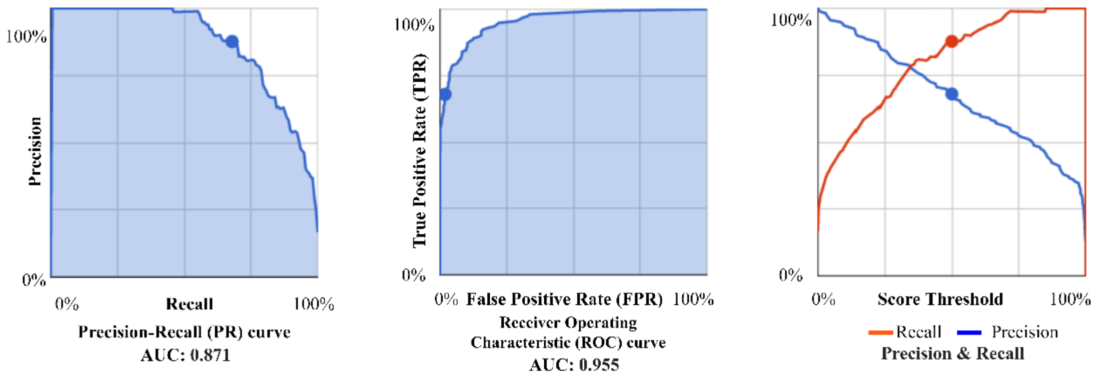


Fig. 4.6. Accuracy measures presentation of M_o

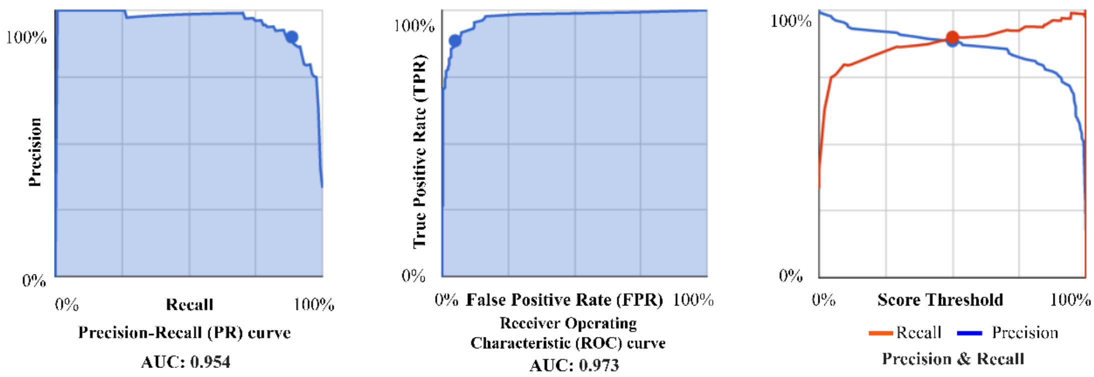
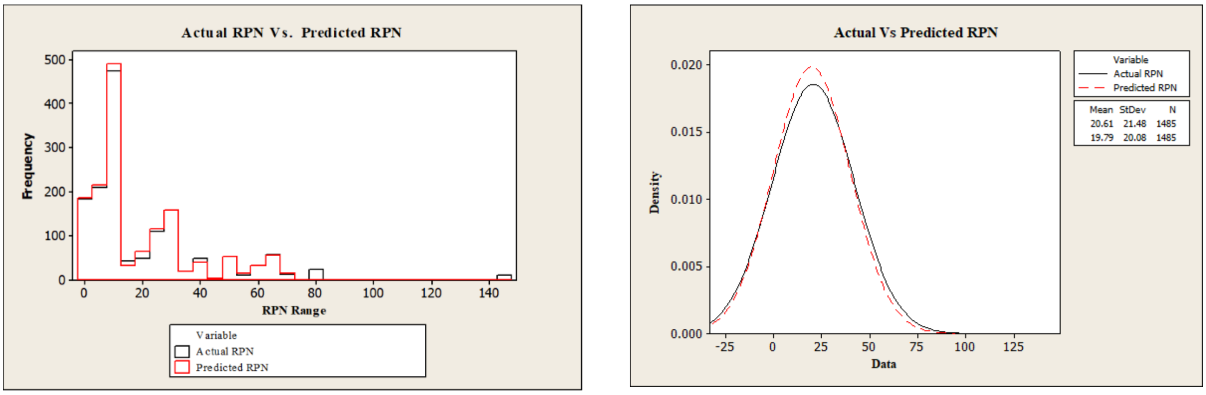


Fig. 4.7. Accuracy measures presentation of M_i

4.4.4. Evaluation of predicted RPN value against the original dataset RPN

Another approach to evaluate the developed models is to examine the RPN in the original dataset (actual RPN) against the RPN which is resulted from applying equation 3.1 to the three predicted elements, call it (predicted RPN). Fig. 4.8a compares the two RPN frequency histograms (Actual vs. Predicted) for the overall dataset. The histograms show a high overlapping of results between the two RPN values. In the meanwhile, Fig 4.8b represents the probability density function for both actual and predicted RPN values. The graph shows a very slight error magnitude between the two bell shapes, which also supports the hypothesis that the implemented approach is a high degree of conformity. Similarly, applying statistical accuracy measurements between actual and predicted values, resulted in a mean absolute error of 3.86 and a root-mean-squared error of 12.76 which both represent acceptable accuracy of predicted against actual.

However, the histogram in Fig 4.8a shows a shortage in predicting higher RPN values when the multiplication result is higher than 80 (the values larger than 140 in the histogram is a clear example). The reason behind this weakness is due to a lack of data at high classes for severity and occurrence in the training dataset. Such weakness can be resolved by providing a larger dataset for model training.



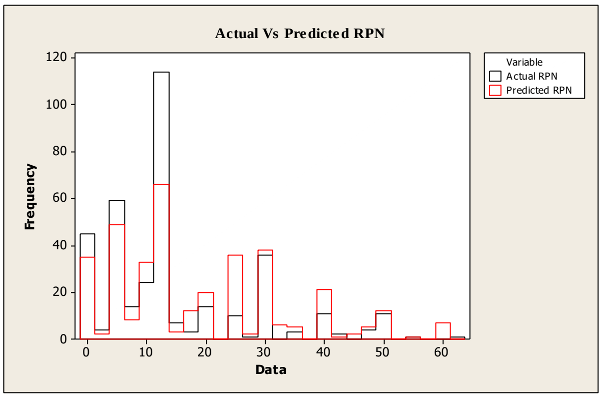
a. Frequency histogram

b. Probability density function

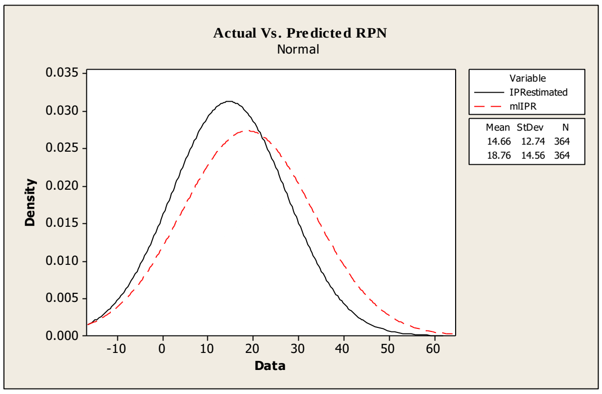
Fig. 4.8. Models evaluation by comparing actual Vs. predicted RPN values

4.4.5. Evaluate models using a new dataset

A new dataset consisting of 361 new claims, which have never been evaluated or used before for models training, is extracted from the company's ERP system. The new dataset is evaluated manually following the same procedure of the training dataset as in Fig. 3.Fig. 3.17. Where three of CLH experts evaluated the new dataset manually using the developed platform. After that, the same dataset is evaluated using the trained machine learning models. The predicted results are compared to the actual results, and accuracy metrics are developed. The confusion matrices are shown in Tables 4.11 to 4.14. Moreover, frequency histogram and probability density function diagrams are shown in Fig. 4.9a and b. However, although the confusion matrices are roughly validating the approach used here, the quantitative accuracy measures in the confusion matrices show a lower accuracy measures compared to the testing data which is used to evaluate the models as in section 4.4.3. Such a disadvantage has resulted from two reasons, first, the size and quality of the original dataset which is used in the training of the models, and the second has resulted from the quality of the new dataset itself and the details provided to applied machine learning models. However, it is important here to call back the main objective of the experimental approach used here, which is to provide evidence that applying machine learning technologies is efficient and effective to support quality management activities such as FMEA.



a. Frequency histogram



b. Probability density function

Fig. 4.9. Models evaluation by comparing actual vs. predicted RPN values

It worth mentioning here that in this experiment of new data evaluation, the time consumed for manual evaluation using the developed portal was measured and compared to the time consumed by applying the machine learning models to the same dataset. Compared to three hours of manual (human) evaluation, the machine learning models consumed approximately 15 minutes of computing power to predict the values of the RPN elements (severity, occurrence, and impact) in addition to categorizing the claim root cause.

Therefore, utilizing machine learning in quality management practices is cost-effective in terms of time consumed for evaluation, which is minimized here from three working hours to only 15 minutes by using the suggested solution, and the experiences needed to handle the evaluation process. In fact, the suggested system could utilize the experiences needed for other quality-related tasks, as the suggested solution utilized the quality engineers cumulative experience by learning from the previously evaluated claims over one year long. Moreover, the suggested solution minimizes the cost of quality by minimizing the reaction time in response to claims coming from the field regarding quality issues. Such prompt response minimizes the chance of producing more defective products and therefore, minimizes the cost of rework and logistics-related costs.

Table 4.11. Confusion matrix for the model of severity (M_s)

		Predicted labels						
	Class	1	2	3	4	5	6	7
True labels	1	68%	14%	2%	-	16%	-	-
	2	4%	84%	8%	4%	-	-	-
	3	-	11%	53%	25%	7%	4%	-
	4	-	16%	16%	32%	22%	14%	-
	5	2%	9%	-	18%	65%	4%	2%
	6	10%	-	-	-	10%	80%	-
	7	-	-	10%	-	20%	25%	45%

Table 4.12. Confusion matrix for the model of occurrence (M_o)

	Predicted labels						
	Class	1	2	3	4	5	6
True labels	1	61%	4%	14%	4%	17%	0%
	2	1%	36%	38%	11%	14%	0%
	3	6%	8%	58%	8%	16%	4%
	4	0%	3%	24%	61%	12%	0%
	5	0%	5%	21%	21%	51%	2%
	6	0%	8%	0%	3%	27%	62%

Table 4.13. Confusion matrix for the model of impact (M_i)

	Predicted labels			
	Class	1	2	3
True labels	1	65%	33%	2%
	2	16%	82%	2%
	3	33%	50%	17%

Table 4.14. Confusion matrix for the model of category prediction (M_c)

	Predicted labels								
	Class	A	B	C	D	E	F	G	H
True labels	A	66%	0%	3%	0%	0%	6%	24%	1%
	B	6%	82%	6%	0%	0%	0%	6%	0%
	C	21%	0%	77%	2%	0%	0%	0%	0%
	D	11%	11%	6%	72%	0%	0%	0%	0%
	E	17%	15%	3%	0%	65%	0%	0%	0%
	F	0%	33%	0%	0%	0%	67%	0%	0%
	G	30%	0%	0%	0%	0%	0%	70%	0%
	H	10%	13%	9%	5%	3%	0%	6%	54%

4.4.6. Results improvement and enhancing models' accuracy

Although the general evaluation results of the experimental approach applied here showing acceptable accuracy for the models, which concludes that the suggested approach is efficient and applicable for larger scale in the same application, the accuracy measures and the experimental approach suffered some shortages which can be avoided in a real application in future works.

For instance, enhanced accuracy can be reached by enlarging the training dataset and this could be fulfilled when more data is accumulated over time. Given that the dataset used for models' training in this activity contained 1532 claims for a single product in one year only. A larger dataset which is extended vertically and horizontally can enhance the accuracy of the predictions. Vertically by providing a larger number of readings for more new failure claims (rows), and horizontally by adding more information to every single claim that includes more details about the failure (columns). Moreover, improvement can be achieved by reviewing the predictions of the models after a testing period, where an expert engineer can compare both the proposed AutoML approach with the traditional approach and conclude an enhanced and extended dataset that can be used for models retraining. Another suggestion to improve the models is to minimize the scale of classification for severity and occurrence from 1-10 to become a 1-5 scale, such change will improve the model precision and accuracy. Hint, the accuracy for M_i is the highest among the other models.

Since the results of the proposed method are showing acceptable accuracy, given the dataset volume and the method used, the models can be deployed at the partner company. The advantage of the proposed approach as compared to the traditional one is that it replaces the human intervention in the process and automates the decision-making process. In the traditional approach, once a claim is received from the mother company in Germany, a quality engineer in the quality management office in Hungary reviews the claim, decides the failure mode type, and then assigns values to the three elements to calculate the RPN. Based on this judgment, further actions are decided. These actions can be by transferring the issue to critical issue resolution by using strategies such as the eight disciplines for problem-solving methodology (8D) if the RPN is above 160 points, or by updating the quality checklists at the production shop floor, or it could be both.

However, this human intervention may imply some implementation error as it depends on the evaluator's experience. For example, assume a claim was evaluated by a quality engineer to be 160 points, while another engineer may underestimate the claim by ranking it to be 140 points based on his experience and memory. In the first situation, the engineer will transferee the claim to a more sophisticated process (8D strategy) which entails using more resources by forming a team to follow up and resolving the issue. On the other hand, the claim is only highlighted to the production management (the second case). This is because such a process depends mainly on individual judgment and experience of the staff members who may give inaccurate estimation. Meanwhile, if such a process is done by a machine learning supported system that predicts decisions based on the accumulated leaning process, such uncertainty in decision making can be avoided. Thus, the proposed solution replaces this human intervention and confusion with a machine learning algorithm that evaluates claims based on the accumulated, none individualized experience and avoids the uncertainty in the experience of quality engineers.

Moreover, the proposed approach can automatically analyze the new claims and construct correlations between incidents and therefore get a better ability for future prediction. Such process saves time, efforts, and improves responsiveness to failures either by instantly alarming the quality management team to serious issues or by automatically updating the dynamic quality checklists in the production shop floor by notifying labor and production staff of this issue in a real-time manner. From a business perspective, the proposed solution can be operated at any time and will provide higher efficiency and effectiveness. Finally, it is also essential to keep updating and maintaining the models by conducting periodical review sessions for the predicted RPN values and correct them when needed. Retraining the model using a larger volume of data will accumulate the model experience and improve model accuracy.

4.5. New scientific results

In this section the unique scientific results investigated in this study are shown as follows:

1. Identifying Total Quality Management - Industry 4.0 interaction interface

Based on the intensive literature analysis on TQM practices and Industry 4.0 features and technologies, a clear interface describing the relationship between TQM and Industry 4.0 is identified. Hence, the main goal of this study is fulfilled; to define the impact of Industry 4.0 on TQM common practices. In this study, TQM principles as defined by the ISO 9000:2015 standards family are discussed from the perspective that one or more of the Industry 4.0 features and technologies are anticipated to support the successful implementation and optimization of one or more of the TQM principles.

The research work concluded that Industry 4.0 is a key enabler toward the successful implementation of total quality management practices and the proposed interface is illustrated clearly in Fig. 4.1. The novelty of this result is that it has never been discussed precisely and comprehensively before, although it was discussed on an individualized approach.

2. Identified sets of qualitative and quantitative measures

Along with the identification of the Industry 4.0 - QM interface, it is important to measure and assess the impact of Industry 4.0 on every single item of the TQM principles. Therefore, this study successfully developed the relevant set of performance indicators for each one of the seven TQM principles, quality control, and quality assurance practices, and suggested the performance indicators along with their respective measurement methods (see Table 4.1).

For example, customer focus is one of the TQM principles as defined by ISO 9000:2015 principles. As a result of utilizing Industry 4.0 features and technologies, enhanced customer satisfaction and loyalty is expected. Such satisfaction is resulted due to the enhanced response time, improved communication, and the ability to afford individualized and customized products. Consequently, the enhancement that occurred to customer satisfaction due to the application of Industry 4.0 must be measured and evaluated. These measures are identified in this research work. Moreover, the research work suggested utilizing Industry 4.0 technologies like Big-Data, ERP and CRM systems to gather data that could be used for impact evaluation. Such data is customer retention, sales growth, market share, and social media comments and insights.

This data could be gathered and analyzed using machine learning methods and natural language processing where natural language can be rendered on dashboards in the form of useful knowledge for the company leadership.

3. Suggesting an updated quality management system (QMS)-Industry 4.0 integrated model

In this result, a traditional QMS model is adopted (as in Fig. 3.4) as a basic QMS that can be upgraded to become an Industry 4.0 – QM integrated system. The proposed new model is illustrated in Fig. 4.3 where the major functions of the QMS are integrated with Industry 4.0 features and technologies.

Customers are integrated into the quality management system using the Industry 4.0 features and technologies. Therefore, their requirements and feedback along with their satisfaction measures are communicated to the QMS plan-do-check-act cycle very efficiently. Such information is transformed into useful knowledge and transmitted to the management which can utilize Industry 4.0 technologies such as CPS to re-plan and optimize the resources management and maintain the continuous improvement strategy. An example of a specific integration of Industry 4.0 features and technologies with the production value chain is illustrated in Fig. 4.2.

4. Suggesting a novel approach to enhance FEMA and the generation of RPN

In this novel approach, a cloud solution namely auto-machine learning (Google AutoML) is used to automate one of the quality management methods which is failure mode and effects analysis. The development of such an analysis was conducted in partnership with an agricultural machinery manufacturing company located in Hungary. In previous scenarios, quality issues were reported from the mother company in German to the company in Hungary. An expert engineer was responsible to review and evaluate every one of these claims. According to the evaluation result and the value of RPN, further actions are decided. Such a process was costly from many perspectives; the time and effort consumed, cost of quality, and above all, its human-based nature.

The adopted novel methodology is developed based on the accumulated previous decisions extracted from archived data. AutoML is used to develop an automatic cloud service where the flow of claims is evaluated in the cloud and the final evaluation result for RPN is processed instantly, suggesting a recommendation for quality engineers on how to handle important claims.

The resulted models minimized the time needed to process a set of claims containing 361 claims from three working hours to 15 computing minutes. Consequently, the results are processed automatically on the cloud without consuming any other resources on the location of the company. Therefore, the resulted approach is cost-effective and efficient in terms of accuracy. Similarly, such a solution can be applied to other fields such as analyzing customers' feedback. It is very common to deploy machine learning models to suggest solutions or operating instructions to frequent complaints by customers.

5. Provide an efficient web-based platform to automate FMEA process

During this research work, a web-based platform was developed to manually evaluate the claims needed for data training. Later, after developing the machine learning models, the models were integrated into the platform, so the platform is used as an interface to evaluate new claims. This process is illustrated in Fig. 3.20. As a result of such integration, the platform displays the evaluation results as recommendations to quality engineers. Moreover, the platform is extended to conclude the top 10 quality issues instantly and list them on a separate screen according to their manufacturing process. Therefore, top issues per the manufacturing process are displayed at the manufacturing shop floor, which will directly transfer the claims to their respective sources.

5. CONCLUSIONS AND SUGGESTIONS

It is obvious that Industry 4.0 has a great potential to enhance total quality management practices. TQM practices are backed by capabilities offered by Industry 4.0 features and technologies. The following are the main contribution offered by Industry 4.0 to such enhancement, as concluded from this research work:

- Developing real-time monitoring and efficient failure prediction systems.
- Application of in-process intelligent quality assurance systems which enabled inspection for the entire production.
- Data analysis and visualization of information that facilitated factual decision making.
- Enhanced integration of the production systems, from suppliers to the end customer, which minimized product lead time, increased responsiveness, and improved customer satisfaction.
- Optimized lean production systems, and the ability to produce customized products for different customers' demands.
- Optimizing supply chain and logistics management strategies.
- Provided bases for a successful implementation of TQM practices.
- Minimizing the cost of quality due to early defect detection (quality control) and early elimination of defects' causes (quality assurance).
- Reliable, smart, dynamic planning techniques due to rich decision supporting systems and visual information provided by ERP, Big-Data, and CPS.

All the above-mentioned implications of Industry 4.0 on production systems influenced the quality management strategies and obtained new methodologies for quality control, quality assurance, and total quality management. However, future research could contribute more to find new implications and examine the impact of Industry 4.0 in further quantitative methods.

Industry 4.0 provided a stone rock support for a successful implementation of TQM principles. This research work highlighted the zone where TQM can benefit from Industry 4.0 features. A wider perspective as suggested by this research work to integrate Industry 4.0 features with TQM practices where Interconnectivity, Integration, and Big-Data can enhance the implementation of quality management practices.

This research work matched the possibilities offered by Industry 4.0 to support the implementation of TQM from a theoretical and experimental approach. An industrial partnership is made with a leading agricultural machinery manufacturing company in Hungary. After two years of cooperation, this research work successfully implemented a novel approach to improve the FMEA process by using AutoML method.

The suggested application of Industry 4.0 features and technologies such as cloud computing, machine learning, and integration, improved the performance of a single quality management method namely FMEA. Such an application can be extended to other quality management methods and could be implemented to cover other products and processes.

The main goal of this research work is to discuss TQM in the context of Industry 4.0 and to provide evidence from real life on the proposed model.

6. SUMMARY

This research work is conducted through two approaches, theoretical and experimental. In the theoretical approach, total quality management major practices as in ISO 9000:2015 standards were investigated in the context of Industry 4.0 technologies and features. An intensive literature review is made to define the interface where TQM practices could be served by the features and technologies of Industry 4.0. Afterward, an upgraded Industry 4.0 based QMS is suggested, where all tasks and responsibility of a QMS is linked to Industry 4.0 features and technologies. Accordingly, as the link between Industry 4.0 and TQM/QMS is established, there is a need to evaluate the impact of such a link. This study suggested a set of indicators along with its respective measurement tools by which the performance of an Industry 4.0- QMS based system can be measured and evaluated.

On the other hand, such a model must be examined to provide experimental evidence that Industry 4.0 technologies can support TQM methods. Here comes the experimental approach of this study; auto-machine learning was utilized to optimize FMEA handling by automatically identifying the failure mode, obtain its RPN and identify the manufacturing process related to the root cause of the issue. Three multiclass-classification machine learning models were developed to predict values for the RPN three elements namely severity, occurrence, and impact. A fourth multiclass-classification model was developed to classify failures to their root cause process. The models' evaluation indicated relatively high accuracy models that can be deployed and integrated to enhance the company's ERP system.

One of the features of the selected AutoML platform is its simple integration through the API, which is offered on the cloud. Such technology performs efficiently for large applications at the macro level of the factory. Utilizing such a solution enhanced the capabilities of the quality management team to handle any volume of claims data under high flow velocity. Such a solution allowed the quality team to focus on other strategic issues and enhanced the team's performance and results.

The benefits of such technology do not end by this, but also could be furtherly extended to link claims and defects to the relevant manufacturing machine and operator. Once a claim is reported to the quality management it will be processed by the deployed model and instantly will be communicated to the relevant operators or managers and deeper to the shop floor in the factory.

In conclusion, this study supported the theoretical approach with the experimental one. In this experiment, one effective Industry 4.0 tool is used which is machine learning, executed on the cloud, which is Google cloud AutoML platform, to automate a single TQM method which is failure mode and effects analysis (FMEA) and its respective evaluation metric risk priority number (RPN). This experiment is conducted in partnership with an industrial partner from the agricultural machinery industry and is implemented in cooperation with the quality management office at the company.

7. ÖSSZEFOGLALÁS (SUMMARY IN HUNGARIAN)

Az értekezést megalapozó kutatómunka elméleti és kísérleti megközelítésben folyt. Elméleti megközelítésben a teljes körű minőségmenedzsment (TQM) gyakorlata és az Ipar 4.0 jellemzői közötti lehetséges kapcsolódások kerültek feltárásra. Széles körű szakirodalmi áttekintéssel kerültek meghatározásra azok a kapcsolódási pontok, illetve felületek, amelyeken a TQM és az Ipar 4.0 a gyakorlatban segíthetik egymást. Olyan továbbfejlesztett minőségmenedzsment rendszer (QMS) került kiépítésre, melynek elemei kapcsolódnak az Ipar 4.0 funkcióihoz és eszközeihez.

A kutatások eredményeként modell-szintű mérési módszertan és mutatórendszer került kidolgozásra, amely alkalmazásával mérhető és értékelhető a QMS alapú Ipar 4.0-rendszer teljesítménye. Mindezek igazolására üzemi keretek között kísérletek, vizsgálatok kerültek elvégzésre.

A kutatás kísérleti fázisában az automatikus gépi tanulást (AutoML) a hibamód- és hatás-elemzés (FMEA) optimálására használtuk. Automatikus azonosításra kerültek a hiba-okok, a kockázati prioritási szám (RPN) bevezetésével és a hiba-okhoz tartozó gyártási folyamat megjelölésével. Három többosztályos besorolású gépi tanulási modellek került kifejlesztésre az RPN három összetevői – súlyosság, előfordulási gyakoriság és hatás – értékeinek előrejelzésére. A hibáknak a gyökér-ok szerinti besorolásához egy negyedik modell is kifejlesztésre került.

A modellek értékelése viszonylag nagy pontosságot igazolt. A kifejlesztett modellek telepíthetők és integrálhatók a vizsgált vállalat informatikai rendszeréhez az erőforrás-tervező (ERP) rendszer javítása érdekében. A kiválasztott AutoML platform egyik jellemzője az egyszerű integráció az alkalmazásprogramozási felületen (API-n)) keresztül. amely a felhőből érhető el. A kidolgozott megoldás javítja és bővíti a minőségmenedzsment-csapat munkáját a jogcím-adatok nagy áramlási sebesség mellett történő kezelésében. Ennek révén a csapat teljesítménye fokozható, illetve jut idő más, fontos feladatok elvégzésére is.

A javasolt megoldás előnyei ezzel nem érnek véget. Mód van az észlelt hibák adott berendezéshez, illetve dolgozóhoz való hozzárendelésre is. Amint egy hibajelzés érkezik a minőségügyi csapathoz, azt a telepített modell feldolgozza, és azonnal jelzi az érintett dolgozónak, illetve az üzem meghatározott vezetőinek.

Összegezve: a kutatómunka eredményeként sikerült az elméleti megközelítést kísérletekkel, próbaüzemben a gyakorlatban igazolni. Az Ipar 4.0 eszköztárból átvett gépi tanulás a Google Cloud AutoML platformon automatizált módon végzi el a TQM egyik elemének az FMEA-nak és a hozzá tartozó RPN-nek a meghatározását és ennek alapján a reklamált hibák besorolását.

A kidolgozott modell-rendszer és eljárásrend tesztelése ipari együttműködésben valósult meg.

8. APPENDICES

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A2. Publications related to the thesis

Refereed papers in foreign languages:

1. **Sader S.**, Husti, I., Daróczi, M. (2017). Suggested indicators to measure the impact of Industry 4.0 on total quality management. International scientific journal: Industry 4.0. Vol. 2 No. 6, pp. 298–301. ISSN (Print) 2535-0153. ISSN (Online) 2535-0161, https://stumejournals.com/journals/i4/2017/6/298/pdf
2. **Sader S.**, Husti, I., Daroczi, M. (2019). Quality management practices in the era of Industry 4.0. Zeszyty Naukowe Politechniki Częstochowskiej Zarządzanie, Vol. 35, No. 1, pp. 117-126. ISSN 2083-1560, https://doi.org/10.17512/znpcz.2019.3.10
3. **Sader, S.**, Husti, I., Daróczi, M. (2019). Industry 4.0 as a key enabler toward successful implementation of total quality management practices. Periodica polytechnica social and management sciences, Vol. 27 No. 2, pp. 131-140. https://doi.org/10.3311/PPso.12675 (Scopus: Q2)
4. **Sader S.**, Husti, I., Daróczi, M. (2020). Enhancing failure mode and effects analysis using auto-machine learning: A case study of the agricultural machinery industry. Processes, 8(2), p. 1-16. https://doi.org/10.3390/pr8020224 (IF: 1.963*, Scopus: Q2)
5. **Sader S.**, Husti, I., Daróczi, M. (2020). Introducing “Quality 4.0”: A survey for definitions, features, technologies, applications, challenges, and future research areas. Total Quality Management & Business Excellence. (Under review, submitted: 04. 01. 2020)

Refereed papers in Hungarian language:

6. Husti I., Daróczi M., **Sader S.** (2017): A minőségügy új kihívásai az „Ipar 4.0” tükrében, Magyar Minőség Társaság, 2017. nov.Vol. XXVI, No. 11, 23-41 o. ISSN 1789-5510 (Online). ISSN 1789-5502

International conference proceedings:

7. **Sader S.**, Husti I., Daróczi M. (2018): Integrating Industry 4.0 features with quality management practices, Proceedings of the 8th International conference on management 2018, "Leadership, Innovativeness and Entrepreneurship in a Sustainable Economy", Częstochowa University of Technology, Poland, Faculty of Management, June 7-8. 2018, pp. 533-538. ISBN 978-83-65951-28-1
8. **Sader S.**, Husti I., Daróczi M. (2017): Total quality management in the context of Industry 4.0, Proceedings of Synergy international conferences - Engineering, agriculture and green industry innovation, Gödöllő, Hungary, October 16-19. 2017, pp. 7-16. ISBN 978-963-269-680-5.
9. **Sader S.**, Husti I., Daróczi M. (2017): Suggested indicators to measure the impact of Industry 4.0 on total quality management, International scientific conference (Industry 4.0), Borovets, Bulgaria, December 13-16, 2017, pp. 230-233. ISSN (Print): 2535-0153. ISSN (Online): 2535-0161.

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