Quality 4.0 in Digital Manufacturing – Example of Good Practice

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ABSTRACT

Purpose: The ever-evolving market dynamics and the trend toward increased product individualization demand a high degree of adaptability in production management. This calls for novel approaches, such as Industry 4.0 (I4.0), which integrates the Quality 4.0 (Q4.0) model as well.

Methodology/Approach: I4.0 builds upon the foundation of digital manufacturing and entails three key dimensions: (i) The employment of advanced digital technologies to enable digital production, (ii) The development of smart products, which incorporate novel production methods and innovative features, and, (iii) The adoption of an intelligent supply chain, designed to facilitate the procurement of raw materials and the delivery of finished goods. In our research studies, we focus specifically on the first and third approaches.

Findings: A bilateral flow of information in collaborative manufacturing is facilitated through digital platforms that span the entirety of the production process, from the inception of cutting-edge product designs to the final delivery to end-customers, integrating quality management (QM) as well.

Research Limitation/Implication: The current study outlines a QM model developed for a digital factory in Serbia, utilizing the Q4.0 model, with particular emphasis on the workshop section, integrated within the Enterprise Resource Planning/Manufacturing Execution Systems module.

Originality/Value of paper: The manuscript serves as a notable illustration of best practices for digital manufacturing, and the implementation of a digital QM model within the metalworking industry.

Category: Research paper

Keywords: digital manufacturing; enterprise resource planning; manufacturing execution systems
1 INTRODUCTION

Presently, Industry 4.0 (I4.0) and its quintessential component, Quality 4.0 (Q4.0), have several definitions by various scholars (Javaid et al., 2021; Broday, 2022; Souza et al, 2022; Sader, Husti and Darócz, 2019). However, I4.0 epitomizes a collaborative manufacturing system that is fully networked through cyber-physical system/cloud manufacturing (CPS/CM), operating in real-time, which distinguishes it from prior manufacturing models (Rauch, 2020). The Q4.0 model encapsulates the new and improved features arising from the I4.0 model, functioning simultaneously online, and primarily pertains to the factory as a manufacturing organization in our example.

MES (Manufacturing Execution System) acts as the fundamental framework for online management in accordance with the I4.0 model for real-time manufacturing activities in the workshop (WS), encompassing quality management (QM) procedures. Furthermore, it comprehensively integrates all digital product models, configuring the backbone of engineering (Computer Aided Design (CAD)/Computer Aided Process Planning (CAPP)/Computer Aided Manufacturing (CAM)/Computer Aided Inspection (CAI)), and business (Customer Relationship Management (CRM)/Supply Chain Management (SCM)/ERP) planning functions, thereby facilitating the growth of manufacturing control in workshop (MES) (Rauch, 2020). The Q4.0 model presented in this manuscript penetrates the aforementioned entities of engineering and business planning, meticulously fulfilling ISO 9001:2015, IATF 16949:2016, as well as the HACCP model’s stipulations.

This manuscript comprises three distinct sections. Firstly, an overview of global research on Q4.0 in the I4.0 context, focusing on various aspects. Secondly, a digital model of the organization is presented with practical case studies exhibiting Q4.0 components. Lastly, the paper culminates with conclusions and recommendations for future research.

The objective of this manuscript is to demonstrate the developmental trajectory and practical implementation of the Q4.0 model in a manufacturing enterprise through exemplary instances of effective digital manufacturing practices, upon which the edifice of the I4.0 model is based.

2 QUALITY IN MANUFACTURING AS CONTEXT OF INDUSTRY 4.0 – LITERATURE REVIEW

Upon closer examination of the I4.0 model and its key constituents, QM forms an integral component that can be evaluated from six distinct perspectives: Firstly, the formulation of effective digitization strategies at either the national or organizational level (in the form of good practices) to serve as the foundation for I4.0 and concurrently Q4.0. Secondly, the digitization of an establishment with emphasis on quality as a function. Thirdly, the implementation of established QM models such as ISO 9001 and Total Quality Management (TQM) within the
I4.0 framework. Fourthly, the application of quality engineering techniques like Six Sigma and Lean within the I4.0 structure. Fifthly, modern definitions of Q4.0 and lastly, exemplary case studies that illustrate best practices of Q4.0 in the industry.

2.1 Industry 4.0 and Digital Manufacturing

In present times, the notion of I4.0 has transformed into a global enterprise, as evident from the adoption of national programs by 46 of the world’s most industrially advanced countries for its implementation within the realms of industry and economy (Butt, 2022; Majstorovic and Mitrovic, 2019). Digital manufacturing serves as a critical element for the successful execution of the I4.0 model, culminating in the creation of sustainable digital ecosystems and smart manufacturing (SM), as depicted in Tab. 1.

Table 1 – Overview of the Realities of Industry 4.0 and Digital Manufacturing

<table>
<thead>
<tr>
<th>Main issue</th>
<th>Source</th>
<th>Main messages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strategies and roadmaps for the development of the national I4.0 Project.</td>
<td>Butt (2022); Majstorovic and Mitrovic (2019)</td>
<td>Digital manufacturing is a key element for the application of the I4.0 model.</td>
</tr>
<tr>
<td>A model for evaluating QM with eleven dimensions in an organization.</td>
<td>Zulqarnain, Wasif and Iqbal (2022)</td>
<td>The digital manufacturing model and Q4.0 are being integrated.</td>
</tr>
<tr>
<td>AI/ML in support of Q4.0 for SMEs.</td>
<td>Huang, Shahzadi and Khan (2022)</td>
<td>Application of one element of I4.0 in the digital manufacturing model for Q4.0.</td>
</tr>
<tr>
<td>I4.0 and Q4.0 as technologically driven innovations in application.</td>
<td>Rauch (2020)</td>
<td>The next level of these models in application will be data-driven innovation (BDA, AI/ML).</td>
</tr>
<tr>
<td>PMI. Driven Dimensional Quality Lifecycle Management.</td>
<td>Fang et al. (2016)</td>
<td>Digital Q4.0 as a subsystem of PMI.</td>
</tr>
</tbody>
</table>

Notes: QM – quality management; AI/ML – Artificial intelligence/Machine Learning; SMEs – Small and medium-sized enterprises; I4.0 – Industry 4.0; Q4.0 – Quality 4.0; PMI – Product and Manufacturing Information; BDA – Big Data Analytics.

Organizations engaged in digitization procedures evaluate and adapt established QM models for integration into the Q4.0 model. With a view towards this, eleven distinct dimensions of the Q4.0 model have been defined, the evaluation of which supplies guiding principles for the successful execution of this project within an organization (Zulqarnain, Wasif and Iqbal, 2022).

Incorporating AI/ML (Artificial intelligence/Machine Learning) as a fundamental facet of I4.0 to formulate the Q4.0 model represents a promising pathway for small and medium-sized enterprises (Huang, Shahzadi and Khan, 2022). In this vein, this approach is particularly instrumental in leveraging Big Data Analytics (BDA) to facilitate comprehensive analyses of the circular economy model.
Today’s level of application of the I4.0 model means the application of technologically driven innovations, and more and more is moving towards the next level of this model, which is based on data-driven innovation (Rauch, 2020). This means that we will move from digital production to the same production that will be self-optimizing.

As part of the I4.0 model, conformity quality is managed according to the concept of PMI (Product and Manufacturing Information), Driven Dimensional Quality Lifecycle Management (Fang et al., 2016). This means that Q4.0 is defined as a digital subsystem of digital production, as a framework for smart production.

We can conclude that in this area we have two approaches to the Q4.0 model: (i) it is developed in the context of the overall I4.0 model, with all its constituent elements, or (ii) some elements of I4.0 are, depending on the needs of the organization, “build” into its Q4.0 model.

Our research, which constitutes the second part of this paper, is founded upon the aforementioned initial approach (Majstorovic et al., 2021). Furthermore, the very foundation of our research resides on the fundamental presumption that digital manufacturing stands as the cornerstone of I4.0.

### 2.2 Digitization of Organization and Quality

Today’s trends of personalized production in large series, require specific ERP/MES (Enterprise Resource Planning/Manufacturing Execution Systems module) models for each work order (WO) separately, where digitalization in these cases helps tremendously, and QM is an integrated part of this process (Filz et al, 2016) (see Tab. 2). Artificial intelligence/Machine Learning (AI/ML) is used to define the product inspection strategy, as part of the overall data-driven concept analysis of product property propagation, which enables digitization.

#### Table 2 – Overview of Quality Digitization Models

<table>
<thead>
<tr>
<th>Main issue</th>
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<tbody>
<tr>
<td>And 4.0 as a disruptive technology.</td>
<td>Kumar, Ganesh and Rajendran (2022)</td>
<td>Q4.0 as a technological dimension of quality (MES).</td>
</tr>
<tr>
<td>Digitization of the TQM model, with the support of top management.</td>
<td>Maganga and Taifa (2023)</td>
<td>Q4.0: BDA and MES.</td>
</tr>
<tr>
<td>Professional competencies of employees for promotions and teamwork.</td>
<td>Martin, Dang and Gremyr (2023)</td>
<td>New models of education for Q4.0.</td>
</tr>
</tbody>
</table>
Q4.0 as an integration of strategic, cultural and technological issues. Küpper et al. (2019) Q4.0 as a model for working in real time.

The elements of I4.0 essential for the development of the Q4.0 model are: BDA, AI/ML horizontal and vertical automation. Sony, Antony and Douglas (2020) Quality elements for Q4.0 are: strategy, leadership, training and organizational culture.


TQM as infrastructure Q4.0. Villegas Forero and Sisodia (2020) Digitization of quality as TQM4.0.

Digital transformation is the basic framework for building I4.0, as well as Q4.0. Vial (2019) Digital transformation is an innovative process.

Notes: I4.0 – Industry 4.0; Q4.0 – Quality 4.0; BDA – Big Data Analytics; AI/ML – Artificial intelligence/Machine Learning; TQM – Total quality management.

Some researchers (Kumar, Ganesh and Rajendran, 2022), believe that I4.0 represents a disruptive technology, which requires a digital transformation of the organization, which is particularly important for business processes and employees. In connection with Q4.0 in this context, the emphasis is still placed on the technological dimension of quality, i.e. QM of conformity at workshop level (MES).

National I4.0 projects are developing particularly intensively in the Far East and Southeast Asia, and the Q4.0 model is based on the digitization of the TQM model (Maganga and Taifa, 2023). The specific segments that are being researched and developed for Q4.0 in these approaches are: BDA and workshop-level conformance QM through operational technologies (MES). Top management’s support for these processes is the most important.

One of the particularly important aspects of Q4.0 in practice is the professional competencies of employees for this area (I4.0). Conducted research shows (Martin, Dang and Gremyr, 2023), that in order for Q4.0 to succeed in practice, the focus of education must be on the application of I4.0 technologies in improvements, teamwork, and especially in researching phenomena in quality (cause – effect). That is why BDA and AI/ML, the main elements of I4.0, are extremely important for professional competencies in the field of quality, and for the Q4.0 model.

In the study Küpper et al. (2019), it is shown that the Q4.0 model represents the integration of strategic, cultural and technological issues. It is considered that I4.0 technologies are key to improving product quality, as they can monitor processes and collect data, as well as perform their analytics in real time. All of
this enables evaluation and prediction of quality, which transforms quality to a higher level.

The research shown in Sony, Antony and Douglas (2020), showed that the most important elements for the application of the Q4.0 model in practice are the combination of two groups of factors: (i) the elements of I4.0 (BDA, AI/ML and horizontal and vertical integration, and (ii) the elements of quality (strategy, leadership, training and organizational culture). Organizational self-assessment is one method for determining the current state of affairs in relation to these elements.

The integrated Q4.0 model, according to Carvalho et al. (2020), integrates the following elements: (i) digital QM with the application of I4.0 elements, (ii) QM of digital products, and (iii) QM of digital product development. In this way, product development and its manufacturing are integrated through the concept of I4.0.

TQM as a basis for the development of the Q4.0 model is presented in Villegas Forero and Sisodia (2020). This approach is characterized by QM through entity connectivity, management intelligence and online monitoring of quality process performance.

Digital transformation is a strategic project of every organization during the development and implementation of I4.0, i.e. Q4.0. However, research in Vial (2019), shows that these processes are innovative, because new technologies are used that shape a new way of functioning of the organization, including quality.

Digitization of the organization is a conditional paradigm for the development and application of the Q4.0 model, which is explicitly shown by the analyses in this chapter. It is also important to say that the digitalization and innovative development of the organization is also based on disruptive technologies, which gives its products and services additional value.

Our research in this paper further stems from this paradigmatic standpoint.

### 2.3 Quality Management Models and Industry 4.0

Through the MES model as a part of I4.0, and with the support of Internet of Things (IoT), a traditional QMS as a Q4.0 model (Singh et al., 2022), was developed and applied, based on the online monitoring of quality parameters in the manufacturing of one group of products, Tab. 3. Impressive results were achieved, the sigma level is increased from 1.5 to 5.5 sigma. This concept will be extended to other products in this plant of the automotive industry.

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<tr>
<td>Q4.0 as a QMS model.</td>
<td>Singh et al. (2022)</td>
<td>Sigma manufacturing level increased from 1.5 to 5.5.</td>
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</tbody>
</table>
Main issue | Source | Main messages
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Q4.0 as a QMS model with seven elements (ISO 9001:2015). | Carvalho et al. (2021) | Increased sigma level.
SOP model of material QM. | Ammar et al. (2021) | Q4.0 based on IoT, SPC and BDA.
Factors for applying the PDCA model in the I4.0 organization. | Silva, Borges and Magano (2022) | PDCA4.0 model for the automotive industry.
Dimensions of Q4.0 for organization. | Prashar (2023) | The consistency matrix for the organization.
TQM in model I4.0. | Chiarini (2020) | TQM4.0 through four dimensions.
The QM model as a quality loop. | Park et al. (2017) | The quality loop as a framework for Q4.0.
The elements of the model are: TQM, Lean Six Sigma and Business Process Management. | Komkowski et al. (2023) | BE as a basis for the development of BE4.0.
Building the organization’s business model from the point of view of quality. | Gunasekaran, Subramanian and Ngai (2018) | Q4.0 is a framework for quality costing, monitoring and decision-making, and manufacturing technology (CPS).
T(QM) models as static structures. | Asif (2020) | Q4.0 as dynamic, networked structures for real-time operation.

Notes: QM – quality management; PDCA – The Plan–do–check–act; TQM – total quality management; IoT – Internet of Things; SPC – Statistical Process Control; BDA – Big Data Analytics; BE – Business excellence; CPS – cyber-physical system; Q4.0 – Quality 4.0.

Research in Carvalho et al. (2021), showed that the QMS model can be translated into the Q4.0 model with the following elements: Management Leadership, Customer Management, Supplier Management, Employee involvement, Process Management, Quality information and their analysis, Planning (strategic and operational) and SPC (Statistical Process Control) tools and techniques. If we know that there are more than 1.2 million QMS certificates in the world today, then this approach for about 0.7 million production organizations can be an interesting approach.

I4.0 has enabled advanced approaches to materials management in production. In Ammar et al. (2021), an applied material quality management model on the SOP platform, with IoT support and the application of SPC methods as a tool for BDA, is presented.

The PDCA (The Plan–do–check–act) quality improvement model has been well known for several decades, but now in the Q4.0 model it takes on new dimensions. In the study Silva, Borges and Magano (2022), the factors that must be used in the development of the PDCA4.0 model were investigated and defined: ranking of product quality factors, teamwork, leadership for continuous improvements, motivation and user-centeredness. The pilot project is a
mandatory approach, and all this was done in a company from the automotive industry (ERP and MES model), as part of the overall I4.0 project.

In the era of accelerated development and application of I4.0, the technological aspects of QM are gaining more and more importance. For these reasons, in (Prashar, 2023), the dimensions of Q4.0 for manufacturing organizations were investigated and defined: manufacturing preparation and manufacturing (ERP and MES), QM model (most often QMS, sometimes IATF), digitalization of QM model, monitoring of key performance indicator (KPI) quality parameters and basic principles of Q4.0 models for organization. In this way, the consistency matrix for the organization is obtained.

In the Far East, there is more and more research related to the digitization of TQM. This should not be surprising, because this model was first developed there and applied since the eighties of the last century. Research, shown in Chiarini (2020), shows that TQM in model I4.0 develops through four directions: (i) creation of new values through quality in the organization (BDA and AI/ML), (ii) development of best practice Q4.0, (iii) customer participation in the creation of new products and services, and (iv) CPS (cyber-physical system) and ERP/MES model for QM in manufacturing.

QM as a quality loop modal is discussed in the example Park et al. (2017), which is digitized, for the development of the Q4.0 model. Therefore, it is designed in two levels: (i) integration of information from the QM quality loop as a basis for creating new value, and (ii) application of I4.0 elements (BDA, AI/ML, IoT and CMM as CPS). All this led to the construction of a new model of quality culture in the organization.

Business Excellence (BE) is an advanced model of TQM, which is used in this research as a framework for building BE4.0. It is developed through three dimensions: TQM, Lean Six Sigma and Business Process Management (Komkowski et al., 2023), as a holistic model. The basis of the integration of these three elements is shown to be data-driven, which means that the following elements of I4.0 are applied: BDA, AI/ML and horizontal/vertical integration.

QM for Q4.0 in Gunasekaran, Subramanian and Ngai (2018), is viewed in the context of the business model for I4.0, as an approach that should improve product quality: from the point of view of costs (ERP and MES model), monitoring and decision-making (BDA) and manufacturing technology (CAPP/CAM) with the application of CPS. All this works in turbulent market conditions, with often undefined customer expectations.

The research shown in Asif (2020), shows that there is a gap in the development and application of I4.0 elements in manufacturing and the QM model in their integration. Namely I4.0 is based on the integration of information through information technologies (IT) and IoT, with the support of AI, cloud computing and CPSs. This concept enables the manufacturing of highly customized products, which results in a controllable dynamic manufacturing structure,
supported by an ERP and MES model. On the other hand, QM models are based on formalized structures, which are immanent in the concept of I4.0. Therefore, for these reasons, we should work on the development of the interface between these two approaches. In order to clarify this approach, it is necessary to perform an in-depth analysis of the QM and Q4.0 models, as indicated in Tab. 4, which was made according to Asif (2020).

Table 4 – Towards Q4.0 (Adopted According to Asif, 2020)

<table>
<thead>
<tr>
<th>Characteristics of Q4.0</th>
<th>From (T)QM today</th>
<th>To Q4.0 tomorrow (as a part of I4.0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(T)QM models</td>
<td>1. By automation</td>
<td>1. Cognitive engagement</td>
</tr>
<tr>
<td></td>
<td>2. Used of standardized routines</td>
<td>2. Mindful task execution</td>
</tr>
<tr>
<td></td>
<td>3. Compliance with requirements and procedures</td>
<td>3. The direction of attention towards one’s ongoing experience</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Evaluating and questioning the value of a routine</td>
</tr>
<tr>
<td>Intellectual capital management (HR)</td>
<td>1. Managing employees (experience, training)</td>
<td>1. Managing human, social, and intellectual capitals</td>
</tr>
<tr>
<td></td>
<td>2. Managing human resources (education)</td>
<td></td>
</tr>
<tr>
<td>Making quality predictions from big data (BDA and AI/ML)</td>
<td>1. Anticipating customer requirements and addressing them</td>
<td>1. Making accurate predictions using big data.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Using big data to determine changing customer preferences, enable agility, flexibility, and responsiveness, to create delightful customer experiences.</td>
</tr>
<tr>
<td>Lean structures (organization and/or processes) (ERP and MES)</td>
<td>1. Developing formal systems through manuals, procedures, work instructions, and records (documented information)</td>
<td>1. Coexistence of technology and human-based simplicity</td>
</tr>
<tr>
<td></td>
<td>2. Establishing documented evidence for quality processes</td>
<td>2. Alignment of human-side with new lean structures</td>
</tr>
<tr>
<td>Managing networked firms in business ecosystems (products or suppliers) – I4.0</td>
<td>1. Define boundaries and scope of operations</td>
<td>1. Management of networked firms operating in business ecosystems</td>
</tr>
</tbody>
</table>

Notes: I4.0 – Industry 4.0; Q4.0 – Quality 4.0; QM – quality management; TQM – total quality management; BDA – Big Data Analytics; AI/ML – Artificial intelligence/Machine Learning; ERP and MES – Enterprise Resource Planning/Manufacturing Execution Systems module.

This analysis was carried out through five dimensions: (T)QM models and their structure, new knowledge for Q4.0, big data management and quality predictions, lean process models and supply chains and factories as eco-systems.
Our research, as showcased in this paper, shall draw upon the latter approach, commencing with the QM model IATF 16949:2016, as a foundation for constructing the Q4.0 model.

2.4 Quality Engineering Techniques and Industry 4.0

The basic element of the I4.0 model in the industry is the CPS, because it ensures the high quality of the product on the one hand and is the hub of information for it on the other hand. Starting from these facts, in Neal et al. (2021), a CPS model from the automotive industry is presented, equipped with Radio-frequency identification (RFID) and IoT entities, with the help of which the online state of the process is monitored from the aspect of its quality. In this way, their analytics (BDA) and prediction are performed, which achieves high key performance indicator (KPI) values, including traceability, which is extremely important for this type of production, and thus the key element of Q4.0 in this case, Tab. 5.

Table 5 – Overview of Quality Engineering Techniques and Their Relevance to I4.0

<table>
<thead>
<tr>
<th>Main issue</th>
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<tbody>
<tr>
<td>CPS with RFID and IoT in the automotive industry.</td>
<td>Neal et al. (2021)</td>
<td>Traceability and high KPI values – Q4.0.</td>
</tr>
<tr>
<td>ZDM is the ideal framework for Q4.0.</td>
<td>Powell, Eleftheriadis and Myklebust (2021)</td>
<td>Bring people to the six sigma level.</td>
</tr>
<tr>
<td>Big data and decision making.</td>
<td>Escobar et al. (2022)</td>
<td>The IADLPR² model as an intelligent decision support.</td>
</tr>
<tr>
<td>AHP technique for ranking 12 quality parameters.</td>
<td>Sureshchandar (2022)</td>
<td>The three most important parameters in Q4.0 are: analytic thinking, competence and customer centricity.</td>
</tr>
<tr>
<td>Framework for Q4.0 with nine elements.</td>
<td>Zonnenshain and Kennett (2020)</td>
<td>Q4.0 as context I4.0.</td>
</tr>
<tr>
<td>Integration of I4.0 and LSS.</td>
<td>Skalli et al. (2023)</td>
<td>Q4.0 as a basis for LSS4.0.</td>
</tr>
</tbody>
</table>

Notes: I4.0 – Industry 4.0; Q4.0 – Quality 4.0; RFID – Radio-frequency identification; CPS – cyber-physical system; ZDM – Zero Defect Manufacturing; KPI – key performance indicator; IADLPR – Identify, Ascensorize, Discover, Learn, Predict, Redesign and Relearn; AHP – hierarchy process; LSS – life-support system.

Zero Defect Manufacturing (ZDM) is an ideal framework for the full application of the I4.0 model, because with its elements: strategies (Detection, Repair, Prediction, and Prevention) and three policies (Correction, Compensation, and Cultivation) (Powell, Eleftheriadis and Myklebust, 2021), ensures six sigma manufacturing quality. A special element of this concept that needs to be worked on in the Q4.0 model is the knowledge of people for application (education, skill, experience), in order to improve it, because the quality of the process in relation to the part and the machine has been brought to the level of perfection. So, we need to raise the sigma level of the process – people, in order to complete Q4.0.
Research so far shows that manufacturing organizations have gone the farthest in applying the Q4.0 model. According to the same researches, the only pronounced problem in this application is the large volumes of data on current processes as well as their prediction, on the basis of which appropriate decisions should be made. For these reasons, and according to Six Sigma and Define, measure, analyze, improve and control (DMAIC) methodology, the IADLPR² model was developed and applied (Identify, Ascensorize, Discover, Learn, Predict, Redesign and Relearn), which improves decision-making procedures (Escobar et al., 2022). It helps us decide in which direction the Q4.0 model should be further developed, and gives advice to quality engineers, using AI/ML, on how to solve systemic quality problems.

In Sureshchandar (2022), analytic was used hierarchy process (AHP) technique, in order to rank the twelve quality parameters in the Q4.0 model, which have an impact on organizational performance, agility and sustainability. Those parameters are: strategic leadership, quality culture, customer centricity, QMS, compliance, competence, analytical thinking, metrics and data driven decision making, advanced analytics, data governance, innovation and new-age technology. On a sample of thirty-six organizations, it was shown that the first three influential parameters are: analytic thinking, competence and customer centricity. This tells us that Q4.0 is still based on traditional quality management approaches.

It is considered, which is written about, that in relation to I4.0, innovative models of quality lag behind in development. Namely, while in manufacturing we are talking about the full application of I4.0 elements, that is not the case today in terms of quality, the old QM models are on the scene. The birth of Q4.0 is going very hard. Why? Scheduled by quality researchers and engineers, worldwide! For the above reasons, research is proposed in Zonnenshain and Kennett (2020) to define a framework for Q4.0 that would include: (a) quality as a given driven disciplines, (b) the application of modelling and simulation for evidence-based quality engineering, (c) monitoring and prognostics for quality, (d) integrated QM, (e) maturity levels with respect to the I4.0, (f) integrating innovation with quality and managing for innovation, (g) Q4.0 and data science, (h) integrating reliability engineering with quality engineering, and (n) information quality.

From our point of view, the proposed framework can really be a good basis for building the Q4.0 model, which was also shown in our research, presented in this paper.

Conducted research shows that I4.0 and Lean Six Sigma (LSS) are complementary and synergistic models (Skalli et al., 2023). This means that it is possible to develop and apply the LSS4.0 model, which would include the nine elements of I4.0 and the 21 elements of the DMAIC model, which is applicable to all industries, types and sizes of organizations. Also, the exposed approach enables managers to connect advanced I4.0 technologies with the LSS methodology, followed by a large amount of data, managed by BDA and AI/ML models.
2.5 Quality 4.0 Definitions

The key elements of I4.0 consist of hardware and software components, and in Antonino et al. (2022), the Q4.0 model for the software structure of I4.0 is presented, Tab. 6. The starting element is ISO/IEC 25010:2011, for which a list of five groups of requirements is defined: monitoring and resource utilization I4.0 specifics (with two subgroups), maintainability and compatibility (with eleven subgroups), portability (with one subgroup), fault tolerance (with two subgroups) and security (with one subgroup). The mentioned subgroups have their engineering and operational aspects in the I4.0 model and are related to the corresponding industry standards or recommendations: ISO/IEC, ISO, IEC or VDMA. So, in this way, a quality model (Q4.0) with a comprehensive taxonomy of quality attributes was provided for software engineers (software architects I4.0), which created prerequisites for the development of an intelligent factory, Tab. 6.

<table>
<thead>
<tr>
<th>Main issue</th>
<th>Source</th>
<th>Main messages</th>
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<tbody>
<tr>
<td>Q4.0 model for software structure I4.0.</td>
<td>Antonino et al. (2022)</td>
<td>ISO/IEC 25010:2011 is the framework for this model.</td>
</tr>
<tr>
<td>Digital quality chain in the product life cycle.</td>
<td>Javaid et al. (2021)</td>
<td>Q4.0 with support for: BDA IoT, AI/ML and VR/AR.</td>
</tr>
<tr>
<td>Building Q4.0 models using digital tools.</td>
<td>Broday (2022)</td>
<td>Translation of the QM model (QMS, TQM, BE) into the Q4.0 model.</td>
</tr>
<tr>
<td>Q4.0 can be defined as the integration of I4.0 technologies, quality and people.</td>
<td>Souza et al. (2022)</td>
<td>From QC, through TQM to TQM4.0.</td>
</tr>
<tr>
<td>Q4.0 model for manufacturing organizations from the automotive industry.</td>
<td>Chiarini and Kumar (2021)</td>
<td>Robust Q4.0 model with eleven elements.</td>
</tr>
<tr>
<td>Q4.0 is based on strategic, cultural and technological entities.</td>
<td>Antony, McDermott and Sony (2021)</td>
<td>Quality experts with soft and hard skills are needed.</td>
</tr>
<tr>
<td>Integration of traditional QC models with I4.0 technologies.</td>
<td>Sader, Husti and Daroczi (2021)</td>
<td>Q4.0 – improvement of quality performance.</td>
</tr>
<tr>
<td>Making decisions.</td>
<td>Schmidt Goecks, Santos and Korzenowski (2020)</td>
<td>Q4.0 – outsourcing management, forecasting, customer expectations, as well as employee involvement.</td>
</tr>
</tbody>
</table>

The digital quality chain in the product life cycle, supported by I4.0 technologies, is an ideal framework for the development and application of the Q4.0 model (Javaid et al., 2021). Therefore, with conventional QM models, which through digital technologies and with the support of CAD/CAI/MES models are developed as a Q4.0 model, the extended Q4.0 model includes quality...
monitoring in the exploitation of the product itself. This is where 4.0 technologies come to the fore, such as: Digital twin (DT), BDA, IoT, AI/ML and Augmented reality (AR) and Virtual Reality (VR) (VR/AR), so that we move from the management model to quality prediction.

There is still no universal definition for Q4.0, but digital tools (DT, BDA, ...) are increasingly used in the practical development of this model (Broday, 2022). At the moment, they enable online monitoring of technological processes at the CPS level, which realizes the ZDM concept, which is an exceptional improvement. Also, the need for the development of a digital culture of quality, with a new place and demands on people, is increasingly entering the scene. All this leads to digitalization, step by step, of existing QM models (QMS, TQM, BE).

Q4.0 can also be defined as the integration of I4.0 technologies, quality and people, in the construction of an intelligent factory (Souza et al., 2022). In this research, emphasis is placed on QC, as a key factor in QM in the WS. Starting from this, a TQM model is then built, which is then translated into Q4.0, as TQM4.0.

In the study Chiarini and Kumar (2021), the factors (eleven in total) of the development of the Q4.0 model in Italian manufacturing companies from the automotive industry were investigated. They are defined as: Q4.0 based on I4.0, quality 4.0 based on ISO 9001 (PDCA model), top management (involved, committed), process mapping, automatic data collection (internal data, product life cycle data, customer data), integration of data with ERP (customer relationship management, product life cycle management, MES), artificial intelligence and predictive software, machine-to-machine communication, smart technologies for identification and traceability (product identification and traceability, measurement instrument control), automated document control, and digital skills for quality staff. All of them proved to be relevant, and they are grouped into three areas that make up the framework of the Q4.0 model: people, processes and technologies. In this way, a robust Q4.0 model for manufacturing companies was obtained.

The study Antony, McDermott and Sony (2021), provided the theoretical framework of the Q4.0 model, which is based on strategic, cultural and technological entities, which in application provide the organization with a competitive advantage based on increasing: customer satisfaction, increasing operational efficiency and quality of products/services. The study also presents the advantages, critical factors and challenges of the Q4.0 model, factors of organizational readiness and the role of leadership in this model. The role of experts is extremely important in the new model with hard and soft skills features, as well as predictive analytics with sensors for online monitoring with feedback. This completes the Q4.0 model based on the I4.0 technology.

The expansion of the application of the I4.0 model in the economy also contributed to the development of the Q4.0 model. One of the first definitions of Q4.0 reads: the integration of the latest technologies (I4.0), with traditional
quality models (QC, QA, TQM), improves and expands quality activities in the organization (Sader, Husti and Daroczi, 2021). This definition tells us how I4.0 improves quality performance in the organization, in every sense of the word. In this study as well, the importance of quality experts on the basis of I4.0 is especially emphasized.

Decision-making in the complex infrastructure model of I4.0, especially Q4.0, is becoming an increasingly difficult problem, so research in this area is extremely important. Research, shown in Schmidt Goecks, Santos and Korzenowski (2020), showed that new approaches and decision-making tools can especially help in managing outsourcing, anticipating customer expectations, and involving employees in quality improvement according to the PDCA model.

2.6 Quality 4.0 in Practice

In Christou et al. (2022), an IoT platform for collecting, managing and routing data streams from heterogeneous CPS, on a configurable and interoperable basis, is presented. It uses advanced data analytics based on AI/ML data mining models. It is applied in industrial conditions for preventive maintenance (increasing Overall Equipment Effectiveness (OEE) parameters) and quality management (ZDM), Tab. 7.

Table 7 – Overview of the Case Study Q4.0 Model

<table>
<thead>
<tr>
<th>Main issue</th>
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<th>Main messages</th>
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<tbody>
<tr>
<td>IoT platform.</td>
<td>Christou et al. (2022)</td>
<td>Predictive maintenance and ZDM.</td>
</tr>
<tr>
<td>SBD model for welding quality management – BDA.</td>
<td>Stavropoulos et al. (2021)</td>
<td>7V and ANN for BDA.</td>
</tr>
<tr>
<td>BDA analyzes are hyperdimensional spaces of quality characteristics.</td>
<td>Escobar et al. (2021)</td>
<td>MCS model for BDA analyses.</td>
</tr>
<tr>
<td>Horizontal exchange of quality information in the supply chain.</td>
<td>Brandenburger et al. (2020)</td>
<td>FADI Platform.</td>
</tr>
<tr>
<td>Product development on platform I4.0.</td>
<td>Carvalho and Lima (2022)</td>
<td>Q4.0 as an integrated model of CE and QMS.</td>
</tr>
<tr>
<td>Q4.0 in production quality control.</td>
<td>Bousdeakis et al. (2022)</td>
<td>BDA model: multiple given sources, integrate data and knowledge, data – driven, predictive and prescriptive analytics algorithms.</td>
</tr>
<tr>
<td>Q4.0 Maturity Assessment Model.</td>
<td>Nenadál et al. (2022)</td>
<td>Seven levels of maturity.</td>
</tr>
<tr>
<td>Quality engineering techniques as the basis of Q4.0.</td>
<td>Barsalou (2023)</td>
<td>BDA model for QA, cause-effect analysis and prediction of quality characteristics.</td>
</tr>
</tbody>
</table>
Measuring the maturity of the Q4.0 model.

Armani et al. (2021)

Eleven organizational dimensions and five maturity levels.

Q4.0 in plaster manufacturing.

Ramezani and Jassbi (2020)

Artificial neural networks (ANN) and Expert System (ES) for QM using Statistical process control (SPC).

The most important factors for implementing Q4.0 in practice.

Sony, Antony and Douglas (2020)

Three technical and three organizational factors.

Q4.0 model for printed circuit board (PCB) manufacturing.

Schmitt et al. (2020)

ML and edge cloud computing model framework.

Service-oriented manufacturing (SOM) and Q4.0.

Song et al. (2016)

Formal semantic network and process-oriented ontology.

Online monitoring of data from technological processes is a special challenge due to: volume, discontinuity, sampling method and simultaneous provision of multiple values. In order to overcome these problems, the “Subjectively Big Data” model was developed, which was applied to the QM of the welding process (Stavropoulos et al., 2021). Here, 7V (SBD indicative characteristics for welding monitoring) and ANN are used for training to manage this process.

BDA analyses are a hyperdimensional feature space, especially for process QM. For these reasons, it is necessary to use the meta-learning algorithm for classification (MCS) of features (Escobar et al., 2021). In the mentioned reference, one such model is shown, with a learning algorithm, by means of which the sigma level is increased to the ZDM level, which is for applied industrial production (electronic components) and a realistic production requirement.

From the perspective of product QM, horizontal information integration is extremely important for supply chains. In this sense, big data platforms for this area, such as FADI, are extremely important (Brandenburger et al., 2020), for building the Q4.0 model. In this research for the European steel industry, quality information of high reliability, improved decisions about achieved product quality and automatic exchange were achieved, information which are adapted to existing customers and orders.

The Cognitive Engineering (CE) model, one of the solutions for QM, which in this case refers to the QMS model Carvalho and Lima (2022). Namely, this approach guarantees high-quality products from the very development and through all stages of its manufacturing, meeting the requirements of the standard.

Data analytics is the most important element for manufacturing QM, but also increasingly complex due to the complexity and variety of products and value chains. Therefore, the quality control of manufacturing processes has a high potential of data analytics (Bousdeakis et al., 2022). By researching several case studies, we came to the key elements of BDA for the development of Q4.0:
data–driven issue solving, predictive and prescriptive analytics algorithms, combining multiple given sources (CRM, ERP, MES) and combining and integrating data and knowledge.

Quality is a key factor for economic sustainability and business excellence of an organization. Now supported by the I4.0 model, these elements come to the fore even more, and the quality through the construction of the Q4.0. However, each organization in the field of digitization is a story for itself, and in order to determine its readiness and maturity for the application of the Q4.0 model, a model was developed to evaluate these elements (Nenadál et al., 2022). It has four dimensions (strategic directions, propel and culture, processes and methods and tools), and twenty-two elements. The maturity level for Q4.0 is defined over seven levels, from not applied (0-10%) to leader (85-100%) criteria fulfilment. For each level, the elements of Q4.0 in application are clearly defined, and this model has been checked in several organizations in the Czech Republic.

Quality engineering techniques, especially SPC methods, play an important role in the development of the Q4.0 model as well. That is why BDA analysis, for example in Barsalou (2023), is used in this area for: control charts, cause-effect analysis and predictive recognition of trends in quality characteristics. An additional aspect of this concept is the experts in these methods and their understanding of the Q4.0 model.

In the study Armani et al. (2021), a model for measuring the maturity of the Q4.0 model is presented, with examples of application. It is evaluated through the organizational dimensions of Q4.0, of which there are eleven, from data to leadership and competencies. The model itself has five maturity levels: absent quality – from 0% to 19.99%, basic quality – from 20.00% to 39.99%, traditional quality – from 40.00% to 59.99%, advanced quality – from 60.00% to 79.99% and Q4.0 – from 80.00% to 100%. An analysis of the application of this model in the automotive industry and energy is given.

Quality is at the core of all manufacturing organizations, and Q4.0 will be its framework for factories of the future in SM supported by intelligent argoliths. In Ramezani and Jassbi (2020), the hybrid model Q4.0, which uses ANN and an expert system (ES) for online plaster QM, is presented, using control charts (SPC). ANN is used to generate knowledge and learn about the process in the context of quality parameters, and ES provides recommendations for corrective actions.

Q4.0 is increasingly becoming a good practice and less a theoretical concept. In the study Sony, Antony and Douglas (2020), the constituent elements of the Q4.0 model in application were investigated, and it was concluded that they include: (a) BDA (collection, analysis and synthesis of data), (b) horizontal and vertical integration of quality data, (c) Q4.0 as a strategic advantage, (d) leadership in Q4.0, (e) training shows that technical and management factors are equally important for the application of this model in practice.
The following example refers to the PCB assembly (Schmitt et al., 2020), and the application of the Q4.0 model in online mode. The essence of the model is the use of machine learning techniques and edge cloud computing technology, and the result of this model is a significant reduction in the scope of the final inspection of PCB entities. The predictive model is trained on the basis of historical data from the cloud, and new process quality parameters are returned to the machine’s computer, with the help of which the entire process is managed.

Service-oriented manufacturing (SOM) is a new manufacturing paradigm, where CPS are key elements for ensuring high product quality. The key element of the Q4.0 model is a formal schematic network, which is used to construct a process-oriented ontology for managing process quality parameters (Song et al., 2016) and data quality for the process.

The conducted analysis demonstrates that sundry methodologies are utilized to implement the Q4.0 model in the enterprise, with emergent specialized platforms being established for this purpose, signifying the most current approach.

In summary, it can be affirmed that the digitization of the corporation forms the foundation for the implementation of the I4.0 paradigm, while the digitalization of manufacturing operations serves as the cornerstone for the creation and application of the Q4.0 model.

Analogous methodology was employed in our example.

3 DIGITAL MODEL OF INMOLD PLAST COMPANY

The manufacturing of plastic containers for food and parts for the automotive industry is the core business of this organization. She has been working on the digitization project for several years, simultaneously introducing elements of I4.0, as well as Q4.0. The basic framework of the digital model of this organization is shown in Fig. 1.
“Islands” of automation, business and engineering-development activities were created, which are now being integrated according to the concept of I4.0 into the cloud model of digital manufacturing (Majstorovic et al., 2021). The digital manufacturing model, which is being developed in this organization, has an integrated database (knowledge) on the cloud about all business entities, updated on a daily basis – with the latest (current) versions of products and the history of their changes. The Q4.0 model is an integral part of the overall digital model of this organization and permeates all elements, from the definition and adoption of customer requirements (CRM), to the delivery (DP) of that product to that customer.

3.1 Functioning of Digital and Q4.0 Models in Practice – Case Study

How the formation of the digital chain for the product in this organization begins, and how it develops further?

Based on the customer’s request, an offer is created in the CRM module. The customer defines his requirements by email, technical drawing, by submitting a STEP model, or a sample (on the basis of which a 3D model is made), with a list of requirements. In order to clearly define all requirements (and in accordance with the stated standards that are applied in this organization), a document is filled out that defines the quality characteristics that are defined and agreed both by the customer and by Inmold and they are stated in the offer, which is shown in Fig. 2.

![Figure 2 – Creation of 0na Offer for the Customer](image)

This activity is performed in several iterations with the customer, using both previous solutions and the product CAD model catalogue, Fig. 3, paying special attention to the quality characteristics and their values (green box on Fig. 3a).
When contracting the work, based on the quality characteristics, CAD model library, previous experience, the planned expected costs for the realization of the project are calculated. When the Offer is accepted by the customer, it becomes Project N (in digital form), for which a Production Request (of products and/or tools) and Planned purchase orders for raw materials and tools are automatically generated. These documents are generated in the ERP system. Also, the following sets of information (reports) are then generated: (i) Planned costs and Actual costs (after product delivery), Fig. 4.

They also contain costs quality (planned) and scrap costs (if it appears), (ii) monitoring of the procurement process (list of entities for procurement with an overview of warehouse conditions), Fig. 5. Then the process of making the tool construction is approached. This is done in the appropriate CAD systems. In addition to the technical documentation as a result of the design process, a bill of...
materials (BoM – Bill of Materials) is generated. The BoM makes a list with clearly defined positions of each part in the tool, name, designation, dimensions and material of the preparation, as a recommended supplier. The item codes in CAD and ERP are harmonized so that system integration is ensured by simple export or import of BoM from one system to another.

Figure 5 – List of Parts, Materials and Services for Project N

After importing the BoM into the ERP system, the warehouse condition is automatically checked in accordance with the required needs. Each item is defined by attribute categories, of which there are six, and each item is defined with a huge amount of attributes (there are 250 of them), including a picture, technical drawing and pdf documentation. This list also contains requirements for the quality of the entities being procured. Also, it immediately calculates the stock of items, calculates existing orders, necessary purchases, gives consumption in the last two years, monitors the stock over time, and records changes in the price of items.

Casting tools (machine, data on the number of cycles, products produced in it, maintenance technology, costs) are monitored especially in the warehouse.
At the next level, manufacturing components (MBOM) are generated, which gives us relevant data for: product/tool production (CAPP operations), as well as tool maintenance technology, Fig. 7.

Figure 7 – CAPP Model for Tools (MBOM) (Shaded Green – Cutting operation)
This document also defines the metrological operations of process quality control, which make up the elements of the CAI model, which are realized on the CMM, for the most important tolerances, of the tool as a rule. The tolerances of the products are not as narrow as the tolerances of the tools in which the products are made, Fig. 8.

Figure 8 – Metrology Sheet for Tool Parts (Shaded in Yellow – Metrology Operations)

After this activity, capacity planning is carried out, since all structural engineering (EBOM) and technological (MBOM) resources are defined, with the aim of planning manufacturing at WS level, Fig. 9.

Figure 9 – Work Order for Tool Manufacturing (Shaded in Yellow – Metrology Operations)
In this way, all the elements for scheduling manufacturing that are monitored through the online ERP module are defined. The procurement process is carried out from the same place. Procurement that is carried out in the form of a tender with a clearly and transparently defined cost center for each position. The record of the beginning and end of operations, as well as the conclusion of procurement documentation or warehouse documentation results, among other things, in the sending of messages – notification of realization, Fig. 10.

![Figure 10 – Online ERP with Automatic Ordering](image)

This is how the MES module is completed, where the WO is monitored in the WS, and their online checking is done after each operation (manufacturing or quality control) is completed. After processing, a WO for heat treatment is created, which also includes heat treatment quality control operations.

After the completion of the manufacturing of plastic products, a final quality control is carried out, using SPC methods, and the test manufacturing of the parts is carried out with the tool, which are controlled and thereby confirm the quality of the tool itself.

All business entities in this organization are marked with a BAR or QR code, including documentation, so their status is monitored through the process.

### 3.2 Achieved Results

Q4.0 concept, was implemented: (a) a single database (knowledge) about all business entities, located on the cloud, (ii) faster, clearer and more accurate definition of offers for the customer, (iii) unambiguous definition of the customer’s requirements (especially in relation to the requirements of ISO 9001:2015, IATF 16949:2016 as well as the HACCP model, and their management in the manufacturing process (iv) online information of all participants in the project about its status (how far it has come, what is the bottleneck, ...), and online monitoring of the project (without paper), (v) realistic definition of time by project activities, better planning and scheduling of capacity.
on each machine, workers are realistically rewarded (vi) complete insight into the complete costs of the project through several types of reports, (vii) informing the customer about the real transit time of delivery, (viii) a detailed overview of procurement/warehouse operations and all related costs, (ix) full management of working documents and ensuring traceability, (x) noticing the weaknesses of the production process in terms of organization and technology, and defining methods for its improvement.

3.3 What is Next

In the next phase in this organization, it is necessary to build real CPS systems (equipped with sensors and IoT entities). After that, a real IoT-based WO online management base will be created. This will enable the synchronous management of ERP processes, through their orchestration, according to the model in Fig. 11 (Krco and Vukadinovic, 2023).

![Figure 11 – Inmold Plast Doo Solution Architecture for Future ERP Model](image)

This structure provides a detailed architecture of cloud computing services, with which applications are managed through data centers, and supports all types of platforms: SaaS, PaaS and IaaS. This organization will decide on its own which platform it will use, according to its capabilities and the achieved technological level.

From the example shown, we can conclude that this organization is building the Q4.0 model in such a way that it raises the existing QM models (especially standardized ones) to a higher level using the framework and elements of digitization from the I4.0 model, as analysed in points 2.2 and 2.3.
4 CONCLUSIONS

Q4.0 represents a model under development, which will be built in the coming years, primarily in accordance with the development and model of I4.0. Its application in this organization has brought great benefits, and at this level, and they will only increase with the application of IoT, BDA concepts, as well as AI/ML models. All these elements will only contribute to the “improvement” of this model (Q4.0) in this organization.

This example comes from a small country and an organization that represents one of the national leaders of digitization. Therefore, this work should be understood as an exemplary example for other organizations in Serbia, which way to go, and for partners from abroad, it shows that they will cooperate with an organization that has its own digital business model, which is compatible with theirs, as stated in its basic characteristics in application.

What is future research? Key machine tools will be selected, which will be translated into CPS, as explained in point 3.3. We will also work on improving the ERP system, as shown in Fig. 11. In this way, we will get a cloud model of digital manufacturing, as the best basis for the development of SM according to the full concept of I4.0.

It will also be a real manufacturing example of I4.0/Q4.0, a sustainable eco-technological system. But more new research results about that in the following papers of this team, as soon as possible.

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AUTHOR CONTRIBUTIONS


CONFLICTS OF INTEREST

The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

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