



## **Quality 4.0 conceptualization and theoretical understanding: A global exploratory qualitative study**

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## Quality 4.0 Conceptualisation and Theoretical Understanding: A Global Exploratory Qualitative study

### Abstract

Purpose – Quality 4.0 has a unique potential to create a competitive advantage for organisations by improving customer experience and enhancing profitability. The purpose of this study is to examine Quality 4.0, the benefits, motivating factors, critical success factors and the skills required by quality professionals in the successful implementation of Quality 4.0. The study also investigates the organisational readiness factors and challenges that need to be addressed before Quality 4.0 adoption and assess their importance.

Design/methodology/approach – A qualitative interview approach was utilised by interviewing a panel of senior management, engineering and continuous improvement professionals working in leading companies in Asia, Europe, and America who are currently deploying Quality 4.0

Findings – This study provides a theoretical base for the Quality 4.0 body of knowledge in terms of an organisation's adoption and overcoming implementation challenges and providing examples of Quality 4.0 application. Organisations can use this study to understand what Quality 4.0 means to industry, the benefits and motivating factors for implementing, the Critical Success Factors, challenges, the organisational readiness factors, and the role of leadership in a Quality 4.0 deployment. In addition, the study looks at the skills required by future Quality 4.0 professionals in terms of hard skills, soft skills and a curriculum for educating future Quality management professionals. The respondents cited that predictive analytics, sensors and tracking, and electronic feedback loops are the most critical technologies for driving Quality 4.0.

Research limitations – One of the limitations of this research was that as this area is a nascent area the researchers were limited in their literature review. The second limitation was that the study was based on 12 interviews. A more comprehensive longitudinal study would yield more data so that better and robust conclusions can be derived from the study.

Originality/value – This is the first empirical study on Quality 4.0, which captures the viewpoints of senior management professionals on a full range of topics related to Quality 4.0 motivation for deployment, implementation and readiness for its adoption.

Keywords: Quality 4.0, Quality Management, Critical Success Factors, Organisational readiness; Leadership; Quality 4.0 Skills

Paper type: Research article

## Introduction

Modern organisations have undergone enormous changes in engineering, manufacturing practices, processes and technologies with the advent of Industry 4.0 (Birkel and Müller, 2021; Sony and Naik, 2019; Silva et al., 2020). Dan Jacob first put forward the Quality 4.0 term, and it is about using technology to show that quality should be a company-wide strategy, with the executives at the helm driving performance (Sony et al., 2020). Quality 4.0, in simple terms, is managing quality in the modern era of Industry 4.0 (Sony et al., 2021). According to the American Society of Quality (ASQ) Quality, 4.0 is a term that references the future of quality and organisational excellence within the context of Industry 4.0 (Radziwill, 2018). Most authors agree that Quality 4.0 closely aligns quality management with Industry 4.0, which will help organisations in enterprise efficiency, performance and improved business models (Sony et al., 2020). Quality 4.0 implementation within an organisation improves quality, customer satisfaction and better products & services; thus, it instils a competitive advantage (Zonnenshain and Kenett, 2020). Digitalisation creates new opportunities for organisations to incorporate technological advances to arrive at new optimums in operational excellence, performance and innovation (Sony et al., 2020). The smart factory of the future will enhance efficient manufacturing operations. For example, companies can monitor processes, collect data in real time, and apply analytics to predict quality issues and maintenance needs (Watson, 2019). The benefits of Quality 4.0 will be reduced costs of quality via improved operational efficiencies, increased revenue, reduced non-conformances, improved product compliance, on-time deliveries, reduced supplier defect rates and increased successful new Product Introductions (Antony, 2014). Industry 4.0 technologies can be applied as part of Quality 4.0, for example, Cyber-Physical Systems (CPS), Internet of Things (IoT), Digital twins and cloud computing. However, Závadská & Závadský (2020), in their study on Quality managers and their future technological expectations related to Industry 4.0 and found a high degree of variability of utilised smart technologies are dependent on a branch of industry. For example, the use of I4.0 technologies was more prevalent in the automotive industry.

Quality 4.0 is an applied concept in a nascent stage (Javaid et al., 2021; Chiarini and Kumar, 2021). Theoretical understanding should be developed to conceptualise Quality 4.0, to develop a thorough and comprehensive understanding of the concept (Sony et al., 2021). Hence, there is a need to capture the viewpoints of practitioners of quality 4.0 so that the practical experience of these Quality 4.0 practitioners could be analysed to develop the theoretical understanding. However, hardly any study has conceptualised Quality 4.0 from a practitioner's point of view. Thus, the main research questions for this study are to understand the concept of Quality 4.0 from a practitioner viewpoint to conceptualise Quality 4.0 to develop the theoretical understandings. There is no study yet which has conceptualised various facets of Quality 4.0 from a practitioner's perspective.

The main research questions for this study are to understand the concept of Quality 4.0 from a practitioner viewpoint with various sub-research questions including:

1. What does Quality 4.0 mean for future quality professionals regarding soft skills, hard skills and educational curriculum to develop quality professionals?
2. What are the motivations for and benefits of adopting Quality 4.0?
3. What are the CSFs, challenges and organisational readiness factors of Quality 4.0?
4. What roles can leadership play in the successful adoption and deployment of Quality 4.0?
5. What Industry 4.0 technologies can be leveraged for Quality 4.0?
6. How do we define Quality 4.0?

## Literature Review

Gregory Watson, former president of the International Academy for Quality (IAQ) and the American Society for Quality Control (ASQ), has put forward in 2021 a manifesto for the IAQ on Quality 4.0 and discussed that now Quality 4.0 can "deepen the science and art of the quality profession". The "science" element focuses on quality professionals keeping up with data science and data mining, while the "art" is cultural transformation, vision creation and strategy formulation (Ramanathan and Watson, 2021). While many may not refer to Quality management roles as an art or a science, traditional quality managers have skills that can include communication, teamwork, time management, assessment and analysis, leadership, problem-solving, role modelling, decision-making, learning and managing people (Garad, 2007). Organisations implementing Quality 4.0 need a robust skill set and competencies in; Critical thinking and analysis, Problem-solving, Self-management, Working with People, Management and Communication of activities, technology use and development and core literacies (Gunasekaran et al., 2019a; Kannan and Garad, 2020; World Economic Forum, 2020). Shortages of digital skills being further slowed by challenges with technology and data have also been barriers to Quality 4.0 implementation (Santos et al., 2021; Sony et al., 2021). Santos et al. (2021) found that Quality 4.0 professionals must have skills such as creative thinking, be leaders, know how to communicate, and work as a team and besides that, they must have knowledge of new technologies and combine that with the best quality management practices, where their decisions will be based on big data (Küpper et al., 2019). The ASQ and others have also put forward that many of these aforementioned job skills of the future will be required by Quality professionals as part of Quality 4.0. (Santos et al., 2021; Watson, 2019; Küpper et al., 2019; Sony et al., 2021). As the world is changing and technology is evolving, quality professionals need to evolve to prepare, educate, and train future quality professionals. While there is literature available on skills required of quality professionals of the future, there is not as much written on what subject areas will be on the quality practitioner curriculum (Hernandez-de-Menendez et al., 2020; Santos et al., 2021; Watson, 2019; World Economic Forum, 2020). Some are paranoid that data scientists will take over the equality function (Duarte and Dame, 2019). Employers expect graduates to have several generic skills, such as communication skills, creativity and innovation skill, problem-solving and decision making, critical thinking, self-management, teamwork skill, and the ability to learn and that needs to be incorporated into the curriculum for quality professionals of the future (Suartha et al., 2020). Data science and statistical analysis will become more key than ever before. The distinction between quality professional and data scientists have been discussed as collaborative analytics (Watson, G, 2019), focusing on continuous improvement methodology and data to drive integrated organisational-wide improvement. Elahi et al. (2019) and Radziwill (2018) have both put forward curriculum matrices for universities and industry in relation to an Industry 4.0 curriculum which consists of big data, the internet of things, cloud computing, artificial intelligence (AI) and augmented reality (AR). While this curriculum matrix is proposed for Industry 4.0, it can be extrapolated that components on each can be utilised to educate future quality professionals on Industry 4.0 so that they can maximise the benefits for Quality 4.0. Leadership and top management support and understanding of Quality 4.0 and the extent to which they are willing to support its implementation within the organisation are essential to Quality 4.0 (Sony et al., 2021). A global study by BCG found that few organisations had a defined and detailed strategy or had launched an implementation program (Kupper et al., 2019). However, there is a lack of evidence of a successful implementation strategy of Quality 4.0 (Zonnenshain and Kenett, 2020) and the readiness factors before implementing Quality 4.0 (Gunasekaran et al., 2019b). Organisations have cited the following challenges to implementing Quality 4.0 and Industry 4.0: high costs, lack of cybersecurity, lack of Quality 4.0 skills, training and knowledge, unreliable internet connectivity, lack of leadership support, employees resistance to change and a poor quality and change culture (Chiarini, 2020; Emblemståg, 2020; Sony et al., 2020; Watson, G, 2019) Kupper et al., 2019).

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3 According to Sony, Antony and Douglas (2020), there are fundamental “ingredients” or critical  
4 success factors for the effective implementation of Quality 4.0 in more expansive organisations,  
5 namely: (1) handling big data, (2) improving prescriptive analytics, (3) using Quality 4.0 for an  
6 effective vertical, horizontal and end-to-end integration,(4) using Quality 4.0 for strategic advantage,  
7 (5) leadership in Quality 4.0, (6) training in Quality 4.0, (7) organisational culture for Quality 4.0 and,  
8 lastly, (8 ) top management support for Quality 4.0. (Sony et al., 2020). An ASQ study in 2019 study  
9 reiterated the importance of establishing a strategic road map and quality-oriented culture to enable  
10 technological transformation (Küpper et al., 2019). The literature has highlighted numerous  
11 examples of how Industry 4.0 technology can help Quality 4.0 and aid quality professionals in  
12 improving quality. Systems with built-in quality management also result in greater automation in  
13 production environments (Johnson, 2019). Industry 4.0 can help augment human intelligence,  
14 increase the speed and quality of decision-making, and improve transparency, traceability, and  
15 auditability (Radziwill, 2018). Predictive maintenance can help anticipate equipment failures and  
16 proactively reduce downtime. Data gathered for product servicing in the field can be fed back into  
17 product design, ensuring the quality and reliability of the design of products and services (Santos et  
18 al., 2021; Sony et al., 2021). Blockchain can improve data quality, the quality of transactions and,  
19 more importantly, traceability. Blockchain and RFID help quality professionals "put their arms"  
20 around the products in the field and enable quick recall of products if necessary(Kuhn et al., 2018;  
21 SAGGIN et al., 2019). Statistics and data science provide the foundations that can be applied to all  
22 problem solving and decision making. By identifying the root cause of the product failure with  
23 traceability back to the individual operations, operators, and machines involved in its manufacture,  
24 companies can identify production flaws that can be corrected to reduce or eliminate future  
25 warranty claims (Radziwill, 2018). Success in a transformational change such as Quality 4.0 must  
26 be a multifaceted, cross-functional integrated approach that addresses the full range of strategic,  
27 cultural, and technological issues. Companies that are ready for Quality 4.0 and overcome challenges  
28 to the transformation will be rewarded with lower defect and failure rates and a competitive  
29 advantage in the form of greater customer satisfaction and improved operational efficiency.  
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### 36 **Methodology**

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38 The methodology adopted for this study includes qualitative data collection primarily revolved  
39 around interviews using purposive sampling (Charmaz and Belgrave, 2007). Senior managers with  
40 expertise in Quality 4.0, engineering and continuous improvement and working in manufacturing,  
41 services, small-medium enterprises (S ME's) and large enterprises (LE's) were chosen in this study.  
42 The SME enterprises were classified as organisations employing less than 250 employees  
43 (Anggadwita and Mustafid, 2014). Two hundred and fifty or more employees were classified as Large  
44 enterprises (OECD, n.d.). Purposive sampling was used in this study. Purposive sampling helps a  
45 researcher use judgment to select people, cases, organisations, events etc., to study the particular  
46 characteristics of the sample under study (Etikan et al., 2015; Tonjang and Thawesaengskulthai,  
47 2020). The study adopted an exploratory qualitative design to capture the Senior manager's views  
48 on practical experience of implementing Quality 4.0. Countries such as Germany, UK, US A, Italy are  
49 dominating Industry 4.0 research (Brandenburger et al., 2021; Chiarini and Kumar, 2021; Yurin et al.,  
50 2021). As such, this study included senior quality managers from these countries. As these countries  
51 were developed countries, to include viewpoints from developing countries, a sample from India and  
52 Turkey were included. Besides, professionals from different organisations ( such as consultancy,  
53 automotive, cosmetics etc.) were chosen to include divergent viewpoints regarding the  
54 conceptualisation of Quality 4.0. Senior managers with over five years of experience were chosen in  
55 this study because they are directly involved in decision making about various aspects of Quality 4.0  
56 and in the development of quality management strategy within their organisations; as such, the  
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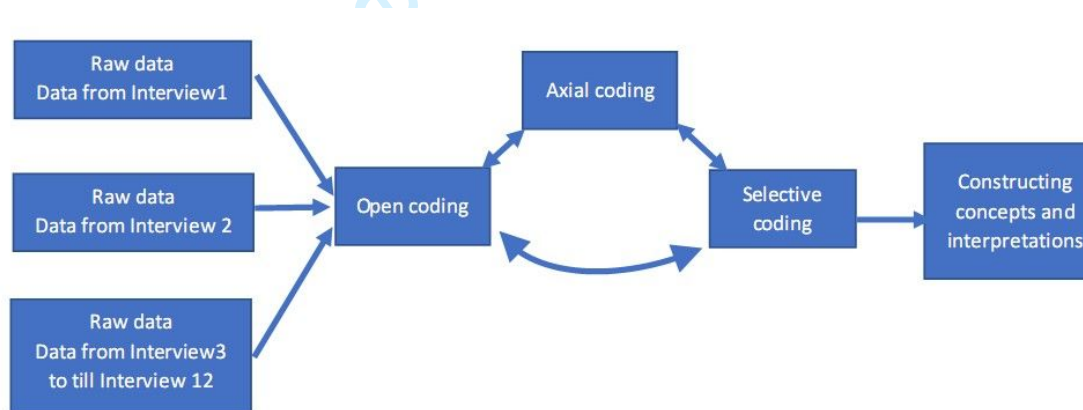
information will be more accurate (Antony and Sony, 2021; McDermott et al., 2021). The participant's details and backgrounds are elucidated upon in Table 1.

**Table 1:** Participant Information by industry/organisation type, location, role and years of experience

Participant Name	Role	Organisation type	Company size/type	Geographical location	Years of Experience
#1	Managing Director/Six Sigma Master Black Belt (MBB)	Consultancy	Small <50 (Consultancy)	Germany	>25
#2	MBB	Automotive	Large Enterprise	Germany	>25
#3	Team Leader	Elevator/Lift	Large Enterprise	Germany	>20
#4	Head of Quality and OPEX	Industrial Production	Large Enterprise	Germany	>20
#5	Head of Quality Management	Industrial Production	Large Enterprise	Germany	>20
#6	Director	Automotive	Large Enterprise	Italy	>15
#7	Head of Quality and CI	Cosmetics	Large Enterprise	UK	>15
#8	Quality 4.0 Lead/LSS MBB	Home appliances	Large Enterprise	Turkey	>20
#9	VP of Quality	Automotive	Large Enterprise	USA	>20
#10	Director of Quality	Consultancy	Small<50 Consultancy	USA	>25
#11	General Manager (Operational Excellence)	Power Engineering	Large Enterprise	India	>20
#12	Operational Transformation Manager	Consultancy	Small <50 Consultancy	India	>15

The details about the participants were obtained from LinkedIn because it is one of the most widely used networking sites for professionals (Unkelos-Shpigel et al., 2015). A personalised email was sent to the potential participants outlining the study's objective and requesting their voluntary participation in this study. Upon agreement to the interview, an online interview using Zoom or MS Teams was conducted. The interviews started with demographic questions around the participant's experience working within Quality management or continuous improvement disciplines, followed by twelve open-ended questions. This was ensured to improve the consistency and comparability of qualitative study, as the same questions would be asked to all respondents. The focus of the

questions was centered around motivation factors for the adoption of Quality 4.0, benefits from the implementation of Quality 4.0, the role of leadership in the successful adoption and implementation of Quality 4.0, readiness factors and Critical Success Factors. Open-ended, more analytical questions were subsequently asked concerning Quality 4.0 regarding various facets of information expressed by the respondents during the study. The interviews and quotes are verbatim and indicate participant number (P number), as pseudo names are given for anonymity. The information gathered was added to ATLAS Ti9 software. Twelve senior managers participated in this study. The sample size was judged to be enough as the data was saturated because no new themes were emerging (Antony et al., 2016; Guest et al., 2006; Gupta et al., 2020; Saunders et al., 2018). The average years of experience of the senior managers were found to be 15 years. They have also executed on an average about 4-5 Quality 4.0 projects each within their organisations. For the qualitative data analysis, this study followed the grounded theory methodology (Hussein et al., 2020). Three techniques of open coding are creating a list of themes within data and axial coding by categorising or linking theme subcategories and selective coding by condensing specific or excessive categories into higher-order themes (Cascio et al., 2019). Open coding consisted of identifying individual meaning units; in axial coding, these were categorised, or sub-categorised and selective master themes or selective coding were linked (Charmaz and Belgrave, 2007). Using the member checking technique, the data was verified, memoing to track the themes while coding and triangulation by multiple investigators (Creswell, 1999). Figure 1 summarises the data analysis process.



**Figure 1:** Data analysis process (Source: Author constructed)

As mentioned previously, 12 questions were asked about Quality 4.0 to the respondents. The themes of Quality 4.0 that were investigated are the 1) definition of Quality 4.0, 2) benefits of Quality 4.0, 3) motivations for Quality 4.0, 4) readiness factors for Quality 4.0, 5) the role of Leadership in Quality 4.0, 6) challenges for Quality 4.0 7) CSFs of Quality 4.0 implementation, 8) tools of Industry 4.0 that can be utilised in Quality 4.0, 9) measures of success for Quality 4.0, 10) topics for the curriculum of Quality 4.0, 11) hard and soft skills required and 12) examples of implementation or application of Quality 4.0 projects.

## Results

The word cloud in figure 2 depicts the most important themes, which have surfaced from the interviews. The word cloud highlights the most frequently utilised author keywords in the of the selected works. The word's size and centrality in the cloud represent its relative prominence in terms of the respective theme (Munoz Lopez, 2010). This is further the most effective method to visually communicate the most frequent words of text documents (Lohmann et al., 2015). As the study's objective was to understand the perception of respondents, through frequently used words from interviews, word cloud afforded a better means of collating, representing and analysing the most frequently used data visually. The main keywords that appear include quality, process, technology,





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3 *collaborative technology to deliver business solutions”(P10), “Quality 4.0 is the utilisation of the*  
4 *latest technologies for improving product quality” (P7), and “Quality 4.0 is using modern technology*  
5 *that is around us, networks, computers for data analysis and continuous improvement to improve*  
6 *our product quality and process quality”(P5).*  
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9 In summary, Quality 4.0 can thus be thought of as combining new technologies and standard quality  
10 tools and methods to achieve superior performance, higher operational excellence, and optimal  
11 innovation. Critically analysing the qualitative data, this study proposes a preliminary definition of  
12 Quality 4.0 is *“the use of advanced technologies such as IoT, CPS, Cloud computing to design, operate*  
13 *and maintain adaptive, predictive, self-corrective, automated quality systems along with improved*  
14 *human interaction through quality planning, quality assurance, quality control and quality*  
15 *improvement to achieve new optimums in performance, operational excellence, and innovation to*  
16 *meet the vision, mission and goals of an organisation”*. However, the authors feel that the definition  
17 proposed here should further be refined based on future research, and this will be the focus of the  
18 next stage of our research. Furthermore, the respondents in this study explicitly stated the  
19 importance of both technological and human components working in a goal-directed manner to  
20 implement Quality 4.0 to meet the business goals successfully. These respondents further reiterated  
21 the importance of the use of modern technology in the different components of quality systems  
22 along with increased interaction of human elements so that it can augment the human capabilities,  
23 increase transparency, auditability, and traceability, facilitate the data-driven decision making,  
24 establishing systems for continuous improvement, and promote systems thinking.  
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#### 28 *Motivations for Quality 4.0*

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30 The research question “what are the motivations for and benefits of adopting Quality 4.0?” were  
31 analysed based on how many respondents gave examples of their organisational motivations in  
32 implementing Quality 4.0. Some of the comments were; *“We can remove human inspection, let the*  
33 *machine carry out a visual inspection and decide if the parts are good or bad”(P4), “We can utilise*  
34 *process information to leverage upstream opportunities”(P9)*. Respondents also commented on the  
35 “synergy” between Lean and Quality 4.0 to motivate for Quality 4.0 implementation. The  
36 participants discussed the benefit of its implementation and discussed how LSS could be “aligned”  
37 with Quality 4.0”. Quality 4.0 driven LSS is becoming imperative for organisations, and many authors  
38 have discussed the linkage between Lean and Quality 4.0 (Yadav et al., 2021). Lean Six Sigma and  
39 Industry 4.0/Quality 4.0 can create differentiation in performance and improve organisations'  
40 competitiveness, besides making them future-ready. Many of the CSF's involved in Lean Six Sigma  
41 deployment are all common to Quality 4.0 implementation (for example, management support and  
42 training). Data management tools of Quality 4.0, such as Cloud Computing and Big-Data, can  
43 accomplish many elements of LSS by eliminating nonvalue added steps and improving flow (Park et  
44 al., 2017).  
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#### 48 *Critical Success Factors for the implementation of Quality 4.0*

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50 To gain a complete understanding of Quality 4.0, in addition to motivations, the respondents were  
51 asked what the CSFs for the adoption of Quality 4.0 in organisations were. Sony et al. ( 2020)  
52 described eight CSFs for implementing Quality 4.0, including top management support,  
53 organisational culture, leadership, vision & strategy, knowledge and awareness of Quality 4.0,  
54 customer-centric approach, supplier management and training [4]. The respondents echoed Sony's  
55 eight CSFs in this study too. There is a  
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3 need for *“a clear vision and strategy”*(P9), *“ the Quality 4.0 strategy needs to be communicated,*  
4 *clear and visualised for everyone”*(P11), and there should be *“ clear buy-in from everyone and*  
5 *acceptance of change”* (P7). Ensuring customer focus was another important theme to ensure that  
6 technology was not implemented that did not add value to customer satisfaction and that the  
7 technology was understood before it was implemented in terms of its benefits. One respondent  
8 stated, *“There is no point implanting sensors if we cannot get information from the sensors or worse*  
9 *get the information and we do not understand what to do with it!”*(P3). Another example of not  
10 understanding the technology was from one respondent from the automotive industry who stated, *“*  
11 *we implemented a robot to replace human inspection. However, the robot cannot handle the*  
12 *exceptions and rejected good product; technology is not always the solution”*(P1). Interestingly as  
13 aligned with the robot example mentioned earlier, the theme of LSS arose in terms of *“utilising*  
14 *DMAIC and problem-solving methodology”*(P10) to deploy Quality 4.0 as a CSF for implementation to  
15 ensure *“you solve a problem, not just adopt the technology”*(P9).  
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### 20 *Organisational Readiness for Quality 4.0*

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22 The research question *“What the organisational readiness factors of Quality 4.0”?* was asked to help  
23 understand the readiness factors for Quality 4.0. The respondents in this study are remarked on the  
24 importance of how ready an organisation should be to implement Quality 4.0 and take advantage of  
25 the technologies of Industry 4.0 as a readiness factor. Quality 4.0 deployment will shift focus from  
26 the operationally oriented task of creating and executing a quality strategy to holistically apply  
27 quality across the entire organisation (Antony and Sony, 2021). The organisation's readiness  
28 depends on how well an organisation is ready to implement the technologies of Quality 4.0 in its  
29 respective organisation to meet the organisation's objectives and goals. Quality 4.0 digitally  
30 transforms an organisation through automation and data integration to meet its quality and  
31 customer satisfaction goals. Having adequate resources to implement Quality 4.0 strategy and  
32 project documents was a recurring theme among the respondents – *“need dedicated people to*  
33 *deploy -have a project to digitise and measure each phase”*(P9), *“need human resources to*  
34 *deploy”*(P4), *“we need a top-down net approach with adequate resources allocated”*(P11).  
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### 37 *The benefits of Quality 4.0*

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39 The research question of the benefits of Quality 4.0 in an organisation was analysed to get a  
40 practical understanding of quality. The application of digital technologies can change the quality  
41 in various ways; for instance, an organisation can monitor processes and extract data from real-time  
42 sensors (Birkel and Müller, 2021). While many respondents outlined the benefits of quality,  
43 customer satisfaction, and improved products, the themes of how revolutionary Industry 4.0  
44 technology will be to quality professionals were reoccurring. *“No more pulling and pooling of data -*  
45 *do it once and not over and over again”*(P9). Another respondent stated, *“The ability to transform*  
46 *customer service that quality 4.0 will provide, for example, will be the ability to detect faults via*  
47 *sensors that will ensure customer safety and urge them to service their products”*(P3). McKinsey  
48 outlined the benefits and application of technology in Quality 4.0 as smart Quality controls and  
49 Quality assurance, process and product mastery, smart quality ways of working and compliance  
50 foundation (Carpintero et al., 2021). Many benefits were highlighted in the interviews by the  
51 participants, as highlighted in figure 4. These benefits were collated and collected and ranked  
52 according to how often they were mentioned, as outlined in Figure 1. The respondents cited big data  
53 tools, improved data analytics, and predictive analysis regarding the data management side of a  
54 Quality professionals' job. The benefits for quality managers in terms of lean program enhancement,  
55 waste reduction, error proofing and enhanced automated quality checks are also highlighted. There  
56 was an overwhelming response from interviewees that Quality 4.0 would make the respondents  
57 lives easier.  
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The benefits of technology for quality have been expedited through COVID-19, for example, in QMS system compliance audits as outlined in Table 2. Traditional Quality management is about compliance to a QMS and getting audited against that relevant QMS to ensure the QMS is effective. Some of the respondents were from the more regulated industries or consultants to those industries (medical device, pharma, aviation and automotive), and these industries are used to have regular and frequent compliance audits by different regulatory bodies and customers.

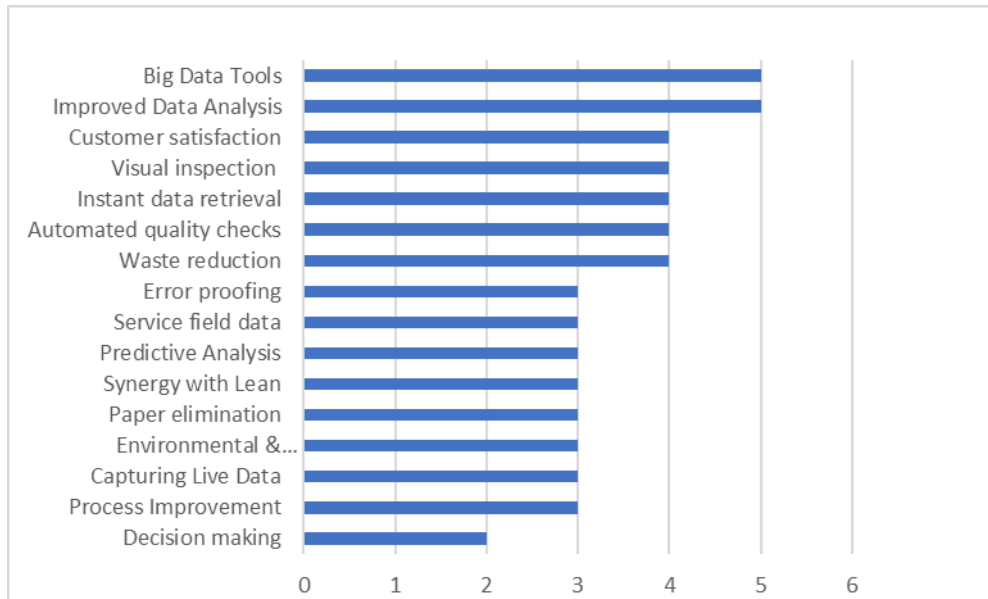


Figure 4: Benefits of Quality 4.0 from the interviews

Table 2: Benefits of Quality 4.0 Selected Quotes

<p><i>"We were audited and had our lab-record reviews and other documents reviewed remotely, harnessing digital technologies. The regulator conducted a virtual audit including remote document reviews, video conferencing, and utilised software for virtual site visits to conduct virtual inspections" P7</i></p>
<p><i>"We switched to an eQMS system, and instead of having to retrieve documents from an archiving facility before the audit and look for them -we were able to find documents at a click." P4</i></p>
<p><i>"Engineers were working on their projects during the audit rather than carrying out non-value add tasks of searching through boxes of documents for documents required by the auditors". P6</i></p>

*Measuring Quality 4.0 effectiveness and success*

To understand the benefits fully, the effectiveness or success of the Quality 4.0 program should be understood. Hence the respondents were asked how the success or effectiveness of Quality 4.0 can be measured; many respondents were unanimous in citing benefits that can be measured in terms of customer satisfaction, headcount reduction, market share increases, financial impacts on profit.

The importance of tracking Quality 4.0 implementation and progress through KPI's was also a dominant theme in order to measure its effectiveness. An example of a successful tangible measure and completed Quality 4.0 project was removing a paper-based system resulting in *"document approval timelines reducing from 3 weeks to 3 days"*(P7). The intangible measurements or not *"obvious"* measures of success that the respondents highlighted were environmental, green and sustainable benefits and increased and more efficient compliance to regulations through improved data integrity and electronic records.

#### *The Challenges associated with the adoption of Quality 4.0*

The respondents were asked the research question what the challenges of Quality 4.0 were to understand it from a practical perspective. The participants cited many examples of the challenges of implementing Quality 4.0, including *"How can we merge with the digital world?"*(P6), *"Our organisation has little or no knowledge or understanding of Industry 4.0, AI, IoT's, CPS"*(P3 ), and *"where do we start?"*(P12). Some new technology features will work for one industry or organisation but not for others *"one size does not fit all"*(P8). Product data can be used to remotely diagnose the product and reduce the time it takes to process customer service requests (Hrehova et al., 2021). One respondent stated that *"Unlike Apple and Tesla who can take data from products in the customer hands and track usage, performance patterns and user trends to drive marketing and future product design changes -in our industry, we do not have that opportunity as we are a wholesaler"*(P3). The interview participants reported the significant challenges in the adoption of Quality 4.0 to be lack of resources (financial, people, time etc.), not sure how to link Quality 4.0 with the organisational strategy and goals, lack of understanding the actual benefits of Quality 4.0 or indeed the definition of Quality 4.0. The initiative's high initial investment was deemed an obstacle caused primarily by the fact that the current Quality Management systems (QMS) and Continuous Improvement (CI) system is working and delivering good results in terms of compliance to regulations, customer satisfaction, predict customer or patient safety. Hence, organisations are unsure of the need for it.

**Table 3:** Challenges of Industry 4.0 – quotes from participants

<i>"Our changes have to go through long engineering approval processes due to the regulatory nature of our industry". P2</i>
<i>"Challenges will be to ensure that automation keeps quality levels the same as non-automated" P2</i>
<i>"Culture is hard to change". P12</i>
<i>"Our current technology can be old, e.g., production equipment not compatible with Industry 4.0 technology.... So, 100% integration with data systems can be an issue". P11</i>
<i>"Many organisations have little or no knowledge, or understanding of Industry 4.0, big data, Artificial intelligence, digital twins, machine learning - organisations do not understand it. How can we merge with the digital world"? P1</i>
<i>"In the new environment, where everything is digital, we still need to have people and problem-solving."P6</i>

*"Challenges of Quality 4.0 adoption are to prioritise capacity, a willingness to change, be open-minded, keeping the entire workforce in the loop and creating acceptance of workforce". P5*

*The complex and soft skills for Quality Professionals to embrace Quality 4.0.*

The authors would argue that the role of Quality professionals will change with the evolution of Quality 4.0; hence the respondents were asked what does Quality 4.0 mean for future quality professionals regarding soft skills, hard skills of quality professionals?. The respondents explicated that advances in artificial intelligence, machine learning, and software automation will impact human employability in an organisation and affect how Quality professionals carry out their roles. The theme of data analysis and data mining was recurring amongst participants, as was understanding the technologies. The definition of data science, in general, can be viewed as *"the process of asking questions and getting answers from data"*(P9). By that definition, quality professionals of tomorrow should need to be well acquainted with data science and data analytics skills (Duarte and Dame, 2019). Moreover, apart from data analytics skills, it was also observed that project management, knowledge in continuous improvement methodology, and change control are also key skills required by the quality professionals of tomorrow. Some of the core skills highlighted by the interviewees are explicated in table 4.

**Table 4:** The core skills required by Quality Professionals based on participants' views

<i>"Understand statistics; understand how to pull correct info; pool data and properly make correct assumptions. It is challenging to pull 4 or 5 data sets into one pool and model the information." P9</i>
<i>"We need root cause analysis skills." P2</i>
<i>"Change management and change control are not inherent to quality professionals." P11</i>
<i>"Quality 4.0 tools linked to deep learning, machine learning and artificial intelligence will be important". P1</i>
<i>"Soft skills are required and needed for change management for overcoming obstacles and challenges." P10</i>
<i>"Competencies on data mining, Artificial Intelligence, Machine learning, Big Data and overall Data science will be vital." P5</i>
<i>"Data literacy and competency leads to making the right decisions and analysis and graphical interpretation." P4</i>
<i>"Quality personnel do not get project management and change control training." P8</i>

Soft skill sets mentioned included change management, team working, communication, and motivational skills. Some examples explicated were *"Change management for new technology will be vital to managing the change and keeping stakeholders advised and engaged and sustainability"*(P11) and *"The core hard and soft skills for Quality 4.0 are dealing with change, having a positive approach and understanding the technology"*(P5). Change management has also been referenced as a challenge to implementing Quality 4.0, and it is an organisational readiness factor that should not be underestimated in Quality 4.0 adoption.

### *The Quality curriculum of the future for Quality professionals*

Industry 4.0 has transformed the curriculum development of professionals (Fareri et al., 2020; Stachová et al., 2019). The quality discipline has transformed from quality as an inspection, quality as a design, quality as empowerment and quality as a discovery (Radziwill, 2018). Quality as discovery phase warrants a quality management system that uses an adaptive intelligent environment, quality tools and methods (Alzahrani et al., 2021). This demands that quality professionals be trained in the quality curriculum such as structured problem solving, data-driven decision-making, and leveraging cultural change to facilitate improvement, quality analytics, big data management, autonomous processes, quality compliance, and quality culture (Jacob, 2017). Therefore, we asked the research question on the educational curriculum for the development of Quality 4.0. Quality professionals are distinctively good at structured problem solving, data-driven decision-making, and leveraging cultural change to facilitate improvement. In Quality 4.0, these fundamentals will not change, even as the amount and variety of data increase (Radziwill, 2018). Once the big data analytics capability is built-in, the new curriculum incorporates Big data analysis tools. This is due to the synergy of Big data tools in different phases of CI programs (Kübler et al., 2017). Some of the curriculum options described by the participants are explicated in Table 5. Universities have already started working on a curriculum for Industry 4.0; several well-established university courses introduced various aspects of Industry 4.0 over the past few years (Babatunde, 2020; Radziwill, 2018). The ASQ has been working on the competencies and curriculum for future Quality professionals for several years (Kupper et al., 2019; Watson, 2019). Thus, the quality curriculum for future quality professionals will consist of core fundamentals of quality management and modern tools and technologies of ICTs. However, the future curriculum is evolving and is still a work in progress.

**Table 5:** Examples of Quality 4.0 curriculum topics based on qualitative data

<i>"Topics for curriculum should be: 8D problem solving, SPC, the curriculum would need a merging of skills and knowledge with data analytics and IT infrastructure; How to solve problems systematically, analyse data, predict data, process data collection, sensory tracking, and real-time reaction" P9</i>
<i>"Big data and machine learning, visual recognition, digital twins". P4</i>
<i>"We need a body of knowledge to go from Industry 4.0 to Quality 4.0 -this is HUGE in terms of curriculum development." P10</i>
<i>"Statistics, statistics, statistics!" P3</i>

### *Leadership role in Quality 4.0*

Leadership plays an essential role in implementing any initiative within the organisation (Antony et al., 2018; Hirtz et al., 2007). Hence, we asked the research question what roles leadership plays in the successful adoption and deployment of Quality 4.0?. Then to explore the role of Leadership in Quality 4.0, the themes highlighted were demonstrated in the leadership word cloud in Figure 5. Much of the previously cited literature and respondent opinions have discussed the role of top management in Quality 4.0 in terms of a critical success factor for Quality 4.0 and an organisational readiness factor. The respondents emphasised the importance

of leadership very vocally ahead of all the other Quality 4.0 themes discussed. Industry 4.0 implementation calls for the digital transformation of the organisation (Verhoef et al., 2021).



Figure 5: Leadership word cloud

Leadership will be the most critical aspect in guiding the organisation, firstly in the digital transformation process and later leading the organisation in the digital environment [37]. Examples of quotations from the respondents are explicated in Table 6. The importance of leaders in setting direction was emphasised repeatedly; *"From a shop floor point of view, Leadership need to get buy-in and get acceptance of change -show employees that the data is not being used against them"*(P5 ). The leadership characteristics which a leader should possess would be 1) innovative visionary, 2) networking intelligence, 3) adaptable, 4) motivating coach, 5) digital intelligence, 6) complexity master, 7) social intelligence, 8) democratic delegative, 9) agile, 10) learning by errors, 11) role model, 12) diversity champion, 13)decisive courageous, 14) creativity, 15) openness, 16) self-awareness, 17) ambidexterity, 18) knowledge-oriented, 19) digital talent scout, 20) employee-oriented, 21) business intelligence, 22) lifelong learner, 23) ethical (Klein, 2020). The respondents' answers correlated with the literature using terms concerning leadership, for example, *"motivators"*, *"allocating resources"*, *"understanding technology"*, *"seeking consensus"*, *"multitasking"*, and *"top-down management"*(P1-P12). The respondents also discussed the role of leaders specifically in terms of technology transformation managers *"The leadership role starts with learning about technologies. We will not want every technology, but we need to learn about fundamentals and how it can be applied"*(P10). A strong leader will lead the employees and other stakeholders in a goal-directed manner to meet the organisation's objectives, and that opens the door to Quality 4.0 transformation".

Table 6 The Role of Leadership in Quality 4.0 – comments from interviewees or participants

<p><i>"Leaders must understand the iterative nature of Quality 4.0 and plan; accordingly, Leadership is the final link to describe what success will look like."</i>  <b>P7</b></p>
<p><i>"Fund the implementation of the "cycle" -Digitalisation and software, programming, personnel to do analytics, all opportunities to leverage info."</i> <b>P9</b></p>
<p><i>"Leadership involvement "talk the talk and walk the walk."</i> <b>P2</b></p>



<i>"Be the sponsor of the Quality 4.0 strategy." P1</i>
<i>"Leadership should set the direction, vision, ownership for strategy, resources and budget." P7</i>
<i>"Investment in primary phase to avoid problems with implementing" P6</i>
<i>"Leadership role is to listen, understand, be connected, and the benefits of technology understood by them." P6</i>
<i>"The Quality 4.0 vision of the future needs to be connected with reality. The current state cannot go to the future state without engagement." P3</i>
<i>"Leadership will say "we need it" and sprinkle "fairy dust" and expect change. There is work behind Quality 4.0 and its priority and capacity need to be committed to". P5</i>

### *Industry 4.0 tools relevant to Quality 4.0*

To answer the research question "What Industry 4.0 technologies can be leveraged for Quality 4.0?", the participants were asked to discuss what tools from Industry 4.0 technology can be most applicable or valuable in Quality 4.0 based on their opinions and personal experiences. Tools such as real-time control of machines, application (APP) driven process control, Big Data, real-time scorecards, cloud computing, artificial intelligence, blockchain, and new apps, such as Augmented Reality (AR)/Virtual Reality (VR), provide new forms of collaboration across operations. This collaboration can exist across all parts of a production cycle and also within a supply chain and can help drive quality improvement, control and assurance (Hrehova et al., 2021; Rainnie and Dean, 2020; Santos et al., 2021). The respondents cited that predictive analytics, sensors and tracking, and electronic feedback loops are the most critical technologies for driving Quality 4.0. Kupper et al.(2019) have reinforced the respondents' opinions, stating that predictive analytics will significantly affect the quality and bottom lines within five years. Investments in predictive analytics for quality management will be a significant source of competitive advantage. The respondents discussed using predictive analytics, particularly preventative maintenance, tracking parts in the field that are failing or wearing and using that data to feedback into the design process. Analysis of data on wear and tear and failure rates of process equipment can anticipate failure modes, highlight the need for preventive maintenance and monitor incoming supplier parts quality. *"We can use Quality 4.0 to maintain data on the % failure rate of parts and monitor wear and tear of parts"*(P3), *"if we can use software to alert customers to issues with their products and that personal action or professional maintenance is required, we will see fewer safety issues and quality complaints"* (P9 ). Identifying replacement parts before breakdown would be a breakthrough in reducing maintenance and breakdowns and enhance product functionality for longer. The theme of using field service data to feedback into the design process to reduce future product warranty claims was also highlighted by the respondents. Further, one participant from the elevator (or Lift) Industry stated, *" We can use service data, but as we cannot get our hands on it, most elevators are maintained by our customers own maintenance departments or service providers. If we can expand our business into servicing, we can not only increase our profits, but we can utilise data to drive better preventive maintenance and ultimately product design"* (P3).

Being aware of the wear and tear on equipment parts and final product components and their reliability can ensure downtime reduction and opportunity for product design improvements. The Internet of Things approach allows manufacturers to analyse product data generated from

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3 devices, and thus, they are informed about the quality of the production processes in real-time.  
4 Automation can create a process that a computer executes, and the computer can make  
5 decisions for an operator to approve or adjust, or the computer can make and execute  
6 decisions. One respondent mentioned, "*Big data and sensors are important for us if looking at*  
7 *digital components, for example in our cars, and the sensors can collect data and thus we can*  
8 *improve the safety of our cars*" (P9). Similarly, machine intelligence is a spectrum: An algorithm  
9 can provide advice, act with approvals or adjustments, or act independently. However,  
10 organisations must decide what value or problem they want to solve and introduce various  
11 degrees of intelligence and automation into their processes.  
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#### 16 *Quality 4.0 Application examples*

17 To further complement the understanding of Quality 4.0, the respondents were asked to give  
18 examples of Quality 4.0 projects that they had worked on in their current organisation or past  
19 employments. This will help to understand Quality 4.0 from a practical perspective in terms of  
20 its real-life application. In addition, the participants discussed projects that they were currently  
21 deploying and any advantages or disadvantages associated with these projects. The consensus  
22 amongst participants was that the projects they were involved in related to Industry 4.0 and  
23 Quality 4.0 were positive and greatly benefited them personally in aiding them in doing their  
24 jobs and helped their organisations.  
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27 **Table 7** Quality 4.0 Projects & Application Examples

28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60
<p><i>"We implemented an eQMS system -eliminated paper, we have real-time document retrieval, and real-time document approval". Another plus is remote compliance audits and not having to host auditors on-site. During COVID-19, we carried on working and approving documents as usual while remaining compliant." P6</i></p>																																
<p><i>"Equipment automation projects -we now have a semi-automated production line with 100% in-process testing and no sampling inspection. We are secure that it is 100% inspection, and it is not adding any extra time to production as it is carried out in the process as product is being made." P7</i></p>																																
<p><i>"Quality 4.0 projects are investing more in sensors on board. Any kind of errors in machines is immediately broadcast to service people so they can go out with the right parts, and this reduces downtime and repair time." P7</i></p>																																
<p><i>"We developed an autonomous measurement test system for printed circuit boards". Processes driven by robots have been implemented, and we have designed interfaces between robot and test systems". P1</i></p>																																

"Implementing a central database, e.g., SAP, ERP." P3

The examples of eQMS and paperless systems discussed in Table 1 under the benefits of Quality 4.0 were also reiterated and expanded upon again in this question. A lot of the other Quality 4.0 project application examples given were manufacturing-based applications of digitalisation and technology. These examples of Industry 4.0 technology helped to provide benefits such as data improvement in process control, less reliance on inspections and testing as it is reactive and too late and can provide real-time data. These projects primarily brought about productivity and quality benefits. For example, one respondent discussed, "*we implemented a new lifting system; we got a 50% space reduction as well as improved safety*" (P2). The importance of data systems integrated central databases, and a complete end to end system that was interconnected was also a theme among projects being implemented in the participant's organisation. For example, "*we removed our legacy software and are currently taking down barriers between data pools by going into one super integrated system*"(P11).

#### *Managerial Implications*

Organisations can use this study to understand what Quality 4.0 means to industry in terms of the motivating factors, CSF's, challenges, and organisational readiness factors. This study also proposes a preliminary definition of Quality 4.0, which organisations can use to understand Quality 4.0 so that all stakeholders understand it in a similar manner. The role of leadership in setting direction, vision and ownership for Quality 4.0 implementation strategy is emphasised. This study also suggests the importance of leaders to get buy-in from the shop floor while implementing Quality 4.0. The leaders should devise a strategy to gain acceptance among employees, as a large amount of data collection for Quality 4.0 implementation can create suspicion among employees that it may be used against them. The study suggests the importance of synergy with Lean or

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3 LSS or Six Sigma with Quality 4.0 strategy. Therefore, while implementing Quality 4.0, managers  
4 should consider strategic areas of resemblance and devise Quality 4.0 implementation strategies.  
5 Among other challenges, the high initial investment was a concern for implementing Quality 4.0. The  
6 managers should consider the benefits of Quality 4.0 in terms of improved quality, customer  
7 satisfaction, better products, and services. Besides, the respondents were unanimous in suggesting  
8 Industry 4.0 technologies in meeting the Quality 4.0 goals. The cost of acquiring these new  
9 technologies may be higher, but the managers should consider the long term strategic importance of  
10 these technologies to meet Quality 4.0 goals which may set them apart from their competitors. Hard  
11 and soft skills are essential for the successful implementation of Quality 4.0; hence, the managers  
12 should strategically devise training strategies for employees to incorporate both of these elements.  
13 On the technological front, the managers need to devise strategies to incorporate Industry 4.0  
14 technologies such as predictive analytics, sensors and tracking, and electronic feedback loops, which  
15 will be decisive elements for driving Quality 4.0.  
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### 19 *Theoretical Implications*

21 This study extends the Quality 4.0 knowledge domain by defining Quality 4.0 from the perspectives  
22 of senior Quality 4.0 professionals. Besides, the motivation, benefits, challenges, CSF's,  
23 organisational readiness factors, skills, quality curriculum, leadership, Industry 4.0 relevant tools  
24 used in Quality 4.0 expand the theoretical spectrum of Quality 4.0 dimensions. It helps researchers  
25 as a preliminary guiding point while embarking on each of these areas. This study also explicates  
26 Quality 4.0 practical examples from industry which will help both Industry and Academia to  
27 understand Quality 4.0 from a practical point of view.  
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### 31 **Conclusion & Further work**

32 Organisations should make digital transformation and Quality 4.0 strategy an integral part of their  
33 corporate strategy and adapt their leadership styles to new ways of working. Organisations must  
34 also focus on building a workforce with the new set of skills required to perform data analytics,  
35 handle big data, and have more technology-centred supplier chain, production, and other functional  
36 area tasks. Organisations must install technology infrastructure that connects their processes and  
37 systems and assess their technology implementation in terms of measurement and results.  
38 Successful transformational change such as Quality 4.0 demands a full range of strategic, cultural,  
39 and technological issues. Organisations that want to implement Quality 4.0 and overcome challenges  
40 to the journey will be rewarded with better quality and competitive advantages via improved  
41 customer satisfaction, quality of the final product/service and improved operational efficiencies.  
42 Companies that embark on the path to smart quality must make a sustained commitment to change.  
43 The study proposed a qualitative study on the viewpoint and understanding of Quality 4.0 in  
44 automotive, power, manufacturing, cosmetic, and elevator organisations and with consultancies  
45 working across industries. Utilising qualitative methods, the study explored various aspects of  
46 Quality 4.0 in terms of benefits, challenges, readiness, among others. The limitation of the study was  
47 that the data collection was qualitative, and therefore subjective judgments of quality and  
48 operational excellence professionals were captured. Moreover, the number of interviews may not  
49 be sufficient to make robust conclusions from this study. However, a future study can explore the  
50 same topic quantitatively via a survey questionnaire, and the authors are planning to conduct more  
51 interviews until the findings are more robust and convergent. Also, it would be helpful to study an  
52 organisation as a longitudinal case study and understand this journey to Quality 4.0 from its  
53 adoption stage to progress further to implementation with some examples of projects executed in  
54 different business functions. The authors are planning to carry out such case studies in different  
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industrial settings (manufacturing vs service, large vs medium size) where they hope to access Quality 4.0 readiness and application to gain more insight into Quality 4.0 topics.

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