5th Asia Pacific Conference on Industrial Engineering and Operations Management
Tokyo, Japan, September 10-12, 2024
Publisher: IEOM Society International, USA DOI: 10.46254/AP05.20240169
Published: *September 10*, 2024

Quality 4.0 Readiness Evaluation of Medical Technology Companies in Malaysia

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Abstract

The emergence of Industry 4.0 technologies and the subsequent digital transformation necessitates a paradigm shift in quality management practices. This shift has led to the development of Quality 4.0, a nascent field with limited research on its application within specific industries, particularly the medical technology sector. This study aims to bridge this gap by establishing an instrument to assess the awareness and readiness for Quality 4.0 implementation among Malaysian medical technology companies. The research employed a three-phased approach. Phase 1 involved a comprehensive literature review to identify key factors influencing Quality 4.0 implementation readiness. In Phase 2, a survey instrument was developed based on the literature review. This instrument underwent rigorous validation by a panel of academic and industry experts before pilot testing. Phase 3 utilized the pilot study results and respondent feedback to refine the survey. Subsequently, the final instrument was administered to six case study organizations within the medical technology sector located in Johor, Malaysia. Data analysis of the field survey results assessed the current awareness and readiness levels of each organization, generating an "organizational score." These scores were then used to categorize the case studies into five distinct Quality 4.0 implementation readiness levels. This research contributes valuable insights into the current state of Quality 4.0 awareness and readiness within the Malaysian medical technology sector. The developed instrument offers a valuable tool for future research and practical applications, enabling medical technology companies to evaluate their own readiness for adopting Quality 4.0 practices.

Keywords
Quality 4.0, Medical Technology, Readiness Assessment, Industry 4.0, Digital Transformation

1. Introduction
Established quality management standards, like ISO 9001 and ISO 13485, have traditionally been the backbone of ensuring organizations meet pre-defined quality standards. While these standards offer a structured approach, the field has also been heavily influenced by the philosophies of quality gurus like W. Edwards Deming, Joseph Juran, and Philip Crosby (Juran 1992; Deming 1982; Crosby 1979). Their emphasis on continuous improvement, customer focus, and data-driven decision-making complements the structured nature of established standards. However, the advent of Industry 4.0 presents both opportunities and challenges, prompting a paradigm shift towards Quality 4.0 (Fleisch et

al. 2015). This transformative approach leverages cutting-edge technologies like big data analytics, Internet of Things (IoT), artificial intelligence (AI), and cloud computing to significantly enhance quality management processes and drive continuous improvement within organizations (Fleisch et al. 2015).

Like all other industries, the medical technology sector is also rapidly adopting Industry 4.0 technologies, highlighting the need for data-driven quality management approaches like Quality 4.0. While research on both Industry 4.0 and Quality 4.0 is flourishing, their specific application within the highly regulated medical technology sector remains a gap in knowledge. Existing Quality 4.0 measurement tools, often designed for general manufacturing, fail to address the unique complexities and stringent quality requirements of medical devices (Kumar et al.2020; Wang et al. 2019). This research aims to bridge this gap by focusing on the medical technology sector in Malaysia.

This research employed a three-phased approach. Phase 1 involved a comprehensive literature review to identify key factors influencing Quality 4.0 implementation readiness. Based on this review, Phase 2 came across whereby a survey instrument was developed and rigorously validated by experts identified from local academia and also practitioners from within the field of quality management. In Phase 3, pilot testing and respondent feedback further refined the instrument. The final instrument was then administered to six medical technology companies in Johor, Malaysia. Data analysis assessed current awareness and readiness levels, generating "organizational scores" for categorization into five distinct Quality 4.0 implementation readiness levels.

1.1 Objectives

The objectives of this research are to determine factors influencing Quality 4.0 readiness, understand the current level of awareness and the current level of readiness for Quality 4.0 adoption among medical technology companies in Johor, Malaysia.

2. Literature Review

Quality management has evolved through distinct eras: Quality 1.0 (inspection & productivity), Quality 2.0 (labor efficiency & waste reduction), and Quality 3.0 (customer satisfaction & continuous improvement) (Javaid et al. 2022). Quality 4.0 leverages Industry 4.0 technologies (AI, Big Data etc.) for automation, data-driven insights, and continuous improvement (Radziwill 2018). It aims to achieve excellence through a socio-technical system, optimizing human resources, technology, and quality management (Radziwill 2018; Watson, 2019). This approach enables real-time monitoring, proactive maintenance, and customer-centric manufacturing (Sony et al. 2020).

Moreover, Industry 4.0's emergence has spurred the evolution of quality practices, leading to Quality 4.0. This approach integrates advanced technologies like sensors, Big Data, and AI to achieve significant benefits (Sader et al., 2022; Radziwill 2018). Real-time monitoring from interconnected machines facilitates proactive maintenance, minimizing downtime and production disruptions (Sony et al. 2020). Additionally, data analysis from these machines empowers organizations to gain a deeper understanding of customer needs, enabling the design of products with a better balance of cost and value (Sony et al. 2020). Quality 4.0 fosters a shift towards design, safety, and service quality enhancement, going beyond traditional product-centric approaches (Hyun Park et al. 2017). Furthermore, prescriptive analytics algorithms offer solutions across all quality phases, aiding human decision-making and optimizing quality control, planning, and improvement (Soltanpoor & Sellis 2016). By leveraging these advancements, Quality 4.0 empowers organizations to achieve not only higher quality but also increased efficiency, reduced costs, and improved customer satisfaction.

While Quality 4.0 promises significant advancements in quality management, its adoption presents substantial challenges, particularly for Small and Medium-sized Enterprises (SMEs) (Li et al. 2021). Unlike their larger counterparts with ample resources, SMEs often struggle with limited financial capabilities. This hinders investments in essential technologies and infrastructure required for Quality 4.0, such as advanced sensors and data analytics tools (Butt, 2020). The lack of readily available skilled personnel to manage and operate these complex systems further impedes adoption. SMEs may not have the resources to train existing employees or attract qualified professionals with expertise in these emerging technologies (Li et al. 2021). Additionally, the level of preparedness for Quality 4.0 varies significantly across different industries. High-tech sectors like automotive and aerospace are more receptive due to their constant need for precision and efficiency. Conversely, traditional and labor-intensive sectors like construction may find it challenging to adapt existing workflows to integrate advanced technologies (Li et al. 2021).

Quality 4.0 builds upon traditional quality practices by integrating advanced technologies like data analysis and AI (Jacob 2017). However, successful implementation necessitates a skilled workforce equipped with these new capabilities. Research by the American Society for Quality and Boston Consulting Group (2019) emphasizes the importance of fostering a "quality culture" alongside strategic planning to facilitate this technological transformation. Santos et al. (2021) identify a new skillset for "quality managers 4.0" that encompasses critical thinking, communication, and leadership. Similarly, Sony and Naik (2019) outline readiness themes for Quality 4.0, including digital literacy within the organization and a focus on employee adaptability.

The World Economic Forum (2023) predicts a future job market demanding less reliance on manual skills and basic technology expertise. Conversely, skills like critical thinking, problem-solving, and technological literacy will be crucial. Additionally, "human" skills like creativity, communication, and emotional intelligence are expected to see a rise in demand. This highlights the need for a workforce that can embrace technology while retaining irreplaceable human traits (World Economic Forum 2023). Finally, Quality 4.0 fosters a culture of openness and collaboration through data sharing and analytics (Sony et al. 2020). This underscores the importance of an organizational culture receptive to change.

Successful Quality 4.0 implementation hinges on an organization's readiness across six key dimensions (Hizam-Hanafiah et al. 2020). First, a skilled workforce with expertise in data analysis, critical thinking, and problem-solving is essential (Santos et al. 2021; World Economic Forum 2023). Second, a well-defined vision, actionable plans, and a strong customer focus are crucial for strategic alignment (Sony et al. 2020). Third, embracing enabling technologies like IoT, Big Data, and AI unlocks the full potential of Quality 4.0 (Frank et al. 2019). Fourth, streamlined and optimized business processes minimize disruptions (Siemieniuch and Sinclair 2004). Fifth, strong top management support, open communication, and a culture of trust empower employees (Siemieniuch and Sinclair 2004). Finally, fostering a culture of continuous learning and adaptation creates a "knowledge-learning organization" well-positioned for success (Martin-de Castro et al. 2011). By addressing these readiness factors alongside a robust IT infrastructure, organizations can establish a solid foundation for successful Quality 4.0 implementation.

3. Methods

This research aims to develop a survey instrument for evaluating an organization's awareness levels and their readiness level for implementing Quality 4.0. This instrument will utilize a multi-item scale approach (Churchill Jr, 1979) to comprehensively capture the various factors relevant to Quality 4.0 implementation. The first step in developing the questionnaire involves identifying the indicators for measuring the current level of organizational awareness towards continuous quality improvement and Quality 4.0. Based on the reviewed literatures, ten (10) Quality 4.0 awareness indicators were derived and modified from the studies conducted by Zulfiqar et al. (2023), Maganga & Taifa (2022), and Sony et al. (2020) and as provided below:

Quality 4.0 Awareness Indicators

- Continuous quality improvement places emphasis on meeting customer requirements.
- Continuous quality improvement is intended to satisfy customer needs.
- Continuous quality improvement is essential in reducing quality costs, losses, waste and inefficiency across end-to-end production cycles.
- Continuous quality improvement requires involvement of all employees.
- Continuous quality improvement utilizes digitalization of quality control system.
- Continuous quality improvement utilizes real-time quality inspection data.
- Continuous quality improvement process integration requires interconnectivity with digital platforms.
- Continuous quality improvement benefits from cutting-edge technologies such as Artificial Intelligence (AI), Machine Learning (ML), Blockchain and Big Data.
- Continuous quality improvement benefits from enabling technologies such as cloud computing, 5G network and Internet of Things (IoT).
- Continuous quality improvements integrated with automation via virtual reality (VR) and augmented reality (AR) improves overall organizational performance and competitiveness.

Subsequently, five (5) key factors and sub-factors that contribute to a successful implementation of Quality 4.0 were identified and summarized in Table 1 below. These factors and sub-factors will serve as the foundation for developing

the survey instrument which intends to measure the organizational readiness in implementing Quality 4.0, which will be further elaborated in this paper.

Table 1. Quality 4.0 Readiness Assessment Factors and Sub-Factors

Factors	Sub-factors	Source(s)
Leaderships	▪ Strategic planning ▪ Vision and strategy ▪ Leadership commitment	Zulfiqar et al. (2023); Sony et al. (2020); Santos et al., (2021); Sony et al., (2021); Antony et al. (2023)
Organizational Culture	▪ Overcoming Hurdles ▪ Collaboration ▪ Transformational Change Culture	Zulfiqar et al. (2023); Siemieniuch and Sinclair, (2004); Antony et al. 2020; Chiarini, (2020); Antony et al., (2021); Santos et al., (2021); Sony et al. 2021 Maganga & Taifa, (2022)
Employee Competency	▪ Education & Skillsets ▪ Employee experience ▪ Optimization of human resources	Zulfiqar et al. (2023); Radziwill, (2018); Benesova & Tupa, (2022); Alcacer & Cruz-Machado, (2019);
Technology Utilization	▪ Utilization of Industry 4.0 technologies ▪ Vertical and horizontal integration ▪ Data automation	Zulfiqar et al. (2023); Sader, Husti & Daroczi, (2022); Radziwill, (2018); Jacob, (2017), Sony, (2018); Mazzuto & Ciarapica (2019); Lalic et al., (2019)
Compliance	▪ Quality management practices ▪ Quality culture ▪ Customer-centric manufacturing	Zulfiqar et al. (2023); Sader, Husti & Daroczi, (2022); Antony, Sony & Cudney, (2020); Javaid *et al*., (2021); Sony *et al*. (2021), Jacob, (2017)

A user-friendly five-point Likert scale questionnaire (1 = "Strongly Disagree," 5 = "Strongly Agree") was developed to assess Quality 4.0 awareness and readiness indicators. The usage of five-point Likert scale intended to minimize respondent frustration which is anticipated among respondents when answering lengthy surveys (Babakus & Mangold, 1992; Sachdev & Verma, 2004; Leung, 2011) besides ensuring a consistent and comparable data for analysis. The survey also gathers demographic data for conducting descriptive statistics.

To ensure the accuracy and effectiveness of the questionnaire, a validation process was conducted (Middleton 2022). While reliability focuses on consistency across administrations, validity ensures the instrument truly measures Quality 4.0 awareness and readiness. Although adapted from validated scales from past researchers, best practices necessitated further validation. Two types of validity assessments were conducted: content and construct validity. For content validity, seven experts (three academics and four practitioners) reviewed the instrument, ensuring clarity and question appropriateness related to Quality 4.0 implementation. These experts also reviewed the identified factors and sub-factors for relevance and completeness, providing valuable insights and identifying potential omissions. All feedback was documented and used to refine the questionnaire. The first survey instrument developed and refined consisted of 77 questions.

A pilot survey with 15 medical technology professionals from Johor, Malaysia (identified via LinkedIn) was conducted to evaluate the questionnaire's construct validity (Forza 2002). This is to ensure that the questions aligned with the research objectives and could be completed by busy industry professionals within a reasonable timeframe of 1 week (Couper & Miller 2008). Using IBM SPSS Version 29, the pilot test analyzed Cronbach's Alpha for each readiness assessment factor, aiming for a value above 0.7 (Nunnally 1975; Ercan et al. 2007). Initial results were promising (Cronbach's Alpha value above 0.8), but feedback indicated the 77-question survey was too lengthy. To

improve completion rates, items were removed from each factor while maintaining a Cronbach's Alpha above 0.7. This resulted in a final survey with 10 questions for awareness and 25 questions for readiness assessment. The pilot test thus helped further refine the questionnaire by identifying and addressing potential flaws before the full-scale deployment.

4. Data Collection

For full-scale survey, a list of 46 medical technology companies in Johor, Malaysia was obtained from the Malaysian Investment Development Authority (MIDA). The list was reviewed and subjected for a vetting procedure, which involves the identification of those companies that lacks an ISO 13485 certification and/or those who are no longer in operation in the state of Johor, Malaysia was meticulously excluded. This procedure yielded a final sample of 17 companies having an established ISO 13485 certification and are still operating in the state. Following a multiple case study approach (Yin, 2005; Zainal 2007), 10 target companies were selected from this pool for their location, size and ease of contact. Out of the ten (10) companies identified, four (4) companies opted not to participate in this study due to their internal company policies, leaving only six (6) companies who agreed to participate in this study. While the sample size of six (6) participating organizations was relatively small, this aligns with previous studies that employed a similar number of cases for comparable research objectives. (Zulfiqar et al.2023; Braaksma et al. 2013; Danese et al., 2021; Boyer & Swink 2008). To safeguard participant confidentiality, the six (6) participating companies were designated as Companies A to F. Given their varying levels of Quality 4.0 implementation, as outlined by Yin (2009), the study is expected to yield valuable insights.

4.1 Population size and sample design

A purposive sampling strategy (Maganga & Taifa 2022) was employed targeted at medical device manufacturers in Johor, Malaysia. Taherdoost (2017) suggests a formula for calculating sample size, where a confidence level of 95% corresponds to a Z value of 1.96 and a margin of error of 5% is represented by the E value (Taifa 2022). However, a crucial element, the population proportion (P), is unknown in our study. This value refers to the anticipated percentage of the target population possessing a specific characteristic relevant to the research question. In our case, the population of interest comprises all respondents working within the medical device manufacturing industry, encompassing all levels from supervisors to top management. Due to the uncertainty surrounding the true P value, a neutral starting point is necessary to determine a suitable sample size for this study.

$$n = \frac{P\,(100 - P)\ \times Z^2}{E^2}$$

Where,
n is the required sample size
P is the estimated percentage occurrence of a state or condition
E is the percentage maximum error required
Z is the confidence level at 95%

While sample size calculations often consider population proportion, Fowler (2002) argues this factor typically has limited influence on sample design. Key determinants of population representation often lie elsewhere. Therefore, we took an assumption that at least 10% of the respondents from all the target organizations will be those holding the positions of directors, general managers, department managers and supervisors from various departments such as Supply Chain, Production, Engineering, Quality from the target participating organizations. Based on the information gathered above, the sample size was calculated as below:

$$n = \frac{10\,(100 - 10)\ \times 1.96^2}{5^2} = 138.29$$

The sample size was determined as 138.29, however for distribution purposes and ease of calculation the figure was rounded-off to 140 respondents, as to achieve a 95% confidence level with a 5% margin of error. Questionnaires were distributed among directors, general managers, department managers, and supervisors within the 10 participating companies. Therefore, an average of 14 people from each target organization, covering all 10 medical technology companies identified.

4.2 Field Survey

An online survey platform, Google Forms, was chosen for its ease of use and integration with widely used Google Workspace applications. This platform facilitates quick data collection, processing, and customization for both researchers and participants (Ball 2019). Online surveys offer several advantages: speed and efficiency for global reach and rapid data collection, reduced costs through email and social media communication, and flexibility for collecting large amounts of anonymous data, mitigating social bias (Dillman et al. 2014; Tourangeau & Yan 2007; Curtin et al. 2005). These benefits make online surveys a valuable tool for researchers.

5. Results and Discussion

The data collection period spanned two weeks, from 26 May 2024 to 6 June 2024. A total of 60 responses were received from the 140 distributed surveys, resulting in a 43% response rate. This rate is considered acceptable based on standards suggesting a 20% minimum response rate (Cummings et al. 2001; Nulty 2008). With a response rate exceeding 40%, this study is likely to provide valuable insights into the research objectives.

5.1 Descriptive statistics

Descriptive analysis was conducted to understand the demographics of the respondents, including age, job title, education level, and years of experience. The results are summarized below:

- **Age:** Majority of respondents (70%) fell within the 31-40 age range. Smaller proportions were aged 41-50 (16.7%), under 30 (6.7%), and over 51 (6.7%). Refer Figure 1.
- **Job Title:** Over half of the participants held roles as engineers, executive, or supervisory positions (51.7%). Manager-level roles were held by 24 respondents (40%), and senior leadership positions were held by the remaining 8.3% (Figure 4.2). Refer Figure 2.
- **Education:** A significant portion of respondents (68.3%) possessed a Bachelor's degree or equivalent qualification. Master's degrees were held by 15%, and diplomas by 6.7%. Refer Figure 3.
- **Work Experience:** Nearly equal proportions of participants had either less than 10 years (41.7%) or 11-20 years (41.7%) of experience. A smaller group had 21-30 years of experience (13.3%), and a very small number had over 30 years (3.3%). Refer to Figure 4.

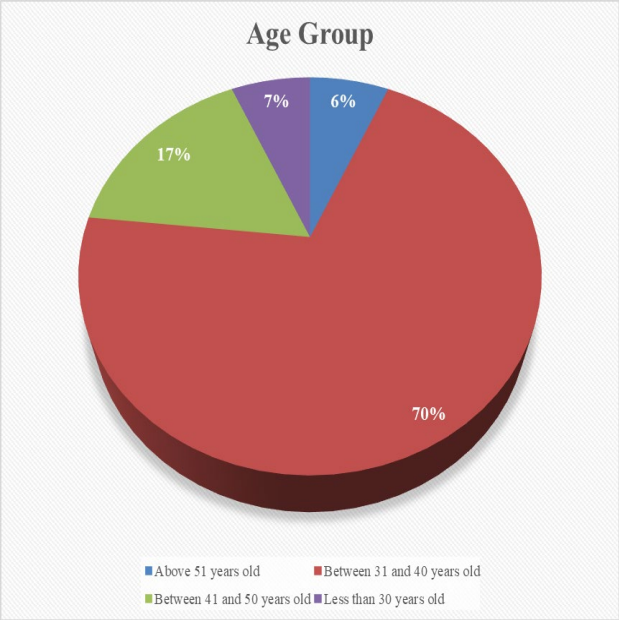

Figure 1. Age group

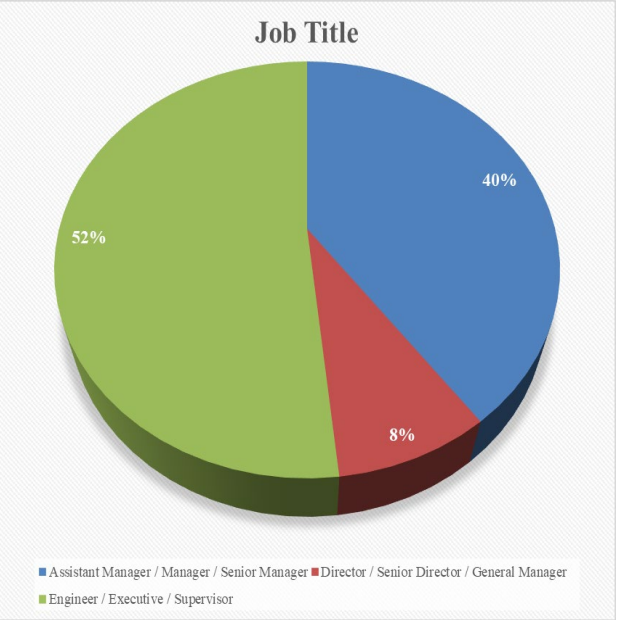

Figure 2. Job title

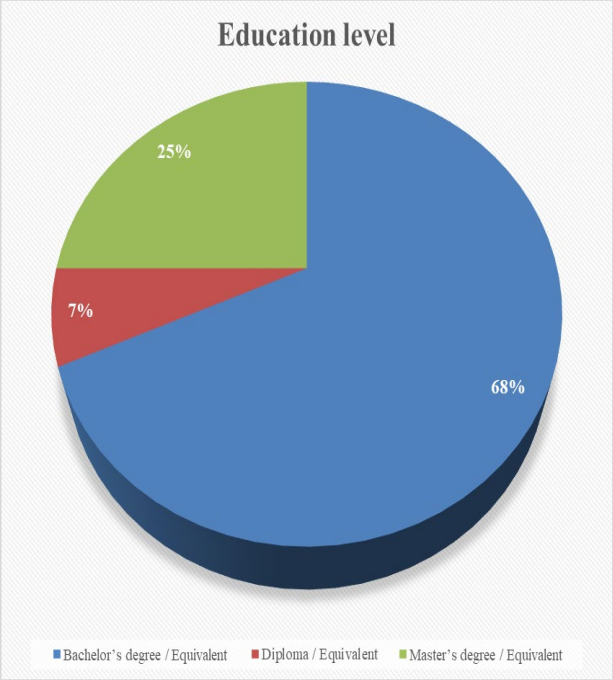

Figure 3. Education level

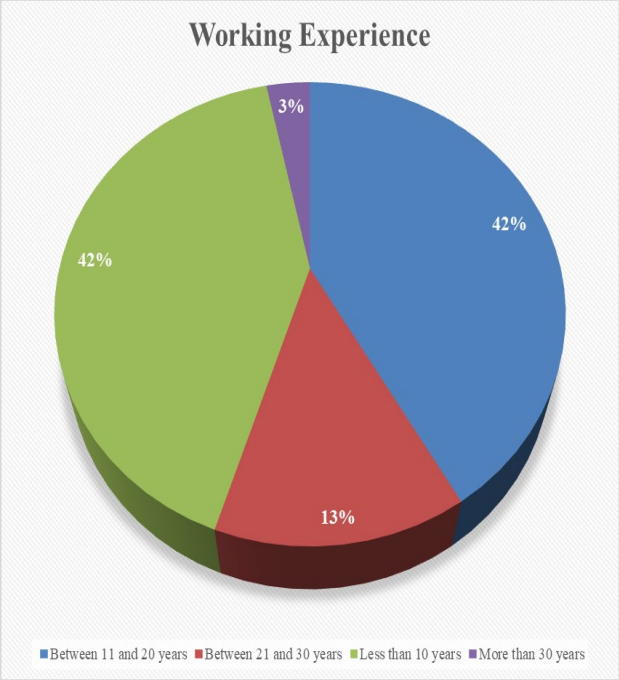

Figure 4. Working experience

5.2 Quality 4.0 Awareness Levels

The survey used ten awareness indicators (AW1-AW10), (Refer to **Table 2 is presented in (APPENDIX -**A) to assess participants' understanding of digital transformation in quality management practices and Quality 4.0. Analysis showed a consistent trend of high agreement. For example, over half of the respondents strongly agreed with the first four indicators (AW1-AW4), with minimal disagreement. The agreement remained strong for AW5-AW7, though slightly lower. The final three indicators (AW8-AW10) saw a wider range of responses, with strong agreement varying from 31.7% to 38.3%. This suggests a less uniform understanding of these specific aspects of Quality 4.0.

Table 3. Organizational Awareness Score

Organization	Mean Scores										Overall score
	AW1	AW2	AW3	AW4	AW5	AW6	AW7	AW8	AW9	AW10	
Company A	4.60	4.70	4.60	4.60	3.90	4.30	4.40	4.20	4.00	4.10	4.34
Company B	4.20	3.90	4.70	4.60	4.70	4.50	4.30	4.40	4.20	3.90	4.34
Company C	3.90	4.10	4.30	4.20	4.20	4.10	4.10	3.90	4.00	3.80	4.06
Company D	4.60	4.60	4.50	4.70	4.40	4.60	4.50	4.50	4.50	4.20	4.51
Company E	4.20	4.00	4.30	4.50	4.60	4.30	4.10	3.60	4.00	3.80	4.14
Company F	4.50	4.60	4.70	4.70	3.90	4.00	3.80	3.40	3.10	3.20	3.99

Mean scores were calculated for each awareness indicator (AW1-AW10) based on Nunnally and Bernstein's (1994) interpretive framework to gauge awareness across companies. Nunnally and Bernstein's (1994) framework provides a crucial lens for interpreting mean scores in research. It goes beyond the raw number, offering guidance on how well the score represents the underlying construct being measured, in this case, the organizational awareness. The framework categorizes mean scores as follows: "Low" (1.00 – 2.00), "Medium Low" (2.01 – 3.00), "Medium High"

(3.01 – 4.00), and "High" (4.01 – 5.00). Additionally, an overall awareness score was calculated for each company by taking an average across all the indicators (Refer to Table 3).

The mean scores indicate a strong understanding of quality and its link to technology. For example, the high mean scores for among organizations for AW1 (4.34) and AW2 (4.34) suggest strong agreement on customer focus as a top priority, which correlates to the intent of the questions AW1 and AW2. Similarly, high scores for AW3 (4.06), AW4 (4.51) and AW5 (4.14) reinforce awareness that quality improvements, which include digital transformation and implementation of Quality 4.0, is a collaborative effort and a common agreement that utilization of digital tools enhances product quality. Figure 5 visually represents these findings.

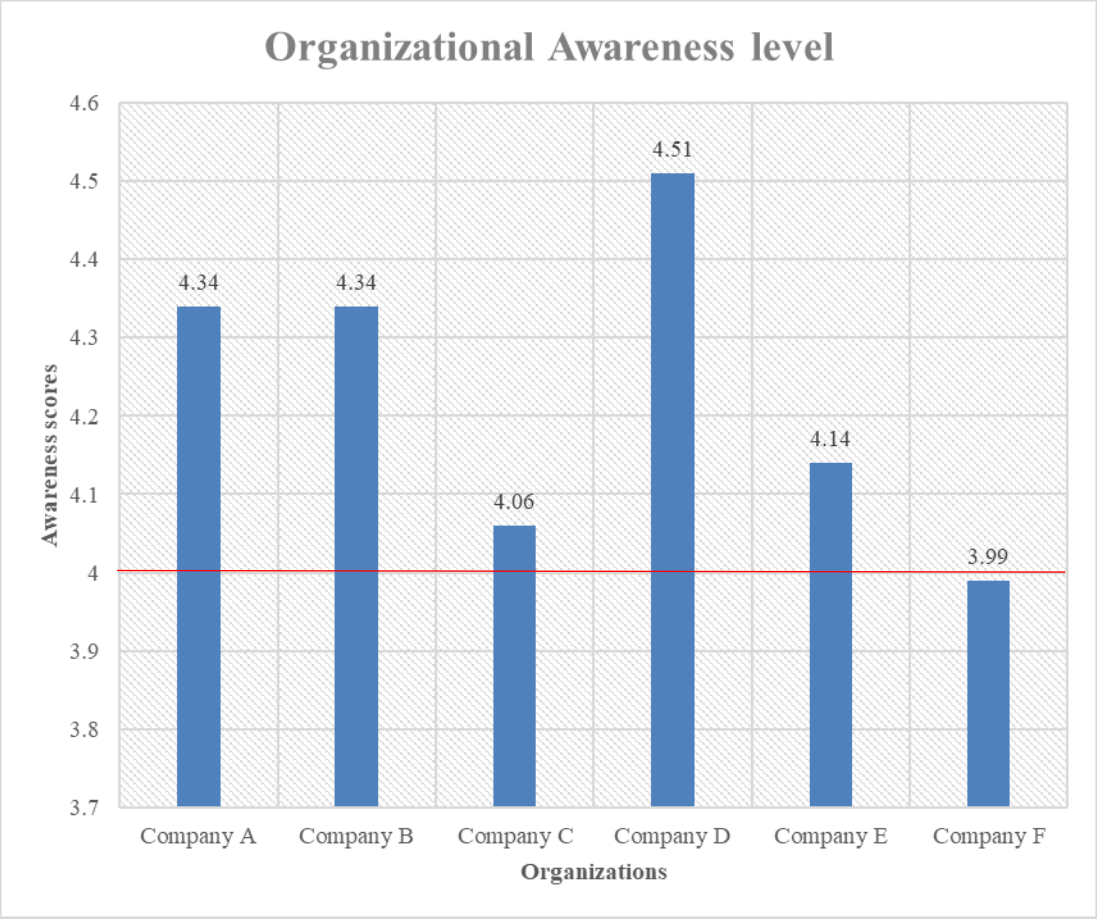

Figure 5. Organizational Awareness Level

Analyzing overall awareness scores, Companies A, B, C, D, E and F exhibited "High" awareness (Refer Table 3). All companies possessed a favorable foundation for implementation, which aligns with research by Adolph et al. (2014) and Ratnasingam (2019) who emphasize the importance of a skilled workforce for technology adoption in manufacturing. The high overall awareness scores suggest a collective commitment to understanding Quality 4.0 implementation. In addition, a deep understanding of continuous quality improvement initiatives substantiated with digital transformation, as evidenced by high indicator scores, positions Companies A, B, and D to gain a competitive advantage. Their ability to integrate technology into their quality management systems suggests a forward-thinking approach that can lead to improved product quality, reduced costs, and increased customer satisfaction.

5.3 Quality 4.0 Readiness Levels

This study also evaluated medical technology companies' readiness for Quality 4.0 using a structured questionnaire (Refer Table 4). Each factor influencing readiness (Leadership, Organizational Culture, Employee Competency, Technology Utilization, Compliance) was assigned an abbreviation (LD, OC, EC, TU, CP). Participants rated their agreement with each statement on a scale of 1 (strongly disagree) to 5 (strongly agree) (Refer to **Table 4 (APPENDIX** B)). Internal consistency of the questionnaire was ensured through Cronbach's Alpha, exceeding 0.8 for all factors (Refer Table 5), indicating high reliability (Nunnally 1994; Ercan et al.2007).

Table 5. Reliability test outcomes

Readiness assessment factors	Cronbach Alpha	No. of items
Leadership	0.945	5
Organizational Culture	0.974	5
Employee Competency	0.960	5
Technology Utilization	0.875	5
Compliance	0.958	5

Organizational mean values and standard deviations for each factor were calculated (Refer to Table 6).

Table 6. Organizational mean values

Organization	Statistics	Readiness Assessment Factors					Overall Score
		LD	OC	EC	TU	CP	
Company A	Mean	4.4400	4.1400	4.2200	4.1400	4.2200	4.2320
	Std Dev	0.5317	0.6867	0.6070	0.7121	0.6762	
Company B	Mean	2.1600	2.2200	2.3000	2.6000	2.2400	2.3040
	Std Dev	1.1768	1.1868	1.3140	1.0667	1.1462	
Company C	Mean	3.7800	3.7600	3.8400	3.8600	3.8600	3.8200
	Std Dev	0.7627	0.8682	0.7412	0.6995	0.6398	
Company D	Mean	2.9800	2.8200	2.8800	3.5600	3.1600	3.0800
	Std Dev	0.7208	0.9449	0.8854	0.7229	0.8884	
Company E	Mean	3.4400	3.4600	3.5600	3.2800	3.4200	3.4320
	Std Dev	0.7168	0.9143	0.7471	0.7254	1.2488	
Company F	Mean	3.3800	2.9000	3.5400	3.5000	3.8800	3.4400
	Std Dev	0.9682	1.2763	0.9240	0.8756	0.6812	

Note: LD: Leadership, OC: Organizational Culture, EC: Employee Competency, TU: Technology Utilization, CP: Compliance

The raw data in Table 6 can be difficult to interpret directly. To facilitate interpretation, these mean values were converted to percentage-based readiness scores and categorized into three readiness levels as described in Zulfiqar et al., 2023 (Refer Table 7).

Table 7. Readiness classification (adopted from Zulfiqar et al. 2023)

Readiness Scores	Classification
0 – 55%	At risk
56 – 75%	Fair
76 – 100%	Safe

Based on the mean values obtained, a readiness scores formula was developed based on central tendency and scoring method equations developed by Comrey and Lee (1995) and Groebner et al. (2010). Given the absence of established

scoring methodologies for Quality 4.0 readiness in prior research, this study developed a modified formula. Similar calculations were also employed by past researchers such as Aamer et al (2017) and Sadikoglu and Zehir (2010) but from a TQM index standpoint.

$$Readiness\ Score\ (\%) = \left[\frac{\frac{\sum_j^i \sum i_1 + i_2 + \cdots + i_j}{j}}{m}\right] \times 100$$

Where,
i is the mean value each of indicator items per factor
j is the maximum number of indicators per factor
m is the number of readiness assessment factors, i.e. m=5

The proposed approach calculates Quality 4.0 readiness scores by converting mean readiness values for each indicator within a readiness assessment factor. This approach will thereby enhance the clarity and interpretability of organizational readiness evaluation. Furthermore, the calculation of readiness score aids in addressing potential multicollinearity concerns within the analysis (Sadikoglu and Zehir, 2010). The organizational readiness scores obtained for Company A are calculated below for reference.

$$Readiness\ Score\ (\%) = \left[\frac{\left(\frac{4.44 + 4.14 + 4.22 + 4.14 + 4.22}{5}\right)}{5}\right] \times 100 = 85\%$$

Mean values for each readiness assessment factor were aggregated and divided by the total number of indicators within a factor and further divided by the number of factors to obtain a readiness score, expressed as a percentage. Company A achieved a readiness score of 85%, as depicted in the formula above, while readiness scores for Companies B through F are detailed in Table 8.

Table 8. Organizational Readiness Score

Organization	Readiness Scores	Classification
Company A	85%	Safe
Company B	46%	At risk
Company C	76%	Safe
Company D	62%	Fair
Company E	69%	Fair
Company F	69%	Fair

The analysis exposes clear differences in readiness among the companies (Refer to Table 8). Company A stands out with a high score (85%), indicating strong leadership, culture, employee competency, technology utilization, and compliance. Conversely, Company B's low score (46%) across all dimensions reveals weaknesses in leadership, culture, compliance, and digital tools for quality management.

Company C (76%) shows a balanced performance across all factors, suggesting a "Safe" level of readiness. Company D (62%) needs improvement in leadership and culture despite better scores in technology and compliance, placing them in the "fair" category. Interestingly, Companies E and F have identical scores (69%) but with distinct profiles. With reference to Table 6, Company E exhibits consistency across all dimensions ("Fair"), while Company F excels in compliance but requires significant improvement in leadership, organizational culture and compliance. Based on the outcomes from Table 6, a radar chart was plotted to further ascertain the readiness levels.

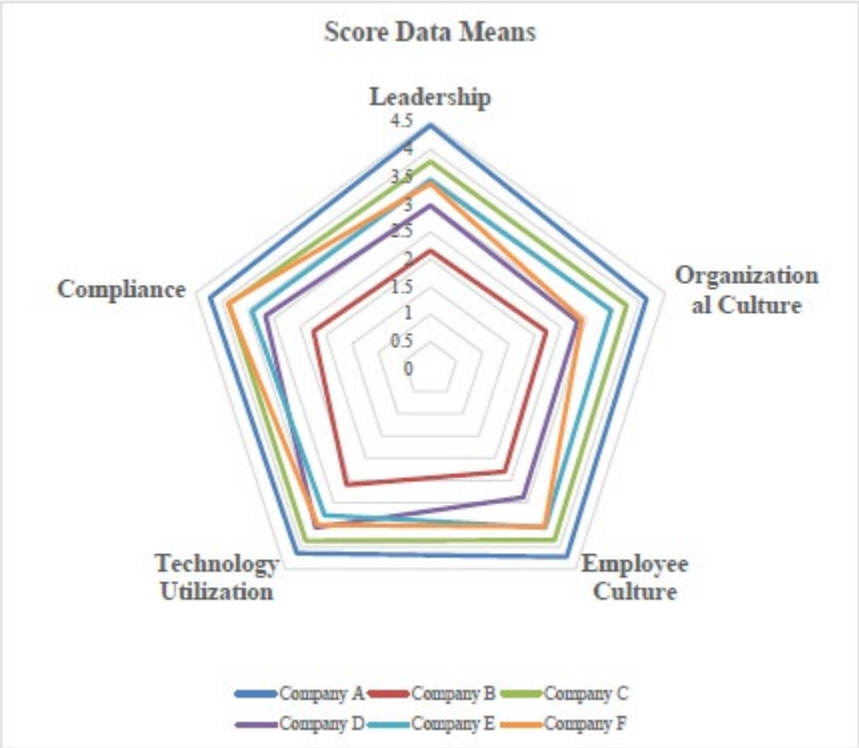

Figure 6. Radar chart

The radar chart (Refer Figure 6) compares two aspects: how important each readiness factor is perceived to be (by respondents) and how well each company is currently implementing those factors. Each axis represents a readiness factor (Leadership, Culture, etc.) with scores plotted for each company.

Companies A, B, C, and E show consistent scores across all factors, suggesting a potentially balanced approach to Quality 4.0 (as supported by research by Zulfiqar et al. 2023; Ramadan and Arafeh, 2016). This aligns with the idea that a well-rounded focus on various aspects is crucial for success (Zulfiqar et al. 2023; Ramadan and Arafeh 2016). Companies D and F have uneven scores, indicating a potential lack of prioritization in some areas. This aligns with the concept of "equifinality" in organizational development (Ford et al. 2021), where multiple paths can lead to success. However, achieving a minimum level across all factors is likely still important for effective Quality 4.0 implementation.

The radar chart underscores Company A's leadership position, demonstrating robust performance across all Quality 4.0 dimensions. In contrast, Company B exhibits areas of weakness, indicating potential hurdles in their digital transformation journey. The visualization emphasizes the significance of a balanced approach to Quality 4.0 implementation, where organizations strive for excellence across multiple domains. While a balanced strategy, with equal attention given towards leadership, organizational culture, employee competency, technology and compliance, is often beneficial, the findings also suggest that diverse pathways to Quality 4.0 implementation may exist, as suggested by Ford et al. (2021).

5.4 Quality 4.0 Implementation Classification

This research assessed the implementation levels of Quality 4.0 among medical technology companies in Malaysia. To categorize the companies according to their level of implementation, a five-tier framework was employed. This framework, adapted from Ramadan and Arafeh (2016) and Dale and Smith (1997), encompasses stages from Chaotic to Proficient (Refer Table 9). A similar approach was utilized by Zulfiqar et al. (2023) in their evaluation of Quality 4.0 readiness among packaging companies, where participants were classified into implementation groups to gauge their adoption levels. These classifications collectively represent a range of quality management practices among the participating organizations.

Table 9. Quality Management Implementation Grid

Classification	Description	Scoring
Chaotic	Disorganized behavior with minimal or no quality practices, lacking a dedicated quality department, and top management prioritizing profit over quality control.	0 – 40%
Primitive	Familiar with better quality practices than chaotic organizations, but top management does not allocate resources for quality improvement, and practices are superficial and primitive.	41 – 55%
Structured	Employees are actively involved in quality management practices, and top management provides resources for quality improvement. However, top management may not include quality cost in the budget.	56 – 75%
Mature	Established organizations with employees knowledgeable about quality tools and strategies, though some barriers hinder reaching proficiency. Recognized for quality adaptation.	76 – 90%
Proficient	Ready to adopt any quality practices, willing to make changes to implement quality techniques. Top management is committed to quality initiatives, positively impacting employee behavior and organizational culture	91 – 100%

The final assessment (Refer Table 10) revealed distinct implementation levels among the companies. Companies A and C achieved a "Mature" classification, indicating a high level of digitalization integration and adoption. This suggests they may be early adopters of Quality 4.0 technologies compared to those categorized as "Structured" (Alzahrani et al., 2021). Conversely, Company B was categorized as "Primitive," indicating a nascent stage of Quality 4.0 implementation. This classification aligns with the findings of Alzahrani et al. (2021) who speculated that initial adoption can be hindered by substantial implementation costs.

Table 10. Implementation Levels

Organization	Overall Score	Classification
Company A	85%	Mature
Company B	46%	Primitive
Company C	76%	Mature
Company D	62%	Structured
Company E	69%	Structured
Company F	69%	Structured

Quality 4.0 represents an emerging paradigm within the realm of quality management. While all participating organizations in this study are medical device manufacturers adhering to the rigorous ISO 13485 standards, thus establishing a robust foundation in traditional quality practices, the integration of digital technologies for enhanced

quality management systems presents a novel frontier. Notably, the companies classified as "Mature" have demonstrated a more advanced level of digital integration, positioning them as pioneers in this evolving landscape.

The emphasis on quality management is steadily increasing due to rising customer expectations, global competition, and the growing integration of digital transformation with organizational objectives, strategies, and policies (Armani et al. 2021). This highlights the importance for companies to continually improve their quality practices to remain competitive.

6. Conclusion

This research tackles three interconnected objectives. First, literature review identifies factors crucial for successful Quality 4.0 adoption through a comprehensive literature review. The review pinpoints five key factors consistently emphasized by researchers: Leadership, Organizational Culture, Employee Competency, Technology Utilization, and Compliance. These factors are considered essential for organizations to embrace Quality 4.0. Secondly, a survey was developed to investigate the level of awareness and understanding and the readiness of Quality 4.0 implementation within Malaysian medical technology companies. Third, the current readiness level of the case companies regarding Quality 4.0 was assessed by analyzing survey data. A radar chart was used to visualize scores assigned to each company, which then formed the basis for categorizing them into five distinct readiness levels: Chaotic, Primitive, Structured, Mature, or Proficient. Intriguingly, the survey results revealed a complex interplay between awareness and readiness. For instance, Companies A, B, and D exhibited high levels of awareness regarding continuous quality improvement initiatives and Quality 4.0 principles. However, their readiness levels varied significantly, with Company A demonstrating a “Mature” level, Company B at “Primitive” level, and Company D at “Structured” level. This disparity underscores the importance of factors beyond awareness, such as organizational infrastructure, resource allocation, and strategic alignment in determining the successful transition to Quality 4.0.

6.1 Implication of Study

For industry practitioners, this research provides a practical tool for assessing their organization’s current awareness and readiness to adopt Quality 4.0. By identifying specific strengths and weaknesses, companies can develop tailored strategies to enhance their quality management systems. This tool enables organizations to benchmark their progress against industry leaders and implement actionable improvements.

For instance, companies categorized as "Primitive" can accelerate their journey towards maturity by focusing on foundational elements such as establishing clear quality objectives, implementing robust quality control processes, and developing a strong quality culture. Investing in basic digital tools and employee training in quality concepts can also be beneficial. Organizations at the "Structured" level can build upon their existing foundation by focusing on advanced quality methodologies, such as Lean Six Sigma or Statistical Process Controls (SPC). Leveraging data analytics and automation to optimize processes and reduce waste can significantly enhance performance. Additionally, fostering a culture of continuous improvement and innovation is crucial for progressing to the "Mature" stage.

On the academic front, this research introduces a novel assessment tool for gauging Quality 4.0 readiness, contributing valuable knowledge to the field. This tool serves as a foundation for further studies exploring the impact of Quality 4.0 on various performance metrics within the medical technology sector. Additionally, the research findings can inform the development of curriculum materials and educational programs, equipping future generations with the skills and knowledge necessary to navigate the evolving landscape of Quality 4.0.

6.2 Limitations of Study

Despite providing valuable insights into readiness levels for Quality 4.0 implementation, this study has several limitations. Firstly, relying solely on self-reported data through questionnaires is susceptible to social desirability bias (Van De Mortel, 2008), where respondents might overstate their awareness or readiness to present a favorable image of their organization. Additionally, the study's relatively small sample size limits the generalizability of findings to the broader medical technology industry. This study also did not consider organizational size, which can impact resources, technology, and change management, exploring readiness variations across small, medium or large medical technology companies. Future research should explore these factors to gain a more comprehensive understanding of the challenges and opportunities associated with Quality 4.0 implementation in the medical technology sector.

6.3 Recommendations for Future Research

Expanding the analysis to small and medium-sized organizations can illuminate the importance of the five readiness factors in those contexts. Additionally, applying the assessment tool across multiple countries would gauge its effectiveness in measuring Quality 4.0 readiness within the global medical technology sector. Finally, incorporating complementary data collection methods, like in-depth interviews or examining existing quality practices, could strengthen the generalizability of the findings. This triangulation would provide a richer understanding of medical technology companies' preparedness for Quality 4.0 adoption.

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Acknowledgements
The authors wish to acknowledge the support given by Universiti Teknologi Malaysia throughout this research.

APPENDIX -A

Table 2. Quality 4.0 Awareness Indicators (Adopted and modified from Zulfiqar et al. 2023; Maganga & Taifa 2022; and Sony et al. 2020)

Questions	Categories	Frequency	Percentage
AW1: Continuous quality improvement places emphasis on meeting customer requirements.	Strongly disagree	1	1.7%
	Disagree	2	3.3%
	Uncertain	5	8.3%
	Agree	20	33.3%
	Strongly agree	32	53.3%
AW2: Continuous quality improvement is intended to satisfy customer needs.	Strongly disagree	2	3.3%
	Disagree	0	0.0%
	Uncertain	6	10.0%
	Agree	21	35.0%
	Strongly agree	31	51.7%
AW3: Continuous quality improvement is essential in reducing quality costs, losses, waste and inefficiency across end-to-end production cycles.	Strongly disagree	1	1.7%
	Disagree	0	0.0%
	Uncertain	1	1.7%
	Agree	23	38.3%
	Strongly agree	35	58.3%
AW4: Continuous quality improvement requires involvement of all employees.	Strongly disagree	1	1.7%
	Disagree	0	0.0%
	Uncertain	5	8.3%

Questions	Categories	Frequency	Percentage
	Agree	13	21.7%
	Strongly agree	41	68.3%
AW5: Continuous quality improvement utilizes digitalization of quality control system.	Strongly disagree	0	0.0%
	Disagree	4	6.7%
	Uncertain	5	8.3%
	Agree	21	35.0%
	Strongly agree	30	50.0%
AW6: Continuous quality improvement utilizes real-time quality inspection data.	Strongly disagree	1	1.7%
	Disagree	3	5.0%
	Uncertain	2	3.3%
	Agree	25	41.7%
	Strongly agree	29	48.3%
AW7: Continuous quality improvement process integration requires interconnectivity with digital platforms.	Strongly disagree	0	0.0%
	Disagree	4	6.7%
	Uncertain	6	10.0%
	Agree	24	40.0%
	Strongly agree	26	43.3%
AW8: Continuous quality improvement benefits from cutting-edge technologies such as Artificial Intelligence (AI), Machine Learning (ML), Blockchain and Big Data.	Strongly disagree	3	5.0%
	Disagree	1	1.7%
	Uncertain	12	20.0%
	Agree	21	35.0%
	Strongly agree	23	38.3%
AW9: Continuous quality improvement benefits from enabling technologies such as cloud computing, 5G network and Internet of Things (IoT).	Strongly disagree	3	5.0%
	Disagree	0	0.0%
	Uncertain	14	23.3%
	Agree	22	36.7%
	Strongly agree	21	35.0%
AW10: Continuous quality improvements integrated with automation via virtual reality (VR) and augmented reality (AR) improves overall organizational performance and competitiveness.	Strongly disagree	3	5.0%
	Disagree	2	3.3%
	Uncertain	16	26.7%
	Agree	20	33.3%
	Strongly agree	19	31.7%

APPENDIX -B

Table 4. Quality 4.0 Readiness Assessment Indicators

Factors	Readiness Assessments	Source(s)
Leadership (LD)	LD1: My organization promotes big data driven decision making culture.	Zulfiqar et al. (2023), Antony et al. (2021), Antony et al. (2020), Sony et al. (2021), Oberer & Erkollar (2018), Akcay Kasapoglu (2018), Frick et al. (2021), Pederson (2017)
	LD2: My organization knows exactly what they want to become by implementing Quality 4.0 digitalization initiatives.	
	LD3: My organization integrated implementing Quality 4.0 digitalization initiatives into operational excellence methodologies. (i.e. lean manufacturing)	
	LD4: My organization communicates the importance of implementing Quality 4.0 digitalization initiatives at all levels of organization.	
	LD5: My organization encourages teamwork and cross-functional problem solving by implementing Quality 4.0 digitalization initiatives.	
Organizational Culture (OC)	OC1: My organization ensures that employees understand that future would be better due to implementing Quality 4.0 digitalization initiatives.	Zulfiqar et al. (2023), Antony et al. (2021), Antony et al. (2020), Kupper et al. (2019), Gimenez-Espin et al. (2013), Kinzel (2017), Radziwill (2018)
	OC2: My organization ensures that insecurities among employees due to implementing Quality 4.0 digitalization initiatives are systematically handled.	
	OC3: My organization breaks down all barriers associated with implementing Quality 4.0 digitalization initiatives.	
	OC4: My organization achieves the common goals of implementing Quality 4.0 digitalization initiatives via collaboration among various departments and functions.	
	OC5: My organization constantly motivates employees to participate actively in the change management program for implementing Quality 4.0 digitalization initiatives.	
Employee Competency (EC)	EC1: My organization is fully aware of the rationale behind implementing Quality 4.0 digitalization initiatives.	Zulfiqar et al. (2023), Antony et al. (2021), Antony et al. (2020), Zonnenshain and Kenett (2020), Brandenburger et al. (2021), Armani et al. (2021)
	EC2: My organization is confident that employees are able to perform different tasks as part of their daily job while implementing Quality 4.0 digitalization initiatives.	

Factors	Readiness Assessments	Source(s)
	EC3: My organization is confident that employees are qualified enough to contribute as a team towards problem solving using Quality 4.0 digitalization initiatives.	
	EC4: My organization able to propose continuous improvement actions based on the Quality 4.0 digitalization initiatives implemented i.e. developing dashboards, creating automated trend reports etc.	
	EC5: My organization has positive growth mindset hence implementing Quality 4.0 digitalization initiatives at our company.	
Technology Utilization (TU)	TU1: My organization fully utilizes Vertical Integration of Internal Information Systems. (i.e. integration, connectivity and interoperability of internal information systems like ERP, MES, CAD, SCADA, PLM etc.)	Zulfiqar et al. (2023), Maganga and Taifa (2022), Jacob (2017), Sader et al. (2019), Lim (2020), Fonseca (2021), Alzahrani et al. (2021),
	TU2: My organization fully utilizes Horizontal Integration of External Information Systems. (i.e. integration, connectivity and interoperability of information systems and secured data sharing between vendors, partner, contractors etc.)	
	TU3: My organization uses digitalized processes which are integrated across all hierarchical levels of the operations. (e.g. production systems are integrated and information flow is bi-directional across these systems.)	
	TU4: My organization uses cloud-based services to analyze and store data and make data-driven decisions using those data. (i.e. Sharepoints, SpotFire, Tableu, Power BI, etc.)	
	TU5: My organization implemented digitalization of products. (e.g. putting scan-able codes to the physical product)	
Compliance (CP)	CP1: My organization has an automated system in place for collecting customer complaints via Quality 4.0 digitalization initiatives such as Big Data and Blockchain, and in combination with traditional QC tools so that problems can be avoided in the future.	Zulfiqar et al. (2023), Asif, (2020), Chiarini (2020), Glogovac et al. (2022), Odubiyi et al. (2019), Prashar (2022)

Factors	Readiness Assessments	Source(s)
	CP2: My organization ensures that suppliers are aware of any new product designs, communicates any changes through Quality 4.0 digitalization initiatives i.e. Product Lifecycle Management platforms, of existing products and involve them during design and development phase, while ensuring full data integrity and future retrievability.	
	CP3: My organization conducts appropriate risk assessment to determine any introduction of new risks from implementing any Quality 4.0 digitalization initiatives along with its mitigation plan are being identified.	
	CP4: My organization ensures successful runs of validation was conducted upon implementation of new Quality 4.0 digitalization initiatives to assure no impact to final product quality.	
	CP5: My organization ensures that any Quality 4.0 digitalization initiatives implemented at site meets the global regulatory requirements.	