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Critical Failure Factors for Factory Automation Project in Medical Device Assembly

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ABSTRACT

Factory automation has become essential in the medical device assembly sector to enhance efficiency, reduce costs, and maintain stringent quality standards. However, many automation projects face significant challenges, leading to delays, budget overruns, and failures. The problem stems from various factors, including technical limitations, operational inefficiencies, organisational barriers, external pressures, and technological constraints. Despite the growing adoption of automation, comprehensive studies do not categorise these failure factors and analyse their impact collectively. This study aims to identify and categorise critical failure factors (CFFs) in factory automation projects within the medical device assembly sector. A literature review was conducted to establish key failure factors, followed by a survey of 63 industry professionals. The collected data were analysed using descriptive statistics to determine the most significant failure factors affecting project success. The findings reveal that unrealistic timelines and budget estimates (operational), difficulty in assessing impact (technological), and cost reduction pressures (external) are among the most prominent challenges. The discussion highlights how these factors contribute to project failures, emphasising the interconnected nature of technical, organisational, and external influences. This study contributes to the field by offering a structured categorisation of CFFs, providing valuable insights for industry professionals to enhance project planning and execution. Future research should explore mitigation strategies and assess their effectiveness in addressing these failure factors.

1. Introduction

Factory automation is pivotal in enhancing efficiency, reducing operational costs, and maintaining high-quality standards within the medical device assembly sector. As the demand for increased production volumes and stricter regulatory compliance rises, adopting automation technologies has become a crucial strategy for manufacturers, as stated by Enriquez *et al.,* [1]. Automation provides

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numerous advantages, including accelerated production cycles, improved precision, and lower labor costs, all of which contribute to the long-term competitiveness of medical device manufacturers [2]. However, despite these benefits, many automation projects within the sector encounter significant setbacks, often resulting in delays, budget overruns, or, in extreme cases, project failure. These challenges not only jeopardize the financial stability of organizations but also hinder their ability to deliver products that meet the stringent standards demanded by the medical device industry [3].

The failure of factory automation projects stems from a wide range of factors across multiple domains. These include technical challenges, such as poor system integration; operational issues, like inefficient workflows; organizational barriers, including resistance to change; external pressures from regulatory demands and market competition; and technological limitations that restrict the scalability or adaptability of automated systems [4,5]. Identifying and addressing these failure factors is essential for improving the success rates of automation projects. However, while existing literature provides valuable insights into specific challenges, there is a lack of comprehensive studies that offer a structured approach to categorizing these issues and providing actionable solutions [6-7]. Specifically, few studies explore the interconnectedness of these failure factors, leading to a fragmented understanding of the root causes of project failure [8].

Most research focuses on isolated aspects of automation projects, such as cost estimation, time management, or technological innovations, often overlooking the broader scope of challenges. For example, while technical issues with automation systems are frequently addressed, organizational factors like company culture, communication, or leadership, which significantly affect project success, are often not considered [9,10,54,55]. Similarly, external factors, including market forces and regulatory requirements, are acknowledged but not always integrated into failure analyses [11].

Despite existing studies identifying various challenges in factory automation, there remains a lack of structured analyses that categorize these challenges comprehensively, particularly within the medical device assembly sector context. This study aims to fill this gap by systematically examining the critical failure factors through a literature review and empirical survey data. By categorizing these factors into five key domains—technical, operational, organizational, external, and technological—the study provides a holistic framework for understanding automation project failures. Additionally, it explores the interactions among these failure factors to offer more nuanced insights into the complexities of automation projects. This research aspires to contribute academically and provide practical guidance for industry professionals by offering actionable recommendations. Ultimately, the study seeks to enhance the success rates of automation projects, leading to improved industry practices and sustainable automation outcomes.

2. Literature Review

2.1 Factory Automation and Its Project

In recent years, the factory automation machine-building industry has undergone significant transformations driven by the growing demands for greater efficiency, productivity, and cost savings. The sector's evolution has made New Product Development (NPD) a vital component in sustaining competitiveness and relevance in the market [12]. At the core of NPD is mechanical design integration, strong sales relationships, and a comprehensive understanding of the unique challenges manufacturers face. Achieving success in a competitive global market requires high-quality products, underscoring the importance of prioritising quality in development [13]. Mechanical design plays a pivotal role in this process, as engineers must develop solutions that meet technical specifications and ensure durability, reliability, usability, and cost-effectiveness, ultimately contributing to both affordability and profitability. Recent studies, such as those by Liang & Xiangyu [14], highlight how mechanical automation in manufacturing reduces labour costs while enhancing output and driving advancements in science and technology.

The success of NPD in factory automation is contingent upon the seamless integration of cutting-edge technology, ergonomic design, and a deep understanding of customer needs. However, reconciling mechanical design with manufacturing technology can sometimes lead to challenges, such as reduced equipment precision. Sun [15] addressed this issue and proposed strategies to support the development of mechanical automation machinery that maintains high precision standards. The initial stages of industrial projects are often the most challenging, particularly when developing new products or machines. Gathering information during these stages is critical, but raw data alone is insufficient unless translated into meaningful "customer requirements". Sofianti *et al.*, [16] proposed a framework for Customer Knowledge Management to address this challenge, emphasising the importance of capturing customer insights early in the design process. Direct collaboration with customers, known as customer co-creation, is another approach that helps developers better understand requirements. Hoyer *et al.*, [17] explored the factors that promote or hinder this concept. Tuli & Shankar [18] examined the supplier-buyer relationship, suggesting ways to eliminate inefficiencies in development processes and improve outcomes.

Introducing a newly developed product to the market, a critical phase known as New Product Introduction (NPI), is influenced by various factors such as product development strategies and supply chain management [19]. While technological innovation and sound development practices are crucial, they do not guarantee market success or return on investment. Several factors impact the success of NPI, as demonstrated in studies examining their effects by Ardito *et al.*, [20]. NPI inherently involves significant risks, making risk analysis a critical component. Zhou *et al.*, [21] proposed a modified Failure Mode and Effect Analysis (FMEA) combined with a Three-Way Decision (3WD) as a practical approach to mitigating these risks and ensuring a more reliable NPI process.

Despite the importance of developing marketable products, achieving market success remains challenging. There is still a gap in understanding the factors that make a technology marketable. As research suggests, the nature and generality of technological breakthroughs play a pivotal role in NPI success. While significant technological advancements can positively influence marketability, overly general technologies may hinder success. Furthermore, international R&D efforts can moderate these effects, as Ardito *et al.*, [20] show. Effective project management is also essential for successful NPI manufacturing, ensuring product development and market performance align. While existing studies have examined NPI challenges across various industries, limited research has focused on project management from the production team's perspective. A case study by Chirumall [22] identified nine key challenges, including scheduling, administration, methods, and communication issues. Quality Management (QM) can also help mitigate challenges in cross-border NPI projects. Based on interviews and workshops, a study involving Swedish and Chinese companies examined the pre-production, production, and post-production stages and revealed additional challenges affecting NPI and product quality. The study proposed applying QM methods to address these issues and improve overall project performance [23].

2.2 Factory Automation in Industry 4.0

The advent of Industry 4.0 has significantly revolutionised factory automation by incorporating advanced technologies such as robotics, 3D printing, the Internet of Things (IoT), and automated production systems. These technologies have led to notable improvements in manufacturing processes, boosting production efficiency, reducing operational costs, and enhancing competitiveness [24]. Research conducted in Slovakia and the Czech Republic highlights the widespread adoption of Industry 4.0 technologies, particularly sensors, programmable logic controllers (PLC), human-machine interfaces (HMI), and industrial robots. However, the research also reveals a significant disparity in the adoption rate between large enterprises and medium or small-sized businesses, with larger companies leading the way in integrating these innovations.

This divide in adoption rates underscores the need for tailored strategies that enable small and medium-sized enterprises (SMEs) to leverage the benefits of Industry 4.0 and remain competitive in the market. As larger companies often lead in adopting automation technologies, smaller manufacturers must navigate challenges such as financial constraints, technological expertise, and organisational readiness to integrate Industry 4.0 solutions successfully.

Integrating Industry 4.0 into existing production systems, particularly those following lean manufacturing principles, presents opportunities and challenges. While lean practices emphasise waste reduction and efficiency, merging these practices with advanced automation technologies requires careful planning [54]. According to Brecher *et al.*, [25], a well-defined migration path is essential for seamlessly adopting technologies like IoT and autonomous guided vehicles into lean systems. Vlachos *et al*., [26] also emphasise aligning technical innovations with organisational culture to foster a successful transition to automated, smart manufacturing systems. Their case study highlights that the successful integration of advanced technologies requires attention not only to technical infrastructure but also to social factors, such as workforce readiness and the design of automated systems.

The key to the successful implementation of Industry 4.0 lies in harmonising technological advancements with lean principles and ensuring that employees are adequately trained to interact with the new systems. Manufacturers can optimise production efficiency, reduce costs, and enhance product quality by fostering an environment where technology, people, and processes align. Combining advanced automation and lean practices can lead to sustainable and efficient production processes, helping companies stay competitive in the evolving manufacturing landscape. However, overcoming technical and organisational hurdles remains critical for maximising the benefits of Industry 4.0 in factory automation.

2.3 Automation Project in Medical Device Assembly

The medical device industry has experienced rapid growth, driven by increasing demand for advanced treatments and lucrative profit margins that attract investors and manufacturers. However, the sector faces stringent regulations and certification processes that make the production and usage of medical devices highly controlled. Maresova *et al*., [27] highlight one of the primary challenges in this industry: balancing innovation with compliance, particularly under the European Union's new Medical Device Regulation (MDR). For small to medium enterprises (SMEs), the financial burden of meeting these regulatory requirements can be particularly challenging, as the administrative costs of compliance can be prohibitive. Despite these hurdles, SMEs remain key drivers of technological advancements in medical device production and overcoming regulatory barriers could lead to societal benefits and broader access to innovative products.

Alongside regulatory challenges, the development of advanced technologies in the medical device industry faces several technical and ergonomic difficulties. Li *et al*., [28] explore using soft actuators inspired by biological systems in medical devices and wearables. While these actuators offer the potential for improved adaptability and multifunctionality, challenges in replicating the complex performance of biological systems remain. These innovations demand engineering breakthroughs for scalability, reproducibility, and self-healing properties. Furthermore, ergonomic issues in medical device manufacturing cannot be overlooked. Md. Noh *et al*., [29] emphasise that workers in the industry are vulnerable to musculoskeletal disorders (MSDs) due to poor ergonomic practices. Addressing these risks by improving workstation design and incorporating ergonomic assessments is crucial to ensuring worker safety and efficient production.

These factors, such as regulatory compliance, technological innovation, and worker safety, play a critical role in shaping the future of medical device assembly. Automation projects within this sector must navigate these challenges while advancing the technology and the safety of workers involved in production. By addressing regulatory requirements and incorporating ergonomic considerations, the industry can continue to evolve and meet the growing demand for innovative, high-quality medical devices.

2.4 Critical Failure Factors in Automation Project

Factory automation projects are complex endeavours that involve several key factors across multiple dimensions, including technical, operational, organisational, external, and technological aspects. Understanding the potential pitfalls in each of these categories is essential to ensuring the success and efficiency of automation initiatives. Below, each category is explored in more detail with expanded insights, as summarised in Table 1.

Technical Factors – The technical aspects of factory automation are integral to ensuring smooth and efficient operations. The quality of the technology and its implementation is essential, as inadequate solutions from suppliers with limited technical expertise can fail to meet industry standards, ultimately compromising system performance [30,31]. Another critical factor is the compatibility of materials with automation systems, as mismatches can lead to malfunctions and reduce overall operational efficiency [31,32]. Material consistency and quality are also crucial; any variations in materials can result in defects, reduced production efficiency, and increased waste, negatively affecting final product quality [33,34]. Furthermore, the type of materials used can significantly impact equipment durability, with certain materials accelerating wear and tear, increasing maintenance costs, and leading to more frequent downtimes [35]. These factors must be carefully considered to avoid operational disruptions and maintain long-term productivity.

Operational Factors – The operational aspects of factory automation significantly affect its overall success and efficiency. Unrealistic timelines and budget estimates often lead to rushed decisions and increased stress, which can negatively impact the quality and outcomes of the project [36,37]. Additionally, incomplete requirements gathering can pose a substantial problem, as failure to collect comprehensive and accurate information can lead to misunderstandings and misaligned project goals, ultimately affecting project success [38,39]. A lack of understanding of existing processes may disrupt well-established workflows, leading to inefficiencies and operational setbacks [40]. Overly optimistic project proposals, which often underestimate complexities, can further strain operations when unforeseen challenges arise [41,43]. Furthermore, hidden costs such as training, maintenance, and unexpected resource adjustments, if not accounted for, can lead to budget overruns and significant operational delays [44]. Inadequate consideration of specialised handling and storage requirements for materials may result in degradation, affecting production quality [31].

Organisational Factors – The organisational elements of factory automation are essential for ensuring project success and minimising disruptions. An inadequately defined project scope often results in scope creep, leading to misunderstandings and misalignment with operational goals, potentially derailing the project's intended objectives [45,46]. Poor communication planning and ineffective communication channels create information silos and misunderstandings, which hinder collaboration and alignment among teams [45]. Moreover, insufficient knowledge transfer can exacerbate these challenges by limiting the sharing of critical information needed for effective problem-solving and teamwork [38,39]. Poor change management practices also pose risks, leading to unexpected financial strain, particularly when project costs exceed estimates due to unanticipated changes [45,47]. In addition, ineffective tender management processes contribute to delays, confusion, and suboptimal vendor selection, which can have long-lasting impacts on project outcomes [44].

External Factors – External factors play a crucial role in the success of factory automation projects, affecting quality, costs, and client satisfaction. Supplier variability, where materials from different suppliers exhibit inconsistent properties, can disrupt production quality and efficiency, making it challenging to maintain consistent standards [30,34]. Inadequate vendor evaluation and selection, mainly when cost is the primary driver, can result in poor-quality materials or services, ultimately undermining the success of the project [30,40]. Cost-cutting pressures may exacerbate these issues, leading to supplier evaluation shortcuts and compromising quality and performance [46, 40]. Budget implications, such as unplanned costs arising from resource adjustments, rework, or timeline extensions, add financial strain to managing external dependencies [48,49]. Furthermore, misalignment with client needs due to insufficient understanding can lead to solutions that fail to meet expectations, negatively affecting overall success and stakeholder satisfaction [38,48].

Table 1
Existing CFFs in the automation projects

Category	CFF	References
Technical	Quality of Technology and Implementation	Cheshmberah [30]; Campilho & Silva [31]
	Material Consistency and Quality	Wang *et al.,* [33]; Strmenik *et al.,* [34]
	Compatibility with Automation Systems	Campilho & Silva [31]; Dung *et a*l., [32]
	Impact on Equipment Wear and Tear	Shebani & Iwnicki [35]
Operational	Unrealistic Timelines and Budget Estimates	Khan *et al.,* [36]; Kwon & Kang [37]
	Incomplete Requirements Gathering	Bourne & Walker [38]; Argote *et a*l., [39]
	Poor Understanding of Existing Processes	Lii & Kuo [40]
	Overly Optimistic Proposals	de Souza Silva *et al.,* [41]; Flyvbjerg & Sunstein [42]; Flyvbjerg [43]
	Hidden Costs and Underestimated Expenses	Revellino & Mouritsen [44]
	Handling and Storage Considerations	Campilho & Silva [31]
Organisational	Inadequate Project Scope Definition	Kerzner [45]; Gido *et al.,* [46]
	Poor Communication Planning	Kerzner [45]
	Insufficient Knowledge Transfer	Bourne & Walker [38]; Argote *et a*l., [39]
	Ineffective Tender Management Processes	Revellino & Mouritsen [44]
	Poor Change Management Practices	Kerzner [45]; Cameron & Green [47]
	Ineffective Communication Channels	Bourne & Walker [38]; Argote *et a*l., [39] Kerzner [45]
External	Inadequate Vendor Evaluation and Selection	Cheshmberah [30]; Lii & Kuo[40]
	Pressure to Reduce Costs	Lii & Kuo [40]; Gido *et al*., [46]
	Budget Implications	Meskendahl [48]; Shenhar *et al.,* [49]
	Misalignment with Client Needs	Bourne & Walker [38]; Meskendahl [48]
	Supplier Variability	Cheshmberah [30]; Strmenik *et al.,* [34]
Technological	Incomplete or Ambiguous Specifications	Revellino & Mouritsen [44]; Kerzner [45] Ward & Chapman [50]
	Difficulty in Assessing Impact	Shenhar *et al.,* [49]; Ward & Chapman [50]
	Impact on Innovation	Heekenda *et al*., [51]
	Increased Financial Risk	Meskendahl [48]; Shenhar *et al.,* [49]

Technological Factors – Technological factors play an essential role in the success of factory automation projects, particularly concerning the clarity of specifications, adaptability, and innovation. Incomplete or ambiguous specifications can result in misunderstandings between technical teams and vendors, which leads to misaligned solutions and delays [44,45,50]. Difficulty in assessing the impact of technological changes can hinder effective decision-making, potentially leading to choices not aligned with the project's goals or operational needs [49,50]. Moreover, poor performance of technology suppliers can increase financial risks, as unanticipated costs for rework or adjustments may arise when systems fail to meet specifications [48,49]. Furthermore, working with less experienced suppliers may restrict access to innovative technological solutions, limiting the project's ability to leverage cutting-edge advancements and maintain competitiveness in a rapidly evolving market [51].

2.5 Gap Identification in Factory Automation Project

Despite significant advancements in factory automation, several gaps remain in understanding and implementing automation projects, particularly in the medical device assembly sector. Existing research on automation failures is often fragmented, focusing on isolated factors such as cost overruns, regulatory challenges, or technical integration issues rather than providing a comprehensive analysis of failure factors. One of the critical gaps identified is the lack of a holistic failure analysis. While technical and operational challenges are widely documented, there is limited research that consolidates failure factors across multiple dimensions, including organizational, regulatory, and technological constraints. As a result, many companies address automation failures reactively rather than proactively identifying interconnected risk factors before project initiation. Additionally, limited research exists on the impact of cross-functional interactions in automation projects. The success of automation implementation depends on seamless collaboration between engineering, production, quality assurance, and regulatory teams. However, existing studies primarily focus on technical feasibility, neglecting the complexities of interdisciplinary communication, training, and knowledge transfer. Another key gap is the insufficient assessment of long-term sustainability in automation projects. While short-term efficiency gains and cost reductions are often emphasized, research on long-term impacts, such as system adaptability, maintenance challenges, and workforce integration, remains scarce. Without a structured evaluation framework, companies may face operational inefficiencies, underutilized automation technologies, or increased downtime due to unforeseen complications. Addressing these gaps is crucial for enhancing the effectiveness of factory automation projects, ensuring sustainable implementation, and maximizing return on investment.

3. Methodology

3.1 Literature Review

A comprehensive literature review was conducted to identify sub-factors related to critical failure factors in factory automation projects. This review analysed 50 scholarly sources, including journal articles, books, and conference papers, to systematically examine industry challenges. The findings highlighted five critical failure factors, each encompassing multiple sub-factors commonly observed in engineering projects. These sub-factors provide a detailed understanding of the root causes contributing to project failures, offering insights into patterns and trends across various contexts. The literature synthesis is a foundation for developing strategies to mitigate these failures and improve project outcomes.

3.2 Survey Deployment

A survey was conducted in a factory automation department within a local medical device manufacturing company to assess the significance of sub-factors contributing to automation failures. These sub-factors, identified through a literature review, were validated through input from automation specialists. The survey collected respondents' demographics (age, experience, job level, and role) and used a Likert scale (1–5) to rank sub-factors based on perceived impact. Administered via Google Forms over one month, with weekly follow-ups, the survey ensured broad participation while maintaining ethical and confidentiality standards.

3.3 Data Analysis

The study employed a quantitative approach using SPC XL software to analyse survey data through descriptive statistics, including sample size (n), mean ($\bar{x}$), standard deviation (SD), and the 95% confidence interval. Results were tabulated to assess the relative importance, variability, and reliability of sub-factors, with the confidence interval ensuring precision in mean estimates. This systematic approach provided accurate insights, supporting evidence-based decision-making.

4. Result

4.1 Survey Result

The survey, conducted among 63 professionals in departments specialising in factory automation within a medical device manufacturing company, aimed to identify and assess critical failure factors impacting automation projects. The survey focused on sub-factors previously identified through a comprehensive literature review, gathering insights from industry experts to evaluate the significance of these factors in real-world automation challenges.

4.1.1 Demography result

The survey, conducted among 63 respondents, provides insights into the demographic and occupational characteristics of the workforce, focusing on age distribution, work experience, job roles, and job levels. An analysis of the age demographics in Figure 1 reveals that the workforce is predominantly young. The most significant proportion of respondents, accounting for 50.79 percent, falls within the 21 to 26 age range, followed by 41.27 percent aged between 27 and 32. The representation of older age groups is comparatively lower, with only 3.17 percent belonging to the 33 to 38 age category and 4.76 percent aged 39 years or older. These findings highlight a relatively youthful workforce, with more than 92 percent of participants aged 32 or younger. Regarding work experience in Figure 2, a substantial proportion of respondents are in the early stages of their careers. The majority, representing 57.14 percent, reported having between one and five years of experience, while 26.98 percent indicated less than one year of experience. This suggests that most of the workforce comprises early-career professionals with limited tenure. Conversely, only 11.11 percent possess six to ten years of experience, and a mere 4.76 percent have accumulated more than ten years of professional experience. These findings further reinforce the predominance of an emerging workforce, with approximately 85 percent having less than six years of work experience. The survey also examined job levels, as in Figure 3, revealing that most respondents, accounting for 93.65 percent, occupy executive positions, indicating a strong representation of professionals in operational and mid-level roles. In contrast, only 4.76 percent hold managerial positions, while 1.59

percent are classified as non-executives. These results suggest that the surveyed workforce primarily engages in technical and functional roles rather than leadership.

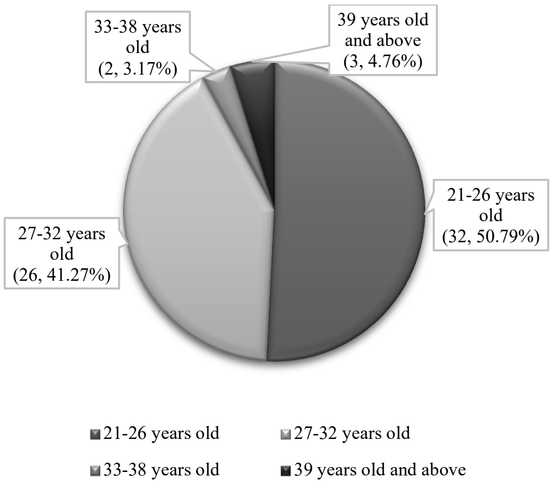

Fig. 1. Demography In terms of Age

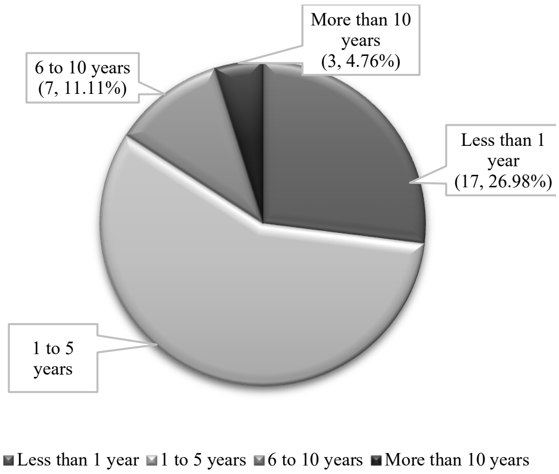

Fig. 2. Demography In terms of Work Experience

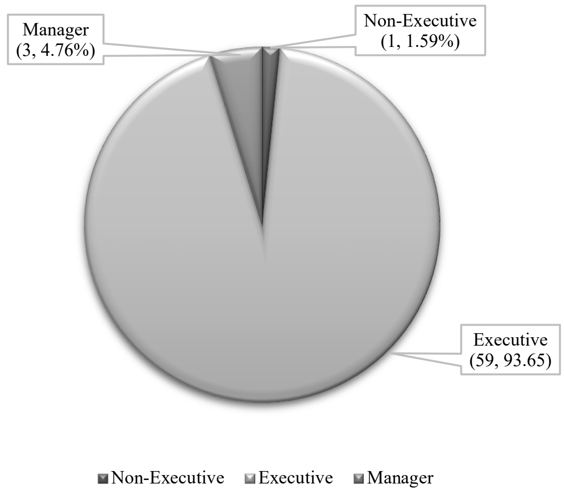

Fig. 3. Demography In terms of Work Level

4.1.2 Statistical result

Table 2 shows the statistical results for CFFs that significantly influence the success of automation projects. Figure 4 illustrates the arrangement of the mean scores, ordered from the lowest to the highest mean, for each category of CFFs. Each factor captures specific areas where challenges commonly arise, with the data offering insights into their perceived criticality based on the mean scores ($\bar{x}$), standard deviations (SD), and confidence intervals.

The technical category is critical to the success of automation projects, emphasising the quality, compatibility, and durability of technologies and materials. The *Impact on Equipment Wear and Tear* received the highest mean score of 4.222 ± 0.832. The 95% confidence interval ranges from 4.01 to 4.43, indicating a generally positive perception of minimal equipment deterioration due to system implementation. However, the more considerable variability suggests differing experiences among respondents. *Quality of Technology* and *Implementation and Compatibility with Automation Systems* obtained a mean score of 4.206 ± 0.722. The confidence interval ranges from 4.02 to 4.39, showing consistent positive feedback on the system's implementation and seamless integration with automation. The relatively lower variability suggests strong agreement among respondents. The *Material Consistency and Quality* received the lowest mean score of 4.127 ± 0.751, with a confidence interval of 3.94 to 4.32. While still favourable, this indicates slightly more variation in responses, suggesting potential areas for refinement in material quality and consistency.

The operational dimension is significant in ensuring the smooth execution of automation projects, addressing project timelines, cost estimates, and process understanding. The *Unrealistic Timelines and Budget Estimates* received the highest mean score of 4.381 ± 0.658, with a 95% confidence interval ranging from 4.22 to 4.55. This suggests that respondents widely perceive scheduling and budgeting issues as significant operational challenges, although the relatively lower standard deviation indicates strong agreement among participants. The *Hidden Costs and Underestimated Expenses* factor was also rated highly, with a mean score of 4.286 ± 0.682 and a confidence interval of 4.11 to 4.46. This indicates that unexpected financial burdens are common, though responses show moderate variability. The *Overly Optimistic Proposals* had a mean score of 4.222 ± 0.750, with a confidence interval of 4.03 to 4.41. This suggests that many respondents believe initial project expectations are unrealistic, leading to potential operational inefficiencies. The *Poor Understanding of Existing Processes* and *Handling and Storage Considerations* both received a mean score of 4.159, with standard deviations of 0.723 and 0.787, respectively. Their confidence intervals range from 3.98 to 4.34 for process understanding and 3.96 to 4.36 for storage considerations. These results suggest that while these issues are notable, they exhibit moderate variability in perceptions. The lowest-rated factor *was Incomplete Requirements Gathering*, with a mean score of 4.127 ± 0.889 and a confidence interval of 3.90 to 4.35. Although rated positively, the higher standard deviation suggests more diverse opinions among respondents, indicating potential inconsistencies in requirements-gathering practices.

The organisational dimension highlights the internal factors that influence the success of automation projects, focusing on project scope, communication, knowledge transfer, and change management. The *Ineffective Communication Channels*, *Inadequate Project Scope Definition*, and *Poor Change Management Practices* all received a score of 4.254, indicating that these factors are perceived as significant organisational challenges. Among them, *Ineffective Communication Channels* had the highest variability, with a standard deviation of 0.761 and a 95% confidence interval of 4.06 to 4.44, suggesting more diverse opinions among respondents. *Inadequate Project Scope Definition* had the lowest variability, with a standard deviation of 0.567 and a confidence interval of 4.11 to 4.40, indicating more substantial agreement on its impact. *Poor Communication Planning* was rated slightly lower, with a mean score of 4.238 ± 0.640 and a confidence interval of 4.08 to 4.40. While still a critical concern, this suggests a somewhat lower level of agreement among respondents compared to the highest-rated factors. *Ineffective Tender Management Processes* had a mean score of 4.206 ± 0.722, with a confidence interval of 4.02 to 4.39. This indicates that procurement and tendering inefficiencies are a notable challenge, though responses showed moderate variability. The lowest-rated factor was *Insufficient Knowledge Transfer*, with a mean score of 4.127 ± 0.772 and a confidence interval of 3.93 to 4.32. This suggests that while knowledge transfer is a concern, responses varied significantly, possibly due to differing project experiences.

The external dimension focuses on factors outside the organisation but significantly impacts automation projects, including vendor selection, cost pressures, and alignment with client needs. The highest-rated factor was *Pressure to Reduce Costs*, with a mean score of 4.286 ± 0.851 and a 95% confidence interval of 4.07 to 4.50. This indicates that cost reduction pressures are a significant concern, though the relatively high standard deviation suggests some response variation. *Misalignment with Client Needs* followed closely, with a mean score of 4.270 ± 0.787 and a confidence interval of 4.07 to 4.47. This suggests that ensuring alignment with client expectations is a critical issue, with moderate response variability. *Budget Implications* and *Supplier Variability* both received a mean score of 4.254. *Budget Implications* had a standard deviation of 0.782, with a confidence interval of 4.06 to 4.45, while *Supplier Variability* had a slightly higher standard deviation of 0.787, with a confidence interval of 4.07 to 4.47. These results suggest that managing budgets and supplier consistency are significant challenges, with comparable levels of concern among respondents. The lowest-rated factor was *Inadequate Vendor Evaluation and Selection*, with a mean score of 4.143 ± 0.800 and a confidence interval of 3.94 to 4.34. While still a notable issue, this factor showed the highest variability, indicating diverse opinions on its impact.

The technological dimension addresses the challenges and opportunities associated with the use of technology in automation projects, including specification clarity, impact assessment, innovation, and financial risk. The highest-rated factor was *Difficulty in Assessing Impact,* with a mean score of 4.333 ± 0.741 and a 95% confidence interval of 4.15 to 4.52. This suggests that evaluating the effects of technological decisions is a significant concern, with moderate variability in responses. *Incomplete or Ambiguous Specifications* followed closely, with a mean score of 4.238 ± 0.777 and a confidence interval of 4.04 to 4.43. This indicates that unclear or insufficient specifications are a significant issue, though there is some variation in perceptions. *Increased Financial Risk* had a mean score of 4.206 ± 0.722, with a confidence interval of 4.02 to 4.39. This suggests that financial uncertainties related to technology implementation are a notable concern, with relatively stable responses. The lowest-rated factor was *Impact on Innovation*, with a mean score of 4.190 ± 0.737 and a confidence interval of 4.00 to 4.38. While still an important issue, it received the lowest priority among the technological challenges.

Table 2
Data analysis from survey responses

TFactor	Sub-Factor	Descriptive Analysis			95% Conf. Interval for Mean		Rating (%)				
		n	$\bar{x}$	SD	Upper limit	Lower limit	5	4	3	2	1
Technical	Quality of Technology and Implementation	63	4.206	0.722	4.39	4.02	31.75	61.90	3.17	1.59	1.59
	Material Consistency and Quality	63	4.127	0.751	4.32	3.94	30.16	55.56	12.70	0.00	1.59
	Compatibility with Automation Systems	63	4.206	0.722	4.39	4.02	33.33	57.14	7.94	0.00	1.59
	Impact on Equipment Wear and Tear	63	4.222	0.832	4.43	4.01	39.68	49.21	6.35	3.17	1.59
Operational	Unrealistic Timelines and Budget Estimates	63	4.381	0.658	4.55	4.22	46.03	47.62	4.76	1.59	0.00
	Incomplete Requirements Gathering	63	4.127	0.889	4.35	3.90	34.92	50.79	9.52	1.59	3.17
	Poor Understanding of Existing Processes	63	4.159	0.723	4.34	3.98	30.16	58.73	9.52	0.00	1.59
	Overly Optimistic Proposals	63	4.222	0.750	4.41	4.03	36.51	52.38	9.52	0.00	1.59
	Hidden Costs and Underestimated Expenses	63	4.286	0.682	4.46	4.11	39.68	50.79	7.94	1.59	0.00
	Handling and Storage Considerations	63	4.159	0.787	4.36	3.96	34.92	49.21	14.29	0.00	1.59
Organisational	Inadequate Project Scope Definition	63	4.254	0.567	4.40	4.11	31.75	61.90	6.35	0.00	0.00
	Poor Communication Planning	63	4.238	0.640	4.40	4.08	33.33	58.73	6.35	1.59	0.00
	Insufficient Knowledge Transfer	63	4.127	0.772	4.32	3.93	31.75	52.38	14.29	0.00	1.59
	Ineffective Tender Management Processes	63	4.206	0.722	4.39	4.02	33.33	57.14	7.94	0.00	1.59
	Poor Change Management Practices	63	4.254	0.671	4.42	4.08	36.51	53.97	7.94	1.59	0.00
	Ineffective Communication Channels	63	4.254	0.761	4.44	4.06	38.10	53.97	4.76	1.59	1.59
External	Inadequate Vendor Evaluation and Selection	63	4.143	0.800	4.34	3.94	34.92	49.21	11.11	4.76	0.00
	Pressure to Reduce Costs	63	4.286	0.851	4.50	4.07	49.21	34.92	11.11	4.76	0.00
	Budget Implications	63	4.254	0.782	4.45	4.06	41.27	46.03	11.11	0.00	1.59
	Misalignment with Client Needs	63	4.270	0.787	4.47	4.07	41.27	49.21	6.35	1.59	1.59
	Supplier Variability	63	4.254	0.787	4.47	4.07	42.86	44.44	11.11	0.00	1.59
Technological	Incomplete or Ambiguous Specifications	63	4.238	0.777	4.43	4.04	39.68	47.62	11.11	0.00	1.59
	Difficulty in Assessing Impact	63	4.333	0.741	4.52	4.15	44.44	47.62	6.35	0.00	1.59
	Impact on Innovation	63	4.190	0.737	4.38	4.00	33.33	55.56	9.52	0.00	1.59
	Increased Financial Risk	63	4.206	0.722	4.39	4.02	33.33	57.14	7.94	0.00	1.59

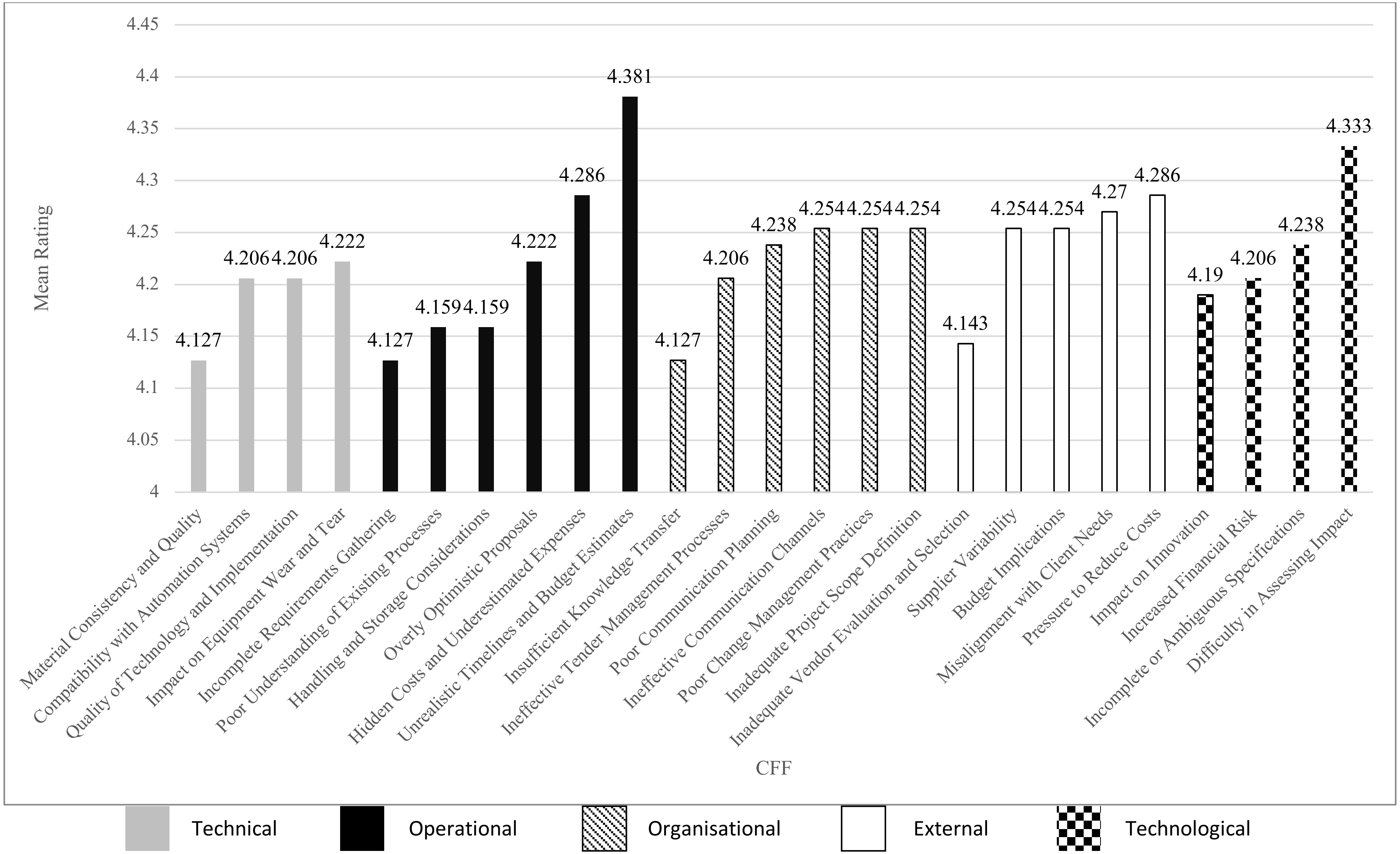

Fig. 4. Mean Rating against CFFs

3. Discussion

The survey findings provide a comprehensive understanding of the Critical Failure Factors (CFFs) that can significantly impact the success of factory automation projects, especially in the context of medical device assembly. These factors were grouped into five key categories: Technical, Operational, Organisational, External, and Technological. Each category highlights specific challenges that must be addressed to ensure the smooth implementation of automation in complex manufacturing environments.

In factory automation, technical factors play a pivotal role in determining the success of a project. Factors such as the quality of technology and implementation, material consistency, and compatibility with existing automation systems were identified as crucial elements. Given the stringent regulatory and quality standards that govern the sector, these technical considerations are even more vital for medical device assembly. Ensuring that automation systems are seamlessly integrated with existing processes and can sustain the wear and tear associated with high-precision manufacturing is key to avoiding costly downtime or failures. A careful selection of technologies that meet the specific needs of the medical device sector can mitigate these risks.

Operational challenges were another major category of concern. Unrealistic timelines, poor budget estimates, and underdeveloped requirements gathering were found to be significant contributors to automation project failures. In medical device assembly, these issues can lead to delays in production, non-compliance with regulatory standards, and subpar product quality. For high-stakes projects, allocating sufficient time and resources, developing accurate cost projections, and ensuring that all project requirements are clearly defined from the outset is essential. A more systematic approach to operational planning, with regular monitoring and adjustment of timelines and budgets, will enhance the likelihood of project success.

Effective organisational practices are critical for the successful execution of automation projects. The survey identified challenges related to inadequate project scope definition, poor communication planning, and ineffective change management. In medical device assembly, where multiple stakeholders are involved—from engineers and production teams to regulatory bodies—misalignment in project goals can result in costly errors or delays. Ensuring clear, consistent communication throughout the project lifecycle and a well-defined project scope will prevent misunderstandings and ensure all team members are aligned with the project objectives. Adopting a strong change management strategy is essential to guide teams through transitions and ensure the smooth implementation of new automation technologies.

External factors, such as pressure to reduce costs and vendor selection, are also influential in the success of factory automation projects. In the case of medical device assembly, selecting vendors capable of meeting regulatory standards is crucial. Any failure to choose reliable suppliers can undermine the entire automation process. Furthermore, cost-cutting measures that compromise quality can negatively affect product quality and compliance. Careful evaluation of vendors and suppliers, coupled with realistic budgeting, will help to minimise these risks and ensure that the automation system meets the required standards for safety and efficacy.

Technological challenges were significant, particularly regarding incomplete or ambiguous project specifications and difficulty in assessing the impact of new technologies. In medical device assembly, where precision and accuracy are paramount, unclear specifications can lead to faulty designs and non-compliance with safety regulations. Establishing clear, detailed, and comprehensive specifications for all automation systems is critical, ensuring that all technological impacts are thoroughly assessed before implementation. Regular technological reviews throughout the project will help identify potential issues early and allow adjustments to ensure the automation system remains effective and compliant.

4. Conclusion

This study has identified and analysed several Critical Failure Factors (CFFs) that significantly impact the success of factory automation projects, particularly in medical device assembly. The findings underscore the importance of addressing challenges across five key categories: Technical, Operational, Organisational, External, and Technological. By examining the perceptions of industry professionals, the study reveals that technical factor such as technology quality, material consistency, and system compatibility are critical for successful implementation. In addition, operational and organisational challenges such as unrealistic timelines, poor budget management, and inadequate communication planning were key contributors to failure. External pressures, including cost reduction demands, vendor selection, and technological issues like unclear specifications, must also be carefully managed to prevent project failure. Addressing these critical factors with a comprehensive project management strategy will enhance the likelihood of successful automation implementation in complex manufacturing environments, particularly in sectors with high regulatory requirements like medical device assembly.

While the findings of this study provide valuable insights, some limitations must be considered. First, the study focuses on a limited sample of industry professionals, which may not fully represent the diverse experiences and challenges across all automation projects. Additionally, the study's data collection was based on subjective perceptions, which individual biases or varying experience levels may influence. Furthermore, the study was conducted within a specific sector: medical device assembly. While the results are insightful for this field, they may not directly apply to all automation projects in other industries. Lastly, the study did not explore the potential interactions between different CFFs, which could provide further insights into how these factors influence one another and collectively contribute to project success or failure.

This study contributes to the growing literature on factory automation and its critical success factors, specifically in medical device assembly. By identifying and categorising the key CFFs, this research provides a valuable framework for professionals in the field to understand better the challenges they may face when implementing automation technologies. The findings can assist project managers and engineers in anticipating potential issues and developing strategies to mitigate risks. Furthermore, the study contributes to applying project management principles in highly regulated industries like medical device manufacturing, offering insights into how automation projects can be better managed for success.

Future research could extend this study in several ways. First, increasing the sample size by including a more diverse group of professionals from various regions and sectors related to factory automation would enhance the reliability and generalizability of the findings. Additionally, incorporating qualitative methods, such as interviews or focus groups, could provide deeper insights into the identified Critical Failure Factors (CFFs) and help counter potential biases from subjective perceptions.

Further research should also analyse the interactions among failure factors, exploring how technical, operational, organizational, external, and technological challenges compound and influence project outcomes. Understanding these interdependencies could lead to more nuanced recommendations for project management strategies. Conducting similar studies across different industries would also be valuable in determining whether these CFFs remain consistent or vary based on industry-specific contexts. Future research also could examine the role of emerging technologies, such as artificial intelligence and machine learning, in automation and assess their impact on project success or failure. Finally, longitudinal studies tracking the long-term effects of managing these CFFs would be valuable in evaluating the sustained impact of effective management practices on factory automation projects.

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