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Abstract: This study addresses the critical issue of cardiovascular diseases (CVDs) as the leading cause of death globally, emphasizing the importance of stent delivery catheter manufacturing. Traditional manufacturing processes, reliant on destructive end-of-batch sampling, present significant financial and quality challenges. This research addresses this challenge by proposing a novel approach: a closed-loop cyber-physical production system (CPPS) employing non-destructive process analytical technology (PAT). Through a mixed-method approach combining a comprehensive literature review and the development of a CPPS prototype, the study demonstrates the potential for real-time quality control, reduced production costs, and increased manufacturing efficiency. Initial findings showcase the system’s effectiveness in streamlining production, enhancing stability, and minimizing defects, translating to substantial financial savings and improved product quality. This work extends the author’s previous research by comparing the validated system’s performance to that of pre-implementation manual workflows and inspections, highlighting tangible and intangible improvements brought by the new system. This paves the way for advanced control strategies to revolutionize medical device manufacturing. Furthermore, the study proposes a generalized CPPS framework applicable across diverse regulated environments, ensuring optimal processing conditions and adherence to stringent regulatory standards. The research concludes with the successful demonstration of innovative approaches and technologies, leading to improved product quality, patient safety, and operational efficiency in the medical device industry.

Keywords: cyber-physical systems; process analytical technology; stent delivery catheters

1. Introduction

Cardiovascular diseases (CVDs) are the number one cause of deaths globally, affecting not only high-income but also middle- and low-income countries [1–3]. According to some statistics published by World Health Organization (WHO), an estimated 17.9 million people’s deaths were caused by CVDs in 2019, representing 32% of global deaths, and of these, 85% were caused due to either ischaemic heart disease or stroke. Clinically, “heart attack” or “myocardial infarction” is a term used to denote the condition when there is evidence of myocardial necrosis in a clinical setting consistent with myocardial ischaemia [4]. Put simply, it is a serious medical condition in which the supply of blood to the heart is suddenly obstructed, usually by a blood clot. This blood clot, referred clinically as atherosclerosis, is essentially a plaque composed of fat, cholesterol, fibrin, and calcium that develops on the inner walls of the arteries [5]. Atherosclerosis is deemed to be the principal cause of myocardial infarction [6].

Acute myocardial infarction is divided into ST-segment elevation myocardial infarction (STEMI) and non-ST-segment elevation myocardial infarction (NSTEMI) [7]. Depending on the type of myocardial infarction, common treatment options include thrombolyis for
NSTEMI, which basically consists of dissolving the blood clots and restoring blood flow through a combination of medication. For STEMI, which is the most serious type of heart attack, the recommended treatment option is percutaneous coronary intervention (PCI), commonly known as coronary angioplasty with stenting [8]. This procedure incorporates a combinational medical device such as a radial metal stent deployed using an inflating balloon via minimally invasive procedures. PCI with bare metal stents has its own set of complications and risks. The biggest post-intervention risks associated with PCI using metal stents are the risks of stent thrombosis (blood clotting) and restenosis (narrowing of arteries) [9]. Stent technology has evolved rapidly and currently since then; the most prominent stents used are drug-eluting stents (DESs). DESs have considerably reduced post-procedure complications related to stent thrombosis and restenosis [10,11].

With the reduction in post-intervention complications for the procedure, demand for immediate intervention for these conditions has led to a surge in manufacturing volumes for these combinational devices. As of 2016, the global market for vascular stents was estimated at $7.22 billion, with coronary artery stents accounting for 67.3% of the vascular stent market [12]. The global stent market is expected to grow at a compounded annual growth rate (CAGR) of 8.1% by 2033 [13]. Currently, these life-saving devices are predominantly manufactured using either a semi-automated production process or a manual assembly process in conjunction with classical quality control approaches [14]. This poses a significant challenge for the manufacturers of these life-saving devices. The current semi-automated manufacturing process and classical approach to quality with acceptance sampling and batch release can no longer support the increasing demands for production. This underscores the urgent need for manufacturers to look for alternatives to classical quality control approaches to move towards more advanced Industry 4.0-based solutions.

In a guidance document released by the US Food and Drug Administration (FDA) in 2004, the regulators encouraged the industry to develop and implement innovative process analytical technologies (PAT) for improving pharmaceutical development, manufacturing, and quality assurance through innovation in product and process development, process analysis, and process control [15]. The FDA advised manufacturers to have extensive understanding of their processes and critical product and process parameters along with the ability to control processes through quality systems and strive for continuous improvement [16]. It continues to emphasize the need for industries to move away from classical batch release and control strategies towards real-time release testing (RTRT) through utilization of PAT. This paper aims to highlight the financial and quality implications of using current destructive end-of-batch sampling in stent delivery catheter manufacturing. Additionally, it will continue to build upon the author’s previous work on the development and adoption of a non-destructive (NDT) PAT (specifically, a closed-loop cyber-physical production system, or CPPS) for this use case and a generalized framework that would be readily deployable within the regulated medical device manufacturing industry in general.

2. End-of-Batch Sampling

The current manufacturing process for these catheters relies on batch sampling technique based on acceptance criteria derived from the product design specifications for accepting or rejecting manufactured lots using destructive tensile testing as shown in Figure 1. Acceptance sampling in pharmaceutical/medical device industry is based on the ANSI/ASQ Z1.4 tables for inspection by attributes and ANSI/ASQ Z1.9 for inspection by variables.

The current lot size for these catheters is 120; therefore, three random parts in every lot are sampled and inspected as per Table 1. Dodge and Romig [17], first to introduce operating characteristics (OC) curve, defines them as a representation of the performance of a sampling plan to that of various defect levels. In this case as shown in Figure 2, the lot’s proportion of defective products \( p \) accepted by the sampling plan (probability of acceptance \( P_a \)) is given by the formula \( P_a = 1 - p \). The OC curve for this sampling plan for acceptance number \( a = 0 \), meaning no rejects in the three random samples inspected for a
lot size of 120, provides an 88% probability of acceptance with a defective proportion of 4% for the lot.

Table 1. Sampling levels in device manufacture as per ANSI/ASQ Z1.4.

<table>
<thead>
<tr>
<th>Lot Size</th>
<th>Total Qty. to Be Sampled</th>
<th>Minimum Qty. to Perform All Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 or less</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>41–80</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>81–120</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>121–160</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>161–200</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>201–240</td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>

With the current manufacturing volume going up and anticipated to grow over a minimum of 5 years, continuing to perform acceptance sampling will become more time-consuming, more costly, and more labour-intensive. For this particular use case, the manufacturer intends an annual planned production volume of 4 million catheters. With a lot size of 120, that is approximately 33.3 thousand batches. Current plan for acceptance sampling needs three samples per test per lot for three different destructive tensile tests which brings the annual volume of testing samples to almost 300 thousand. The average selling price of a DES catheter is approx. $200, and the manufacturing cost is approx. $55 per catheter. This brings the cost of sampling to almost $60 million in lost revenue and $16.5 million in testing costs, excluding the cost of labour, missed opportunities for higher capacity, and the cost of additional samples in case the initial sampling fails and more samples needs to be pulled before releasing the batch.

Acceptance Sampling by Attributes
Measurement type: Go/no go

Figure 1. Destructive tensile testing of catheters.
Lot quality in terms of proportion defective
Lot size: 120

**Method**
Rejectable Quality Level (RQL or LTPD) 0.04

**Compare User Defined Plan(s)**
- Sample Size: 3
- Acceptance Number: 0

Accept lot if defective items in 3 sampled ≤ 0; otherwise reject.

<table>
<thead>
<tr>
<th>Proportion Probability</th>
<th>Probability</th>
<th>Accepting</th>
<th>Rejecting</th>
<th>AOQ</th>
<th>ATI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.04</td>
<td>0.885</td>
<td>0.115</td>
<td>0.0.0450</td>
<td>1.65</td>
<td></td>
</tr>
</tbody>
</table>

**Average Outgoing Quality Limit(s) (AOQL)**
- At Proportion
  - AOQL
  - Defective

![Operating Characteristic (OC) Curve](image)

**Figure 2.** Acceptance sampling and OC curve for 3:120 attribute sampling.

The utilization of acceptance sampling methods also entails certain fallacies that warrant consideration. As highlighted by Wheelers and Chambers [18], these limitations pertain to the acceptance sampling approach. The approach inherently operates under the assumption that lot quality exhibits significant variability across different batches while remaining homogeneous within a given batch. Decisions regarding the acceptance or rejection of each batch hinge on the outcomes of both measured and unmeasured samples within that batch, under the presumption of homogeneity. In cases where product quality displays substantial variation not only between batches but also within individual batches, the foundational assumptions of acceptance sampling are no longer valid. This introduces a significant level of uncertainty concerning the quality of batches delivered to customers, which is deemed unacceptable, particularly in the context of Class III medical devices such as stent delivery catheters. This itself presents a strong proposition for the manufacturer to look for smarter solutions that are more cost-effective than the classical statistics-based approach and that allow for growth and expansion without imposing an additional testing burden.

3. **Literature Review**

The advent of CPPS represents a paradigm shift in modern manufacturing, integrating computational intelligence with physical processes to create more efficient, adaptable, and intelligent production environments. As manufacturing industries increasingly strive for precision, efficiency, and real-time adaptability, CPPS has emerged as a cornerstone technology. This
literature review aims to explore the development, implementation, and impact of CPPS within the context of advanced manufacturing systems. By synthesizing current research, technological advancements, and case studies, this review will elucidate the critical role of CPPS in enhancing operational efficiency, product quality, and overall production agility. The review will also examine the challenges and opportunities associated with CPPS adoption, providing a comprehensive understanding of its potential to revolutionize manufacturing practices across medical device manufacturing.

Parallels between advancements in information technology and manufacturing were realized very early with the advent of Industry 4.0, giving rise to the extension of cyber-physical systems (CPSs) to manufacturing and the birth of the concept of CPPSs [19,20]. Various models from the literature are reviewed to understand the best way forward to address the primary research objectives of the study. One model proposed retrofitting any industrial equipment following a retrofitting process based on a developed platform to facilitate upgrading of the equipment to CPPS level through deployment of smart sensors, communication protocols and servers, establishing monitoring, and deployment of cloud storage [21]. Although the model is generic enough for deployment, there are no considerations for deployment in a regulated manufacturing environment; therefore, further exploration is needed. Another interesting framework is explored for decision making in a CPPS through digital twins [22]. The proposed conceptual framework along with a proof of concept demonstrates that the closed-loop data-based digital twin architecture outperforms other available solutions in automated decision making. Nonetheless, it is not clear how the system would handle erroneous data that might push the system out of its operating limits. Additionally, the author calls out the limitations of the framework in its ability to handle complex real industrial environments with a large CPPS. While the idea of a closed-loop system is related to this study’s research objectives, it would be necessary to further investigate its applicability for the regulated manufacturing. Similar outcomes were presented when a CPPS was deployed for predictive analytics of production systems [23]. The deep learning-based system showed enhanced capabilities in predicting unexpected downtime of the system. Vogel-Heuser et al. [24] explored the idea of an agent-based CPPS and concluded that the intelligent behaviour of the CPPS needs to be considered during the design phase of the system and not after. Additionally, the required knowledge that would be critical for operations needs to be defined sufficiently during engineering design as much as possible for the system to perform successfully.

While the prospects of CPPSs based manufacturing look to be bright, there are significant challenges that need to be overcome before adoption in real-world manufacturing. Designing open, large, complex CPPSs requires work on both the conceptual and technical fronts to address the complexities of achieving a holistic CPPS [25,26]. An in-depth systematic review on the development of CPPSs has been carried out by Wu et al. [27]. The authors concluded with a detailed concept map highlighting more than 50 CPPS-related topics that needed further research and investigation. This establishes the fact that concept of developing a CPPS itself needs to be explored in depth, along with its adoption within highly regulated manufacturing. A systematic review on the adoption of Industry 4.0 technologies in medical device manufacturing highlighted the same issue and the challenges [28]. The importance of this research therefore becomes more relevant, as the existing literature points towards a significant gap in adoption of Industry 4.0 and specifically CPPSs within regulated medical device manufacturing.

4. Materials and Methods

4.1. Research Methodology

This research work is an extension of the work carried out by the authors in relation to developing a closed-loop cyber-physical production system, designed to address three key focus areas for catheter manufacturers and, by extension, the highly regulated medical device industry. The three research objectives for the overall work carried out were quick product changeovers, real-time quality control, and a self-adaptive closed-loop control system [29,30]. This paper in particular focuses on the real-time quality control objective by
proposing a generalized version of a closed-loop system that focuses on moving away from destructive testing of catheters at the end of the batch towards a non-destructive in-line real-time inspection system.

The overall study employed a mixed-method approach to the experimental design, combining qualitative and quantitative research paradigms in an exploratory sequential manner as shown in Figure 3. This approach allows researchers to gain a comprehensive understanding of the research problem by utilizing both qualitative and quantitative methods in different phases of the study ([31] via [32]). The whole process design lifecycle was subjected to Action Design Research (ADR) science for artefact generation through continuous improvement loops as proposed initially by Sein et al. [33] and further improved by Mullarkey and Hevner [34].

In Phase I of the research, a qualitative approach was employed to address two main objectives. Firstly, an extensive review of the academic literature was conducted to gain a comprehensive understanding of manufacturing systems, including their types, advantages, and disadvantages. This thorough exploration allowed the researcher to form a well-informed opinion on the most suitable manufacturing system for the specific research case. Additionally, recognizing the importance of real-world applications, the researcher investigated successful solutions implemented in other industries; international standards; and innovative approaches developed by organizations, R&D departments, and research laboratories. By drawing inspiration from these diverse sources, the aim was to adapt and apply effective solutions to the unique context of medical device manufacturing. Throughout Phase I, a conceptual framework for a closed-loop CPPS was developed, integrating insights from the academic literature and existing solutions/standards. This integrated framework served as the foundational basis for further development and implementation of the closed-loop CPPS.

In Phase II, a quantitative approach was implemented to guide the creation, data generation, collection, analysis, and testing of the CPPS artefact. Building upon the conceptual CPPS model, the focus shifted towards designing a practical machine or artefact that would directly address the research objectives and primary research question as shown in Figure 4. This involved translating the conceptual model into a tangible prototype that could be tested and refined. Throughout this phase, the artefact prototype underwent a series of continuous improvement cycles, following the principles of ADR science. By iteratively refining the artefact based on feedback and insights gained from each cycle, the aim was to enhance its functionality, efficiency, and overall performance.

![Figure 3. Research methodology.](image-url)
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**Figure 4.** Tools used for artefact development and testing.

### 4.2. Artefact Development

In this research, Solidworks served as the primary tool for hardware design and development, providing a comprehensive platform for creating detailed three-dimensional models and prototypes. Leveraging its robust features and intuitive interface, the researcher and the extended mechanical design team utilized Solidworks to design and refine the physical components of the artefact, ensuring precise dimensions and optimal functionality. Subsequently, Microsoft VB.NET version 4.5 played a pivotal role in the software and system design architecture development process, facilitating the creation of a cohesive and efficient software framework to complement the hardware components.

Following this, Cognex Insight software, version 6.5.0, was employed for vision system development, enabling the implementation of visual inspection capabilities. Lastly, Minitab served as a crucial tool for validation testing, enabling rigorous statistical analyses to validate the accuracy and precision of the developed artefact’s capabilities. Through the integration of these software tools, the researcher effectively designed, developed, and validated the prototype artefact, thereby advancing the objectives of this research.

The conceptual CPPS framework, hardware development, software design, artefact creation, and validation testing are covered in detail in the author’s previous work in [29,30] and as shown in Figures 5 and 6. This research article will proceed to explore the impact of the development of this NDT technology on the overall production process of these catheters and whether the research objective has been met. It will also attempt to foresee whether the custom developed conceptual framework for catheter manufacturing can be generalized for the overall medical device manufacturing industry.
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5. Results
5.1. System Performance

The closed-loop system along with the in-line vision system was implemented successfully as part of the experimental test rig (see Figure 7).

The system was also validated successfully per the stringent regulations of the regulatory bodies, as covered in detail in [30]. The performance of the vision system was found to be statistically equivalent to manual inspection carried out by a trained operator (see Figure 8). This equivalency is important from a regulatory point of view, as this provides substantial evidence that there is no compromise in the product's quality or safety.
for patients. The newly deployed automated inspection system performed on par with conventional manual inspection and verification performed by an operator.

![Vision camera inspection outputs.](image)

**Figure 7.** Vision camera inspection outputs.

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![Bland–Altman equivalence test.](image)

**Figure 8.** Bland–Altman equivalence test.

### 5.2. Effectiveness of Closed-Loop Control

Figure 9 illustrates the influence of the closed-loop control framework along with the PAT system on the production process. It shows a Pareto analysis based on the count of missed units in the production process. The analysis clearly demonstrates the significant impact of the models, as the number of missed units in the process was reduced by more than 50% in terms of volume following the activation of the system. This notable reduction underscores the effectiveness of the decision models in improving the overall performance and efficiency of the production system.

A significant impact of the framework can also be seen in the cycle time of the machine and the number of moves the machine made within the production cycle of each unit. Since the prototype was connected to a live database that captured the vision system’s run data in real time, a trending software was able to trend these parameters in real time for the shopfloor engineering staff.
Figure 10 shows a snapshot of the machine’s average cycle time before the models were activated for the machine bonding work step. The cycle time was not consistent over time, and the average cycle time for the machine was approximately 25.3 s. The framework underscores the effectiveness of the decision models in improving the overall performance and efficiency of the production system. A significant impact of the framework can also be seen in the cycle time of the machine and the number of moves the machine made within the production cycle of each unit. Since the prototype was connected to a live database that captured the vision system’s run data in real time, a trending software was able to trend these parameters in real time for the shopfloor engineering staff.

Figure 10 shows a snapshot of the machine’s average cycle time before the models were activated for the machine bonding work step. The cycle time was not consistent over time, and the average cycle time for the machine was approximately 25.3 s.

Figure 11 illustrates a time segment displaying the average cycle time of the machine after the activation of the models for the machine bonding work step. Evidently, the average cycle time exhibits a significantly higher level of stability during the specific time. Furthermore, there was a noteworthy reduction of at least 2 s in the overall cycle time of the machine. Upon activating the models, the machine achieved an average cycle time of approximately 23.5 s per unit.

Similarly, the number of moves performed by the part-holding collet to align the part was examined. The target number of moves for the system was set at three moves. However, Figure 12 demonstrates that the system lacked stability, frequently requiring additional moves before initiating the bonding process. This instability contributed to the overall cycle time. Upon model activation with the vision system, as depicted in Figure 13, the number of moves became considerably more stable.
Figure 11. Machine’s average cycle time after model activation.

Figure 12. Move count before model activation.

Figure 13. Move count after model activation.
5.3. Tangible and Intangible Benefits

Section 2 highlighted the current cost burden due to end-of-batch Acceptable Quality Level (AQL) sampling for the current catheter manufacturing and batch release process. The cost of scaling the current prototype to a high-volume manufacturing line will be approximately $4.5–5 million. This will involve re-designing the current production process to take out the manual assembly and inspection process to be replaced by this newly developed closed-loop automated system. An external machine integrator will be involved in delivering the high-volume manufacturing work cell. Once the work cell is delivered and installed following factory acceptance testing and site acceptance testing, the same will be validated as per the industry norms. The validated system will then be released to commercial production. Associated manufacturing instructions and training will need to be rolled out along with the commercial deployment. This whole change will be managed through industry standard process change notification process that ensures that all the risks associated with the new process have been accounted for and mitigated up front before the change is deployed.

There will be direct cost saving of approximately $11.5 million per year once the scaled-up solution with real-time inspection fully replaces end-of-batch AQL acceptance sampling. There are intangible benefits associated with the solution as well, in terms of saving the intervention efforts of filling out paper records for AQL sampling, eliminating the instances of non-compliance due to tester error, and a major boost in the product quality. The implementation of two data-based feedback control loops has significantly enhanced resource optimization and contributed to a notable reduction in scrap within the manufacturing process. By incorporating closed-loop control systems, the operational efficiency of the production line has been substantially improved across various key performance indicators. The count of product misses for machine-related issues has been significantly reduced from 1890 units to 868 units, representing a substantial 54% decrease within a similar timeframe (see Figure 9). The number of product misses resulting from quality investigations has plummeted from 1357 to 125 units, demonstrating an impressive 90% reduction over a similar period. These improvements underscore the effectiveness of the closed-loop system in enhancing operational efficiency, minimizing waste, and optimizing resource utilization within the regulated manufacturing environment of these catheters.

6. Discussion

The successful implementation of the conceptual closed-loop CPPS underscores the transformative impact of leveraging advanced control strategies and standardized methodologies in modern manufacturing environments. However, while these solutions have demonstrated significant efficacy in the context of specific manufacturing scenarios, there remains a compelling need to generalize the CPPS framework to accommodate diverse manufacturing settings and regulatory requirements. By developing a generalized CPPS framework, tailored to address the unique needs and challenges of regulated manufacturing environments, organizations can unlock greater scalability, adaptability, and interoperability across their manufacturing operations. This holistic approach not only ensures continued process optimization and efficiency gains but also fosters innovation and resilience in the face of evolving market dynamics and regulatory landscapes.

The CPPS model, as initially conceived in [29], is tailored explicitly to the case study concerning catheter manufacturing. Data-driven CPPS models, which are predominantly referenced in the academic literature, tend to share a similar characteristic in that they are custom-designed to address specific use cases. The availability of generalized CPPS models applicable to diverse manufacturing environments remains limited in evidence. Suvarna et al. [35] did introduce a CPPS framework model, designed for broader applicability within manufacturing environment. This framework primarily emphasizes data collection from diverse sources, consolidation within a data repository, and utilization of this data for machine learning (ML) model training. Subsequently, these trained models are redeployed within the production environment to enact essential control measures. While this approach
holds practical merit for deployment in numerous standard manufacturing scenarios, it does not necessarily align with the stringent requirements of regulated manufacturing, particularly in fields such as medical devices. The reason for this disparity lies in the fact that regulatory authorities are still in the process of adapting to the integration of standalone AI/ML models within their regulatory frameworks. Complete acceptance of these technologies, along with the establishment of comprehensive guidelines for their use and deployment, is yet to be achieved. Notably, the model proposed by Suvarna et al. [35] does not delineate how it ensures the maintenance of product quality or the handling of erroneous situations, should they arise in contexts for which the model was not specifically trained.

To address this, this research attempts to close the gap by proposing a Guha model that is generalized enough to be deployable across regulated manufacturing environments, as shown in Figure 14. This generalized model is agnostic to the product being manufactured and solely focuses on the approach a manufacturer will need to take to develop a self-adaptable closed-loop production system that is also in line with regulatory bodies’ requirements.

A model of this nature possesses justifiable attributes for acceptance and deployment by regulatory bodies. This justification stems from its capacity to guarantee that under no circumstances can a manufacturing scenario transpire wherein the product is manufactured beyond the normal processing window. Essentially, this model serves as a mechanism to uphold the system’s operation within predefined optimal processing conditions and limits.

6.1. Research Limitations

This research focused on developing a custom data-driven closed-loop CPPS model to address key issues in the medical device manufacturing industry. While the model fills a significant gap in the existing literature, its applicability beyond the Guha model needs further generalization. Notably, the model is tailored to Class III medical device manufacturing and utilizes the ADR method, primarily covering problem formulation and build stages. However, its deployment in lower-risk device manufacturing may require a streamlined version. Additionally, custom solutions developed for SDC manufacturing may not be directly transferable to other contexts, necessitating redevelopment and revalidation.

Furthermore, the performance of developed solutions is currently limited by the validated process windows of manual manufacturing, which tend to be tighter than necessary. Introducing more precise automated systems could expand process windows, enhancing ef-

Figure 14. Proposed Guha model for CPPS deployment within regulated manufacturing.
ficiency, reducing scrap rates, and improving product quality. However, further research is needed to establish appropriate process windows and ensure regulatory compliance. By refining model parameters and validating manufacturing processes, generalized solutions can be developed for broader applicability across various manufacturing scenarios. This research offers a roadmap for addressing challenges in medical device manufacturing, emphasizing the need for generalized solutions adaptable to diverse use scenarios. By extending the outcomes of this research, efficiency and quality control enhancements can benefit a wider range of medical device manufacturers, fostering industry-wide advancements.

6.2. Future Work

The discussed limitations highlight areas for future research to improve upon the current study. Future work could focus on further generalizing the Guha model to accommodate different medical device manufacturers’ risk profiles or adapting it to various manufacturing scenarios. Additionally, characterizing the automated process and realigning validated process windows would provide valuable insights into the CPPS model’s performance in an automated manufacturing environment. Expanding the CPPS model to other manufacturing scenarios could enhance manufacturing control and visibility across the entire ecosystem. Moreover, integrating ML and AI technologies into the CPPS model presents intriguing research avenues. ML-based decision models can leverage extensive data generated by the system to enhance feedback logic, improving decision-making processes. Furthermore, ML algorithms can revolutionize the establishment of process windows by continuously optimizing based on accumulated data, leading to adaptive and more precise control. Integrating ML and AI technologies has the potential to drive efficiency, accuracy, and regulatory compliance in medical device manufacturing, revolutionizing the industry.

7. Conclusions

This research study successfully addressed the three main research objectives within the context of highly regulated complex medical device manufacturing. Through a comprehensive investigation and extensive literature review, it became evident that existing solutions were inadequate for the unique challenges faced by medical device manufacturers. To bridge this gap, a holistic theoretical framework was developed, leading to the creation of a novel data-driven closed-loop CPPS model. This model effectively integrated the research objectives, providing a cohesive and comprehensive solution to the broader research theme. The implementation of this model along with the custom solutions developed for the research objectives at hand produced significant improvements in the ability of the system to manage quick product changeovers, process control, real-time quality monitoring, and closed-loop decision making. This resulted in reduced scrap, enhanced process cycle times, and improved overall operational efficiency. The successful achievement of the research objectives highlights the potential of innovative approaches and technologies to address the complexities and regulatory requirements of the medical device manufacturing industry, ultimately leading to improved product quality, patient safety, and business performance.

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