INDO AMERICAN JOURNAL OF PHARMACEUTICAL RESEARCH

DISCUSS THE TRANSITION FROM TRADITIONAL VALIDATION METHODS TO AI AND ML-DRIVEN AUTOMATION IN MEDICAL DEVICE MANUFACTURING

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ARTICLE INFO

Article history
Received:
Available online:

Keywords
Predictive Analytics,
Artificial Intelligence,
Machine Learning,
Medical Device Validation,
Risk Assessment,
Regulatory Compliance,
Data Privacy,
Standardized Protocols.

ABSTRACT

The qualification of the medical device, which so far has been regulated by standard practices such as Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ), is now experiencing a revolution of such magnitude because of adopting machine learning (ML) and artificial intelligence (AI). While conventional methods have ensured conformity to regulation according to guidelines like FDA regulation and ISO 13485, they are more likely to be infested with inefficiency, cost, and vulnerability to human error—issues which are now no longer affordable in Industry 4.0. This article discusses the transition towards AI/ML-based automation in the production of medical devices based on a synthesis of knowledge from Scopus-indexed, IEEE, and Elsevier journals during 2020-2025. Enabling technologies like Big Data analytics, cloud computing, and the Internet of Things (IoT) are driving sophisticated applications such as predictive maintenance, real-time process optimization, and smart anomaly detection. Hybrid validation approaches integrating traditional techniques with AI-based solutions are gaining popularity for GxP compliance in sophisticated manufacturing environments. Successful use cases among leading medical device manufacturers demonstrate quantifiable benefits such as higher precision, effective use of resources, and higher traceability, along with factoring in challenges such as transparency in algorithms, ethical regulation of AI, and data integrity. The article also assesses emerging regulatory views, such as the FDA's AI/ML Action Plan and the Medical Device Regulation of the European Union (EU MDR), and suggests pragmatic recommendations for regulators and manufacturers, such as the creation of robust data infrastructures and interdisciplinary teams. Ultimately, it outlines areas of research gap in model validation, cybersecurity, and long-term performance testing, concluding that AI has transformative potential in building a robust, intelligent, and future-proofs validation ecosystem.

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*Please cite this article in press as **Jahnavi Vellanki** et al. Discuss the transition from traditional validation methods to AI and ML-driven automation in medical device manufacturing. Indo American Journal of Pharmaceutical Research.2025:15(06).*

Introduction

Validation processes form the cornerstone of medical devices' safety, efficacy, and regulatory approval. Traditionally, validation processes have relied on human-based protocols and historical data analysis in determining that production systems consistently produce devices that meet standardized standards. With the introduction of Industry 4.0, there has been an introduction of disruptive technologies like Artificial Intelligence (AI) and Machine Learning (ML), leading to a paradigm shift from traditional validation approaches.

The confluence of ML and AI in the manufacturing of medical devices offers the potential for real-time monitoring, predictive analytics, and adaptive control systems for validating procedures in terms of accuracy and efficacy. According to a study, AI-based strategies can transform defect detection, predictive maintenance, and quality control on factory floors for enhanced product reliability along with adherence to regulatory requirements. Moreover, the adoption of these technologies aligns with the recommendations of Industry 4.0, which emphasize the automation and digitization of industrial processes (Kausik et al. 2025). Regulatory authorities are now paying more attention to the AI and ML applications in medical device production.

The United States Food and Drug Administration (FDA), for example, has certified an increasing series of AI/ML-facilitated medical devices, indicating a turn towards the adoption of these technologies in regulatory frameworks.Whereas adopting AI and ML comes with challenges of data privacy, clarity in algorithms, and the requirement for new regulatory guidelines to accommodate the adaptive nature of such technologies (Pantanowitz et al. 2024), this paper will strive to examine the shift from traditional validation processes to AI and ML-based automation for manufacturing medical devices.

It will discuss the pros and cons of such a change, evaluate current regulatory mindsets, and make reference to implications for future factory procedure. In incorporating recent research and case histories, the paper will seek to present a comprehensive overview of the ways in which AI and ML are revolutionizing validation processes in the medical device industry.

2. Traditional Validation Methods: An Overview

In medical device manufacturing, quality of the product and regulatory compliance have always been dependent on the formal validation process involving Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). These steps are core to the process validation lifecycle, as outlined by regulators such as the U.S. Food and Drug Administration (FDA) and international standards ISO 13485 (Tricentis 2025).

Description of Conventional Validation Practices (IQ, OQ, PQ)

Installation Qualification (IQ) ensures that equipment and systems are installed as per manufacturer instructions and design specifications. This step entails verification of equipment location, environmental conditions, and documentation of installation processes (Bhat 2024)Operational Qualification (OQ) tests if installed equipment is functioning within specified parameters. It entails testing of functionalities, alarms, and safety aspects to guarantee the equipment's performance in any given condition (Orr 2024).

Performance Qualification (PQ) ensures that equipment is working as intended within the actual production environment consistently. This stage involves process simulation and testing under regular operating conditions to ensure reliability and effectiveness (Tesse et al. 2024).

These validation steps are recorded carefully to ensure proof of compliance and ease of traceability throughout the life cycle of the equipment (Fission 2024).

Restrictions of Key Importance: Time, Cost, Human Error, Scalability

Despite the fact that the IQ/OQ/PQ model has been instrumental in product quality assurance, it is not devoid of several drawbacks:

I. Long Processes: Each step of the validation requires careful planning, implementation, and documentation and, therefore, long project timelines especially when re-validation has to be done due to equipment or process changes (Borkenstein et al. 2023).

II. High Cost: The resources to be used in complete validation—material, staff, and downtime—may be prohibitively high, compromising the general cost-effectiveness of manufacturing processes (Agents 2024).

III. Human Error Vulnerability: Hand interpretation and manual inputting during validation increase the likelihood of human error, which could contaminate the process of validation and initiate compliance issues (Pharm 2025).

IV. Scalability constraints: With evolutions in production processes to be more intricate, those processes are hard to scale using traditional validation methods as additional technologies and higher production levels are introduced (Conneelly 2023).

V.

VI. Regulatory Frameworks and Traditional Compliance Strategies

Regulatory compliance is of prime importance in the production of medical devices. The FDA's 21 CFR Part 820 lists Quality System Regulations, including process validation requirements to ensure that manufacturing processes yield products of predetermined specifications consistently (Tabasevic et al. 2024).

ISO 13485:2016 outlines requirements for a quality management system in which an organization must be able to demonstrate its capability to supply medical devices and related services that consistently satisfy customer and relevant regulatory needs (Martin 2023).

These standards focus on the role of documented evidence in validation processes, risk control, and ongoing improvement. Classical methods of compliance are strict adherence to such standards through the specified IQ/OQ/PQ processes, whereby all aspects of manufacturing are validated and controlled (Agenta 2024).

By and large, while classical validation methods have played a central role in the setting up of a benchmark for quality and compliance in the manufacture of medical devices, their inherent shortcomings call for the exploration of more streamlined, scalable, and error-proof alternatives, paving the way for AI and ML-based automation to be integrated into validation procedures.

3. Emergence of AI and ML in Medical Device Manufacturing

Predominantly the implementation ofAI and ML in the field of production of medical devices represents a great shift from conventional validation techniques to more data-based, sophisticated means. This is driven by the requirements for increased efficiency, precision, and flexibility in manufacturing processes.

Overview of AI/ML Technologies Applicable to Manufacturing and Validation AI and ML technology are increasingly being implemented in the manufacture of medical devices to optimize and automate multiple processes. AI and ML technology facilitate real-time data analysis, predictive modeling, and decision-making capabilities that are beyond conventional means. For example, AI-based predictive maintenance platforms based on Digital Twin Technology enable real-time monitoring and fault diagnosis, improving operational efficiency and minimizing downtime. Equally, ML algorithms are utilized for process optimization and anomaly detection to maintain consistency in product quality and regulatory compliance (Iso 2016)

Key Enablers: Big Data, Cloud Computing, IoT

Predominant techological enablers have integrated with AI and ML to optimize the outputs of the production of medical devices:

Big Data: The enormous amount of data created during manufacturing processes is a rich source for training ML models, allowing for better prediction and insights (U S Food & Drug Admin 2023).

Cloud Computing: Majorly it is Scalable computing resources and storage solutions which can be made available by cloud platforms. Cloud computing is facilitating efficient computation and big data set analysis. It is majorly beneficial for AI applications which require high computational intensity (Ullagaddi 2024).

Internet of Things (IoT): IoT sensors can capture real-time data from equipment and environment within manufacturing. Then they pass this data to AI to enable real-time monitoring and optimization. The combination of AI and IoT, or AIoT, gave rise to manufacturing processes and enhances responsiveness to new conditions (Kodumuru et al. 2025a).

Types of AI/ML Applications

AI and ML technologies have been applied extensively in several predominant medical device manufacturing areas, including:

Predictive Maintenance:

Crucial AI algorithms have been implemented to analyze equipment data. Possible failures are forecasted ahead of time, and hence maintenance is scheduled in a timely manner. Due to this proactive approach, unexpected downtime is minimized, and equipment reliability is enhanced. The life of the equipment is also increased (Agenta, 2024).

Process Optimization:

Sophisticated ML models are used to discover patterns and relationships in manufacturing data. These patterns are utilized to enhance manufacturing processes for greater efficiency and improved product quality. Parameters are automatically set in real-time to keep operating conditions in their best (Borkenstein et al., 2023).

Anomaly Detection:

High-level AI systems are used for monitoring production processes. Abnormal shifts are detected at once, and possible problems are notified prior to these being major. This warning system is important in safeguarding product quality and compliance with significant regulatory requirements (Klinton and Kashar, 2024).

The use of AI and ML in the production of medical devices is viewed as a leading innovation. Validation procedures are simplified and accelerated. Manufacturing systems are rendered flexible and adaptable. As these developing technologies become increasingly prevalent, they will continue to play a core and essential function in ensuring medical devices are safe, high-quality, and compliant in an industry constantly evolving.

4. Transition Pathways: From Manual to Automated Validation

The convergence of Artificial Intelligence (AI) and Machine Learning (ML) with medical device manufacturing is revolutionizing the conventional validation process. This shift entails hybrid solutions that merge traditional methods with AI-based approaches to maintain compliance with regulatory requirements while maximizing efficiency and accuracy.

Hybrid Approaches: Co-existence of AI and Traditional Methods

Hybrid Approaches: Merging AI with Traditional Methods

Hybrid validation strategies are emerging as a real-world solution. blending traditional validation methods with AI-powered solutions are becoming predominant. These strategies leverage the strengths of both ideologies to ensure an efficient transition that maintains compliance and minimizes risk. For example, incorporating AI into current validation systems can expand data analysis without necessitating wholesale process change (Adrita et al. 2021).

These hybrid models enable the implementation of AI by presenting a known framework for regulatory agencies and manufacturers alike, such that the advantages of AI in terms of predictive analytics and real-time monitoring are leveraged in the existing validation context (Vallayil et al. 2023).

Model Lifecycle and Validation in AI-Driven Environments (GxP Compliance)

Integrating AI into Good Automated Manufacturing Practice (GxP) settings requires an end-to-end approach to managing model lifecycle. The FDA is placing a spotlight on using a Total Product Lifecycle (TPLC) paradigm, which involves design, development, validation, deployment, and post-market surveillance of AI-based devices (Sarkar et al. 2023).

Key points at this life cycle are:

•Design and Development: The incorporation of risk management and human factors engineering throughout all stages of design to prevent risks arising from AI functionalities(Chandler and Tomberman 2025).Validation and Testing: Using robust methodologies to validate AI performance, proof of effectiveness across heterogeneous patient groups and real-world settings (Simpson and Qasim 2025). Post-Market Surveillance: Continuous monitoring in real-time for the identification and adjustment of performance deviations or safety concerns, supplemented with timely update mechanisms (Kodumuru et al. 2025b).

GxP compliance in AI-environment is ensured by transparency, AI bias management, and data quality throughout product life (Pollard et al. 2024).

Transition frameworks: Risk-Based Validation and Digital Twin Concepts Shifting to AI-based validation models involves the implementation of cutting-edge methodologies commensurate with regulatory requirements. Risk-based validation methods center on the detection and minimization of risks posed by integrating AI, such that validation processes are proportional to the extent of risk.

Digital Twin technology provides an active validation framework in the form of virtual duplicates of physical devices or processes. The digital duplicates allow for real-time observation, predictive maintenance, and scenario simulation, which supports the strength of validation processes (Iranshahi et al. 2025).

Proactive identification of issues can be provided by Digital Twins through simulation of different operating conditions in association with the possibility of timely intervention and ongoing device performance and safety optimization.

The innovative step towards digital validation in the development of medical devices is an enhancement that harmonizes conventional approaches and AI technologies. It is highly essential to give raise with perfection and accuracy for a better complaint and response validation by inhering the Hybrid strategies, end-to-end lifecycle management, and emerging frameworks such as Digital Twins come together.

5. Case Studies and Real-World Applications: The introduction of Artificial Intelligence (AI) and Machine Learning (ML) in medical device manufacturing has induced remarkable validation process enhancements. This

part discusses some chosen use cases, measurable advantages, and issues experienced in applying AI/ML-enabled validation, based on current research and industrial trends.

Chosen Use Cases in AI/ML-Assisted Validation

1. Predictive Analytics in Implantable Cardiac Devices

A study by OkechukwuyemOjji (2024) accentuates the use of AI-based predictive models to simulate long-term performance and failure risk of implantable cardiac devices. Through the analysis of large datasets from clinical trials and field use, device manufacturers enhanced device design and lowered malfunction rates, shortening regulatory approval times (OkechukwuyemOjji 2024).

2. AI-Enhanced Quality Assurance in Ultrasound Equipment

Podder et al. (2024) illustrated the application of AI in diagnostic ultrasound device testing. Historical data-driven predictive analytics platforms detected calibration problems, facilitating early problem-solving. This proactive measure minimized the cost of testing and improved device quality(Podder et al. 2024).

3. Digital Twins for Process Optimization

Khinvasara et al. (2024) elaborated on the use of digital twin technology in the production of medical devices. AI-created digital copies of physical operations enabled real-time simulations, highlighting inefficiencies and streamlining production schedules. This resulted in more efficient utilization of resources and decreased time-to-market (Khinvasara et al. 2023).

Measurable Benefits: Accuracy, Regulatory Traceability, Resource Efficiency

Accurate information and Early Problem Identification:

AI and ML models process large sets of data to detect minor patterns. at the same time it detects early problem in design and testing stages. Manraj et al. (2024) indicated that predictive models can predict failure rates using past performance data. so that engineers can identify pre-physical test design changes (Vellanki 2024a).

Facilitated Regulatory Compliance and Traceability:

AI systems automate documentation processes, which are thorough audit trails and regulatory compliance. Khinvasara et al. (2024) highlighted that AI-based inspection systems can find defects in real-time, sustaining product quality and regulatory compliance (Roy and Srivastava 2024).

Process efficiency and Economic costing

Automation of Mundane tasks and optimization of workflow in the process of testing withthe aid of AI can Minimize drudgery and expense . Canay and Kocabıçak (2024) stated that predictive models make it easier for validation procedures, minimizing the need for massive trial-and-error processes and accelerating time-to-market(Vellanki 2024b).

Problems and Mitigation Strategies

Data Availability and Quality

Effective AI models require quality, diverse datasets. Goyal and Malviya (2023) highlighted challenges with having sufficient and appropriate data due to issues of privacy and limited access. Perforrming the operations on diversified datasets and using bias detection during validation processes are considered to be mitigation strategies (Vellanki 2024b).

Regulatory Compliance and Explainability: Regulatory agencies insist on transparency in AI decision-making. The "black-box" nature of some AI models presents explainability hurdles. To counteract this,

producers are investing in developing explainable AI models and engaging with regulators to align on validation standards (Vellanki 2024b).

Technical Infrastructure and Skill Gaps:

Implementation of AI technologies requires advanced infrastructure and skills in machine learning and data science. Ahmed et al. (2023) clarified that smaller manufacturers may have difficulties due to resource constraints. Collaboration with learning institutions and investing in the training of employees is required to bridge such gaps (Roy and Srivastava 2024).

In short, the use of AI and ML in medical device validation has brought considerable gains in accuracy, compliance, and efficiency. Challenges continue to exist, but investments in data quality, model transparency, and talent development are the necessary steps for unlocking the full potential of AI-powered validation processes.

6. Regulatory Considerations and Ethical Implications

Integration of AI/ML in Medical Device Production

Integration of Artificial Intelligence (AI) and Machine Learning (ML) into medical device production has been preceded by significant regulatory and ethical issues. With these technologies evolving, new regulations have been established by regulatory agencies. Emphasis has been laid down on providing safety, efficacy, and ethical responsibility for AI/ML-based devices.

Regulatory Directives in the United States

In America, significant initiatives have been undertaken by the Food and Drug Administration (FDA). In January 2021, an action plan for AI/ML-driven medical software was issued. Subsequent publications followed. These consisted of guidance on good machine learning practices (October 2021), marketing submission guidance (April 2023), and transparency principles (June 2024). Lifecycle management and a risk-based approach have been highlighted. Transparency regarding the application of AI/ML devices has been advocated vigorously as well.

Regulatory Steps in the European Union

In the European Union, there have been new legislations enacted in order to regulate AI use in medical devices. The AI Act, coming into effect in February 2025, has brought with it a system of classification in terms of risk levels. High level regulations have been formulated to mitigate high-risk uses for medical devices. Accountability and transparency have been mandated. Human review has been made mandatory. Data bias and bias management have been necessitated. The new regulations have been harmonized with current laws like the General Data Protection Regulation (GDPR) and the Medical Device Regulation (MDR).

Model Validation:Explainability:

Explainability of AI models has been identified as a primary issue. Often, AI system internal behavior could not be understood easily. This has been referred to as the "black-box" problem. Various attempts have been made to enhance explainability so that users can trust decisions more, such as clinicians and patients.

Model Validation:Bias and Auditability

Bias in AI models has been identified as a severe threat. Unconscious biases in training sets have been observed to lead to disproportionate healthcare outcomes. To achieve fairness, identification and mitigation of such bias

have been highlighted. Auditability has been also emphasized. Logging of AI model development and decision-making has been mandated to enable adequate assessment. This has been viewed as necessary for adherence to ethical and regulatory requirements.

Ethical and Legal Issues: Safety of the Patient and Integrity of Data

By 2025, Artificial Intelligence (AI) and Machine Learning (ML) had been employed in more than 30% of all new medical device technologies globally (National Health Council, 2025). The safety of patients is the most serious problem. It is highly essential to monitor the AI systems and frequently tested to minimize health hazards.

AI systems process huge amounts of patient data, raising significant concerns regarding data privacy and integrity. AI systems are susceptible to breaches, and thus data protection takes center stage. The General Data Protection Regulation (GDPR) of the European Union came into effect to safeguard patient data (Devineni, 2024).

Legal accountability in applying AI in medicine is increasingly becoming a challenge. In 2024, more than 18% of reported safety incidents involving AI in healthcare were due to unclear accountability (Mourya et al., 2024). New legal frameworks are thus being crafted for placing liability where AI systems are involved in causing patient injuries.

There is an increasing need for AI systems that promote patient safety, equity, and confidentiality. Such principles should be the guiding factors in the development and deployment of AI in all aspects of medical device production.

Moving from Traditional to AI/ML-Powered Validation in Medical Device Manufacturing

Medical device validation is evolving from conventional approaches towards AI and ML-based processes. The change has been made to enhance the quality of products and compliance with regulatory requirements. Both systems possess unique characteristics and challenges.

Comparative Analysis: Traditional vs. AI-Driven Validation

Conventional validation entails techniques such as Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). These methods are based on manual, systematic processes and tend to be time-consuming. Human mistakes can also be made during validation (Charles, 2024).

AI and ML-based validation employs automation and data analysis. The systems are capable of tracking devices in real-time, identifying issues early, and adjusting to new data. AI thus enhances the efficiency and validity of validation procedures (Sivakumar et al., 2011).

Industry Readiness: Barriers to Adoption

There are yet various barriers to employing AI/ML validation throughout the medical device industry. One of the challenges is data quality and availability. AI systems require huge, clean, and coherent datasets. Most organizations, however, encounter challenges such as splintered data, non-standardized data, and privacy issues (Ahmed et al., 2023).

The other challenge is regulatory uncertainty. As AI regulations are still under development, companies might hold back from using AI-based validation in the absence of established rules and guidelines (Rao, 2025).

Technical knowledge is also a key issue. Adopting AI tools comes with the need for data scientists and machine learning engineers. Healthcare organisations find it hard to hire or train the appropriate skilled personal to manage AI systems (Harpreet Singh, 2024).

Finally, cost and resource constraints are creating predominant impact adoption. AI infrastructure setup and team training might be costly. This is most difficult for small and medium-sized businesses (Ahmad et al., 2021).

Future Trends and Opportunities

In the future due couse several emerging trends can shape the medical devices in the field of validation: One ote most predominant models is Generative AI which can allow synthetic data generation for training and testing to improve the robustness of validation (Showrov et al. 2024; Sharma 2024).

Self-Validating Systems: AI innovation in health care sector self-validating systems can open the door for systems that are capable of self-validation, nullifying the scope for human intervention and facilitating real-time monitoring of compliance (Chirag 2025).

•Digital Twin Integration leads in the future: Digital twin application—digital replicas of physical equipment—can lead to facilitate simulation-based verification, allowing one to test a variety of scenarios without prototypes (Iranshahi et al. 2025).

• Stricter Regulatory Frameworks: Increasing experience of regulatory bodies with AI technologies will ensure that more informative and transparent regulations follow, making AI-based validation methods simpler to adopt (Palaniappan et al. 2024).

8. Conclusion and Recommendations

Summary of Findings

The transition from traditional validation procedures—Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ)–to computerization driven by Artificial Intelligence (AI) and Machine Learning (ML) is a paradigm shift in the production of medical devices. While traditional processes have provided decades of regulatory compliance, they are increasingly being challenged by Industry 4.0 demands of increased manufacturing complexity, speed-to-market requirements, and real-time monitoring and response needs.

This article has identified how AI and ML technologies, underpinned by Big Data, cloud computing, and IoT, are transforming validation through dynamic, adaptive, and predictive capabilities. Manufacturer case studies validate quantifiable increases in accuracy, regulatory traceability, and resource utilization. Nevertheless, regulatory ambiguity, data quality concerns, and ethical issues (e.g., algorithmic bias, data integrity) remain a major stumbling block to adoption. Moreover, the evolution of hybrid validation strategies—integrating traditional and AI methods—offers a transition path consistent with both innovation and regulatory restraint.

Practical Recommendations for Manufacturers and Regulators

Industry players are urged to pursue hybrid validation approaches by first incorporating AI/ML technologies for ancillary purposes like anomaly detection and predictive maintenance, yet continue to maintain classic Performance Qualification (PQ) methods in order to mitigate risk and facilitate a smooth transition. Investment in solid data infrastructure is necessary, quality, structured, and traceable data via secure and interoperable platforms underpinned by good data governance. Development of cross-functional teams including engineers, data scientists, regulatory experts, and quality assurance experts is vital for developing AI systems that are technically specification-compliant as well as compliance rule-compliant.Testing digital twin technology also provides a risk-free simulation environment to prove AI applications prior to mass deployment. Regular training and best change management techniques are necessary to reskill the workforce and engage stakeholders to develop acceptance and confidence in AI-based systems. For regulators, it is advised to issue more precise

validation guidelines for AI systems, outlining documentation requirements, risk assessments, and lifecycle tracking. Utilization of regulatory sandboxes should be encouraged to enable AI technologies to be tested safely in controlled environments, providing useful feedback for enhancing compliance.Standardizing explainability, auditability, and traceability of data requirements are essential to support transparency and keep the public at ease. Finally, global harmonization of regulatory systems like the FDA, ISO 13485, and EU MDR will facilitate international adoption and verification of AI solutions in making medical devices.

Research Gaps and Directions for Future Studies

Even though we've made a lot of progress using AI to improve how medical devices are checked and approved, there are still some important things we haven't looked at closely enoughWe don't yet know how well AI holds up over time. It's like any tool—we need to see if it still works just as well after months or years of use, especially when lives are on the line:Fairness in AI really matters. When AI is used in health-related work, even a small bias in its decision-making can have big consequences. it is clearly understood that we need to have better understanding to fix these issues to take care of the patients in safe zone. In this connection financial constraints also need to be taken care. The mid-ranged and small scale Pharma companies should understand the worthyness to use AI for their operational efficiency to have the benefits of the AI powered medical device systems. The AI systems and its operating staff should syncronize together to attain the maximum benefits. It is organisations responsibility to train the staff to have the maximum utilization of AI systems in a safer way. The safety, security and maxiumum utility are predominant things in using the smart machines powered by AI protecting the systems from the cyber-attacks and cyber threats.

Author Information

Jahnavi Vellanki

With over 12 years of extensive experience in the medical device and Contract Research Organization (CRO) industries, Jahnavi vellanki has established herself as a highly skilled professional specializing in computer systems validation and middleware validation. Her expertise spans critical areas of technology integration, including the qualification of laboratory equipment and ensuring compliance with stringent regulatory standards.

Driven by a passion for continuous process improvement, Jahnavi is dedicated to enhancing operational efficiency and quality in medical and scientific domains. Their work reflects a commitment to advancing methodologies that align with the evolving needs of the healthcare industry, particularly in maintaining the reliability and accuracy of medical systems.

A thought leader in their field, Jahnavi consistently applies their deep technical knowledge to foster innovation and contribute meaningfully to multidisciplinary teams. Her career trajectory is marked by contributions to critical projects that bridge technology, compliance, and healthcare, making them a valuable asset to research and development initiatives worldwide.

This paper reflects Jahnavi's dedication to advancing academic and practical understanding in their areas of expertise.

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