



## **A Literature Review on Current Application of Artificial Intelligence Technology in Medical Devices Manufacturing**

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### **Abstract**

The medical device industry is currently an industry with very high growth in Indonesia. The growth of this manufacturing industry must be accompanied by the development of aspects in it along with the industrial revolution 5.0. Manufacturing and quality assurance are essential aspects of the medical device industry. They have a substantial impact on the safety, efficacy, and adherence to strict regulations of products. This systematic literature review aims to provide a discusses the critical role of AI in optimizing aspects of quality control and quality assurance in the medical device industry. In manufacturing, AI optimizes quality control through AI-enabled inspection systems that can detect microscopic defects and ensure compliance with stringent regulatory standards. The visual inspection process utilizes AI technology via computer vision and machine learning. In addition, automation of documentation processes for regulatory compliance by performing complex analysis and tasks involving large amounts of regulatory data. AI-based technology has revolutionized medical device manufacturing by enhancing quality control. However, challenges remain for its swift implementation in Indonesia, including issues with data availability and accuracy. It is anticipated that this issue will be resolved promptly to enable the swift implementation of this AI-based technology in Indonesia.

**Keywords:** Artificial intelligence, industrial revolution, medical devices, quality assurance.

### **1. Introduction**

The medical device industry in Indonesia is one of the industries that the government is boosting; it is outlined in Presidential Instruction Number 6 of 2016 concerning the acceleration of the development of the pharmaceutical industry and medical devices as a concrete step by the government in realizing a human security system for Indonesian citizens. In policymaking, stakeholders take concrete action by encouraging the growth of medical device industry innovation and massive absorption efforts to meet the needs of health facilities evenly in the country (Utomo, Nurputra, & Ardhani, 2023). The medical device industry in Indonesia is experiencing significant growth (Handayani, Meigasari, Pinem, Hidayanto, & Ayuningtyas, 2018). The market value is forecasted to increase from USD 3.5 billion in 2021 to USD 6.5 billion in 2026 (Akbar & Putri, 2023).

The increase in the domestic industry needs to be accompanied by an understanding from business owners that the production process of medical devices requires special attention. The medical device production process must follow government regulations and strict procedures to produce consistent and high-quality products. This is strengthened by the enactment of Regulation of the Minister of Health Number 20 of 2017 on Good Manufacturing Methods of Medical Devices and Household Health Supplies as an attachment to the application for a domestic medical device distribution license starting January 1, 2024. Deviations from these specifications cause product failure and can, endanger patients and threaten the company's sustainability. Therefore, the company must improve its manufacturing and quality assurance systems and product quality consistency.

During an era characterized by swift technological advancements, the medical devices manufacturing sector needs to adopt the innovative capabilities of Artificial Intelligence (AI) within the context of Industry 5.0 (Roy & Srivastava, 2024). In contrast to the technology-focused approach of Industry 4.0, Industry 5.0 extends the transformation of manufacturing production methods and technological advancements towards resilience, sustainability, and a focus on people (Ivanov, 2023). Integrating Artificial Intelligence (AI) into quality control processes can enhance accuracy, efficiency, and reliability in the medical devices Industry (Karalis, 2024). Incorporating Artificial Intelligence (AI) in device diagnostics is a pioneering solution that has emerged (Hirani et al., 2024). AI offers revolutionary solutions to simplify quality assurance, minimize human error, and adhere to stringent regulations governing the scrutiny of medical devices.

Using this AI technology, it is anticipated that the medical device sector in Indonesia can enhance its precision and efficiency in advancing the industry. The synergy between these factors reduces the possibility of human error and encourages a proactive attitude toward compliance and safety. This research delves into the utilization of AI technology to enhance quality systems and quality assurance in the production of medical devices, with potential applications in the Indonesian Industry. This research aims to investigate where and to what extent Artificial Intelligence (AI) has been applied within the medical device industry. Specifically, to see how much artificial Intelligence (AI) is used to support the quality assurance process.

## **2. Method**

This research adopts the Systematic Literature Review (SLR) approach, A literature review is a comprehensive summary of existing research within a specific field of study, conducted using a designated methodology. Systematic reviews are typically placed at the highest level of the evidence hierarchy due to their

comprehensive analysis and evaluation of findings from all relevant original research studies addressing a specific research question (Al-Khabori & Rasool, 2022).

The inclusion criteria encompassed the following parameters: year range (2020 - 2024), access type (open access), and article type (review articles - research articles) for the conducted research. This research utilized databases from Science Direct and ResearchGate for data collection. The search and sorting of journals on each page utilize a keyword scheme that combines three schemes keywords:

1. Artificial Intelligent, Manufacturing
2. Artificial Intelligent, Manufacturing, Quality Assurance
3. Artificial Intelligent, Manufacturing, Quality Assurance, Medical Devices

Several relevant journals were identified from the combination of the specified keywords on the two source pages during the journal search.

a. Science Direct, Open access

- 1) Artificial Intelligent, Manufacturing

Finding journals that match the keywords: 12 Journals

- 2) Artificial Intelligent, Manufacturing, Quality Assurance

Finding journals that match the keywords: 2 Journals

- 3) Artificial Intelligent, Manufacturing, Quality Assurance, Medical Devices

Finding journals that match the keywords: 0 Journals

b. ReseachrGate, Open access

- 1) Artificial Intelligent, Manufacturing

Finding journals that match the keywords: 18 Journals

- 2) Artificial Intelligent, Manufacturing, Quality Assurance

Finding journals that match the keywords: 10 Journals

- 3) Artificial Intelligent, Manufacturing, Quality Assurance, Medical Devices

Finding journals that match the keywords: 5 Journals

Based on bellow data, fourty seven results were identified on the topic at hand. Of these, five documents were chosen that specifically discuss the Artificial Intelgent (AI) techniques utilized in quality process, particularly in relation to medical devices. The qualitative approach employed in this Systematic Literature Review involves compiling descriptive qualitative research findings.

### 3. Results and Discussion

The systematic literature review provides valuable insights into the role of artificial intelligence (AI) in the manufacturing and quality assurance processes within the medical device industry. The selected studies highlight various applications of AI, ranging from enhancing operational efficiency and quality control to driving innovation in device diagnostics and predictive maintenance. Table 1 summarizes the key findings from these studies, showcasing how AI technologies are transforming manufacturing practices, improving product reliability, and shaping the future of medical device production.

**Table 1. Systematic Literature Review Results**

No	Author (Year)	Title	Result
1	Roy & Srivastava (2024)	Role of Artificial Intelligence (AI) In Enhancing Operational Efficiency in Manufacturing Medical Devices	AI technologies are significantly improving operational efficiency in the manufacturing of medical devices. By utilizing AI for design optimization, quality control, and predictive maintenance, manufacturers can increase productivity, reduce costs, and enhance product quality.
2	Khinvasara, Ness, & Shankar (2024)	Leveraging AI for Enhanced Quality Assurance in Medical Device Manufacturing	The future appears promising as generative AI models offer improved testing and the ability to detect previously unidentified defects and unique scenarios.
3	Patel (2024)	Impact of AI on Manufacturing and Quality Assurance in Medical Device and Pharmaceuticals Industry	As artificial intelligence is integrated into the manufacturing and quality assurance operations of pharmaceutical and medical device companies, there is significant potential for radical expansion.

4	Raouf & Huidar (2024)	Medical Manufacturing Innovation: AI-Based Troubleshooters for Rigid Bone Positioning and Device Diagnostics	The healthcare industry is increasingly adopting digital transformation. AI technologies have the potential to revolutionize surgical practices and device management, leading to safer and more effective medical interventions. Looking forward, the outlook for AI in medical manufacturing is optimistic.
5	Bibi & Molloholli (2024)	Revolutionizing Medical Manufacturing with AI-Based Leak Detection Devices for Fluid Cassettes	The use of advanced technologies and strict procedures in fluid cassette manufacturing is revolutionizing the medical device industry, prioritizing safety, reliability, and quality. AI integration is at the forefront of advancements, providing unparalleled capabilities in real-time monitoring and predictive maintenance.

The above literature offers several uses of AI that aim to strengthen manufacturing systems and quality assurance systems to realize efficient manufacturing operations and create constant product quality. If only focusing on quality issues, some of the above literatures have in common the use of AI in terms of Inspection processes and regulatory compliance system.

Roy & Srivastava (2024) provides two examples of how artificial intelligence can enhance quality systems: 1) AI-powered vision systems have the capability to enhance quality control in medical device manufacturing by identifying defects and anomalies. This can lead to a reduced reliance on manual inspections and increased product reliability, ultimately strengthening the Quality Control and Inspection processes. 2) AI systems can aid in upholding regulatory standards and requirements through the automation of documentation processes and the creation of thorough audit trails, thereby enhancing the Regulatory Compliance process.

Khinvasara et al. (2024) also provides two examples of how artificial intelligence can enhance quality systems; 1) Machine vision systems can quickly process and analyze visual data, exceeding the speed of human perception. They can identify subtle errors that people may miss with a higher level of accuracy. Moreover, it offers

a higher level of efficiency compared to manual inspections, enabling thorough quality assurance processes to be carried out promptly. Another advantage of utilizing AI for quality control is the ability of advanced algorithms to analyze error data and identify their source. They are well-suited for use in quality control procedures. 2) Artificial intelligence can assist medical device manufacturers in enhancing compliance with regulatory standards, mitigating the risk of human error caused by human fallibility and forgetfulness. Artificial intelligence demonstrates a high level of proficiency in performing complex analyses and tasks involving large amounts of data. AI models can observe and analyze product development data, and then compare it with the latest applicable regulatory framework. The algorithms are capable of detecting and highlighting procedures or documentation that may pose regulatory issues or need further examination.

Patel (2024) even lists 6 out of 11 AI applications that can be integrated into the quality enhancement process stages. And 2 of them are Computer vision for visual checking and document automation in regulatory compliance. 1) AI plays a crucial role in optimizing compliance processes and verifying that products adhere to strict quality and safety regulations prior to market release. This technology expedites clinical trials and facilitates regulatory approvals. 2) Utilizing AI technologies like computer vision and machine learning enhances critical QA procedures, enabling partial or full automation of the processes. AI-powered vision systems have the capability to detect defects and abnormalities in manufacturing processes, thereby reducing the necessity for manual inspection. 3) AI-assisted testing allows for comprehensive and accurate assessment of medical devices, enhancing the overall quality and dependability of the final product 4) Real-time monitoring is beneficial for upholding strict quality assurance standards and addressing production issues promptly. 5) Automation of documentation procedures by AI enhances the accuracy of documentation and enables the creation of comprehensive audit trails. 6) AI algorithms analyze extensive data sets to enhance the manufacturing process and provide valuable insights for informed decision-making.

Bibi & Molloholli (2024) This technological advancement improves the efficiency of the manufacturing process and increases the overall dependability of medical devices, leading to improved patient outcomes. These strategies allow manufacturers to identify and resolve issues promptly, thus lowering the probability of product recalls and enhancing operational effectiveness.

The integration of Artificial Intelligence (AI) into medical manufacturing offers numerous advantages, but requires careful consideration of several challenges to ensure successful implementation. Raouf & Huidar (2024) Delivering that understanding these obstacles is essential for optimizing the potential advantages of AI technologies and mitigating risks linked to their implementation. One of the

primary challenges in deploying AI-driven solutions is the quality and accessibility of data. Roy & Srivastava (2024) also focus on data quality and availability. Obtaining adequate and precise data in the medical device sector can present challenges

#### 4. Conclusion

Artificial Intelligence (AI) is revolutionizing medical device manufacturing by providing innovative solutions to improve operational efficiency throughout different stages of production. AI technologies are significantly improving operational efficiency in the manufacturing of medical devices. Manufacturing and quality assurance are essential aspects of the medical device industry. They have a substantial impact on the safety, efficacy, and adherence to strict regulations of products. Consequently, there is a lot at stake and minimal margin for mistakes. In order to meet important effectiveness and safety standards, it is necessary to implement robust manufacturing systems and strict quality control measures for products, one of which can be through the application of Artificial Intelligence (AI).

The future appears promising as generative AI models offer improved testing and the ability to detect previously unidentified defects and unique scenarios. Using utilizing AI technologies likes computer vision and machine learning for quality control and inspection processes and the automation of documentation processes for regulatory compliance. The utilization of smart sensors and IoT connectivity enhances monitoring capabilities, enabling continuous oversight and data-informed decision-making. However, there are several challenges that must be faced in order to integrate AI with quality systems, including data availability and data quality. One of the primary challenges in deploying AI-driven solutions is the quality and accessibility of data.

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