IJBPAS, November, 2025, 14(11): 6167-6176

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

NAVIGATING THE REGULATORY LANDSCAPE OF ARTIFICIAL INTELLIGENCE-INTEGRATED MEDICAL DEVICES: A GLOBAL PERSPECTIVE

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Received 19th July 2024; Revised 26th Sept. 2024; Accepted 9th Nov. 2024; Available online 1st Nov. 2025

https://doi.org/10.31032/IJBPAS/2025/14.11.9603

ABSTRACT

The synergy of Artificial Intelligence and Medical devices has transformed healthcare, yielding unprecedented opportunities for improved patient outcomes. The integration of AI needs a drastic challenge because of the guidelines framed following traditional medical devices. Navigating these regulatory considerations for AI-MD requires a detailed understanding of regulatory guidelines and technological progress. This article explains the portfolio of AI-integrated devices, spotlighting the major regulatory requisites such as quality, safety, and efficacy.

Recognizing the growing demand for AI-enabled medical devices, organizations are taking steps toward achieving their promise. AI has improved operational efficiency, individualized patient care, and increased diagnostic precision in medical equipment, all of which have revolutionized the healthcare industry. The necessities of the regulatory guidelines considering AI have also been discussed concerning various regulatory authorities like the Food and Drug Administration (FDA), and European Medicines Agency (EMA-MDR) followed by ISO and IEC.

Keywords: Medical device, regulatory compliance, artificial-intelligence, machine learning, regulatory framework

INTRODUCTION

In recent years, there has been a discernible surge in the need for Artificial Intelligence (AI) to analyze and evaluate several critical pharmacy domains, including drug discovery, dosage form & its design, pharmacovigilance, and medical devices. Machine learning (ML) and artificial intelligence (AI) are currently appearing in the constantly evolving arena of regulatory affairs. The integration of AI emerges as a helpful tool as the pharmaceutical business maneuvers through a complicated web of rules **[1]**. The collaboration between AI and regulatory affairs promises improved efficiency and flexibility, from streamlining approval procedures to strengthening, monitoring, and compliance controls. It is significant to mention that the FDA and EMA are currently consulting with stakeholders to identify the best methods to employ and regulate artificial intelligence in the pharmaceutical sector. AI could impact the regulatory affairs landscape, emphasizing the challenges and possibilities ahead **[2]**. AI delivers substantial benefits over human insights in pharmacovigilance, particularly in data mining and regulatory compliance. AI can improve the process of putting together a risk assessment and result in increased patient safety. AI has the potential to be very significant in the identification and categorization of adverse drug reactions (ADRs). Organizations consider using AI-enabled Medical Devices to fully realize their potential, given the increasing need for it **[3]**. AI has transformed healthcare by boosting operational efficiencies, personalizing patient care, and expanding diagnostic accuracy in medical equipment **[4]**.

ROLE OF AI IN MEDICAL DEVICE

Data Analysis:

Artificial intelligence (AI) algorithms have the knack of processing vast volumes of data through clinical trials, empirical evidence, and other sources to find patterns and connections that human reviewers would not see right away.

Predictive analytics:

AI algorithms can predict future medical outcomes based on characteristics, historical data, and empirical evidence. This might help assess the benefits or potential risks of a new drug or piece of technology.

Safety Monitoring and Risk Assessment:

AI can continuously scan post-marketing safety data to quickly detect and assess any unfavorable occurrences. This might result in the capacity to address security issues, facilitating the prompt implementation of regulatory decisions.

Processing for Review of Applications and Dossier Assessment:

Natural language processing may be used to review and extract relevant data from

clinical and nonclinical research papers, medical literature, and patient records. This might help (European Medicines Agency) EMA/ (Food and Drug Administration) FDA professionals focus on critical concerns and expedite the evaluation process. By highlighting crucial facts, inconsistencies, or missing data, AI may also assist with the application of dossier evaluations, freeing up professionals to focus on crucial issues **[5, 6]**.

Personalized Medicine:

AI may help identify patient subgroups that are more likely to respond to medication favourably or negatively, enabling customized treatment regimens.

ADESSA:

The Spanish Agency for Medicines and Health Products created ADESSA (Automated Detection of Signals for Adverse Events), which uses AI algorithms to continually monitor pharmacovigilance data and identify adverse events rapidly and effectively **[7, 8]**.

REGULATORY GUIDELINES/ FRAMEWORK CONCERNING AI IN MEDICAL DEVICES

["MDR(2017/745)"]	"General definition of "medical device", general specifications for performance and safety, technical documents regarding components, functions, and design, purpose, intended use, clinical assessment, and post-market surveillance, etc."
["FDA 21 CFR"]	"FDA 21 CFR part 820, QMS Regulations for MD"
["FDA- Guidelines"]	Guidance "General Principles for Software Validation"
["FDA- Guidelines"]	"Regulatory Framework to Artificial Intelligence / Machine Learning (AI/ML) Based SaMD"
[GDPR]	European "General Data Protection Regulation"
["IEC 62304]	"IEC 62304:2006 + A1:2015, Medical device software – Life Cycle"
["IEC 62366]	"IEC 62366-1:2015, Medical devices – Part 1: Application of technical engineering to medical devices"
["IEC 82304"]	"IEC 82304-, Health software — Part 1: General requirements for product safety"
["ISO 13485"]	"ISO 13485:2016, "Medical devices — QMS — Requirements for regulatory purposes"
["ISO 14971"]	"ISO 14971:2019, Medical devices – Application of risk assessment and management to MD"
["ISO 14155"]	"ISO 14155, Clinical investigation - medical devices for human subjects — GCP"
["ISO/IEC 27002"]	"ISO/IEC 27002, Information technology — Security techniques — Code of practice for AI and information security controls"

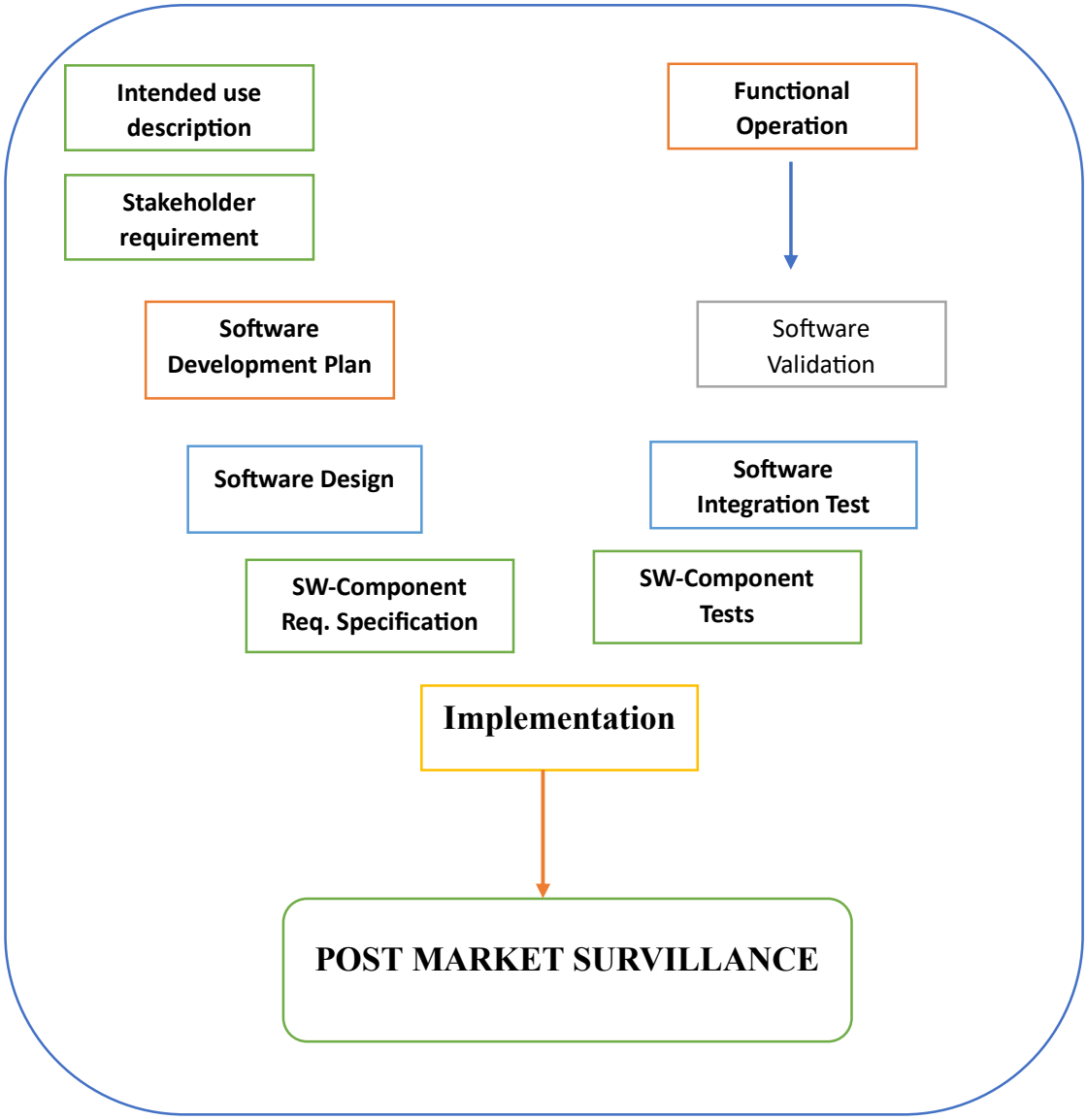

Figure 1: The product life cycle of AI-Medical devices

PRE-MARKET REGULATORY CONSIDERATIONS

Before launching a product, companies must navigate pre-market regulatory considerations to ensure compliance with relevant laws and standards. This involves applicable regulations, risk assessments, and obtaining necessary approval. Regulatory bodies like the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) in Europe require substantial evidence that AI devices function as intended without needlessly endangering people. This often requires rigorous testing and validation techniques, such as clinical trials or simulations, to ensure the accuracy and dependability of the AI system in real-world, practical situations. In addition,

producers are responsible for complying with strict data privacy and security standards to prevent any misuse of patient information. We also mandate post-market surveillance and regular updates to swiftly resolve the developing faults and enhance the device's functionality. According to pre-market regulatory regulations, AI medical devices must adhere to stringent standards before being used in clinical settings, striking a balance between technological advancement and patient safety. Proactive necessities regarding the regulatory guidelines are stated below. Key regulatory considerations are shown in **Table 1-8 [6, 9-12]**.

Table 1: Quality System Requirements

Regulatory requisites	Regulatory Necessities	Product lifecycle (PLC)	Applicable regulatory guidelines
The developer should create a Quality Management (QMS) System for Artificial Intelligence Medical Devices. (AI-MD)	– There should be an SOP containing the design& process, including its verification & validation. – There should be SOP(s) containing PMS and pharmacovigilance – There should be an SOP regarding risk mitigation and management – There should be one SOP regarding Automated Systems Validation (ASV) – SOP about the data set management (process) – SOPs covering software delivery, service, and installation.	Complete Lifecycle	"EU MDR (2017/745) Article 10.9" "ISO 13485 e.g. clause7.1" "ISO 13485 clause4.1.6"
Product Specification Requirements.	– There should be specific product-related development strategies comprising Validation & verification. – Appropriate product-related PMS, clinical evaluation, and risk assessment plans.	Complete Lifecycle	"MDR (2017/745) Annex I (3)" "MDR (2017/745) Annex III (1.3)" "IEC 62304 clause5.1" "ISO 14971:2019 (4.2)"

Table 2: Proficiency requirements

Regulatory requisites	Regulatory Necessities	Product lifecycle (PLC)	Applicable regulatory guidelines
The firm must assess whether processes inside its QMS directly or indirectly connect to artificial intelligence.	Roles and responsibilities within the developer's company involved in PLC activities are listed. These include data scientists, software analyzers, software testing, risk managers, domain experts, experts in clinical evaluations, and software developers.	Development of Software.	"ISO 13485 clause 5.5.1" "EU MDR (2017/745) Article 10.9"

Table 3: Risk evaluation and Mitigation requirements

Regulatory requisites	Regulatory Necessities	Product lifecycle (PLC)	Applicable regulatory guidelines
A list of risk factors relating to employing the strategy of machine learning should be compiled by the manufacturer.	A study of possible risks, as well as the probabilities and severities that can arise from ML models that do not fulfill the standards, is included in the risk management file.	Risk Management Plan	"ISO 14971:2019 clauses5.4 and 5.5" "EU MDR (2017/745) Annex 1 (3)"
The manufacturer needs to assess any possibility of hazards.	The risk assessment file examines the hazards related to: - Non-specified use environment; - Non-specified user type or category. Using goods on people who aren't on the list could put them at serious risk.	Risk Management Plan	"ISO 14971:2019 clause 5.2"

Table 4: Product and software-related requirements

Regulatory requisites	Regulatory Necessities	Product lifecycle (PLC)	Applicable regulatory guidelines
If the inputs don't match the standards, the developer needs to figure out how the system responds.	A specification outlines the method by which the system responds to missing or non-existent data sets. - Incorrect format for the data and large amount of data.	Product and Software Specifications	"ISO 25010" "IEC 62304 clause 5.2" "ISO 14971:2019 clause 5.4"

Table 5: User-interface considerations

Regulatory requisites	Regulatory Necessities	Product lifecycle (PLC)	Applicable regulatory guidelines
In the event of an issue, the developer needs to indicate what the AI user interface looks like	A detailed user interface should be provided. Inaccurate data sets and substantial errors	Product and Software-related Specifications	"IEC 62304 clause 5.2"
If training materials and usage instructions are required, the manufacturer should ascertain this	The user risk analysis reveals no risk mitigation and hence suitable CAPA should be provided if necessary.	Product and Software-related Specifications	"MDR (2017/745) Annex I (23)"

Table 6: Additional Computer automation/software considerations:

Regulatory requisites	Regulatory Necessities	Product lifecycle (PLC)	Applicable regulatory guidelines
The developer should set forth a portfolio to detect errors.	Risk resulting from internal errors is taken into account in the risk analysis. Assessing internal errors and implementing CAPA	Product and Software-related Specifications	"MDR (2017/745) Annex I (17, 18, 23.4)" "IEC 62304 clauses 5.2, 5.3 and 7.1" "ISO 149781:2019 clause 5.4"
The developer needs to clarify if the device makes decisions on its own based on automated programs or data.	Data integrity and reliability of the AI are taken into account. There should be a data protection impact assessment system.	Product and Software-related Specifications	"Art. 22 of the GDPR. Exceptions of Art. 22 section 2 may apply."

Table 7: Testimony and version consideration

Regulatory requisites	Regulatory Necessities	Product lifecycle (PLC)	Applicable regulatory guidelines
The developer needs to trace the dataset back to the dataset source.	- A collection of dataset sources should exist. A document outlining the steps involved in dataset processing. - Determining the criteria for including and excluding data	Data Management	"ISO 13485 clause 4.1"
The developer should compile all software-related datasets for data processing.	– List of all computer automated applications needed to be evaluated for the version control and dataset assessment.	Data Management	"ISO 13485 clause 4.1"

Table 8: Market release requirements

Regulatory requisites	Regulatory Necessities	Product lifecycle (PLC)	Applicable regulatory guidelines
The developer needs to verify the complete set of documentation.	- A risk assessment report concludes that all operations connected to risk mitigation have been carried out by the plan, and any remaining risks are deemed acceptable. - A report on the usability evaluation concludes that all of the tasks in the formative and summative assessment plans have been completed.	Market release	"MDR (2017/745) Annexes I and II"
The company must gather the necessary paperwork if it intends to sell its goods in the US market.	- A "Software as a Medical Device Pre-Specifications" (SPS) exists that accounts for potential modifications to the device. The "Algorithm Change Protocol (ACP)" outlines how these system modifications are to be carried out.	Product release	"FDA: Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)"

POST-MARKET REGULATORY CONSIDERATIONS

After a product reaches the market, post-market regulatory considerations ensure ongoing compliance and safety. This includes monitoring product performance, reporting adverse events, and implementing corrective actions. Post-marketing regulatory requirements for medical devices are critical for maintaining their safety and effectiveness once they are available to the public. These requirements mandate continuous oversight and proactive management to ensure that devices continue to meet safety standards throughout their lifecycle. Manufacturers require effective post-market surveillance systems for tracking device performance, tracking adverse outcomes, and acquiring real-world use data. This means reporting problems or malfunctions to regulatory bodies regularly and, if necessary, taking corrective action. Additionally, manufacturers need to update their risk management plans through ongoing data analysis and feedback from healthcare providers. This approach consists of assessing whether design modifications, software updates, or labeling modifications are required to address new safety risks. Effective post-marketing management also involves being clear about potential risks and the steps taken to mitigate them, as well as maintaining open channels for communicating with users and regulatory bodies. These ongoing regulatory requirements are essential to ensure that medical devices operate reliably and securely for the rest of their product lives, as well as to adapt to new information. Key post-market considerations are given in **Tables 9 and 10 [11, 13]**.

Table 9: Market distribution and device installation considerations

Regulatory requisites	Regulatory Necessities	Product lifecycle (PLC)	Applicable regulatory guidelines
The developer needs to verify configuration control.	SOP, or installation guidance, describes how the developer determines artifacts and guarantees that the right artifacts are delivered in the right version. There needs to be a unique identification (ID) of the marketed product enlisted as per the design.	Post-Market Surveillance	IEC 62304 clause 8 FDA Cybersecurity Guidance ISO 13485:7.5.8

Table 10: Post-market surveillance considerations

Regulatory requisites	Regulatory Necessities	Product lifecycle (PLC)	Applicable regulatory guidelines
Regular monitoring of Products after released into the market and compilation of data.	There are specifics on the method, frequency, and identity of those in charge of keeping an eye on safety monitoring and reevaluating the state of the art.	Post Market Surveillance	MDR (2017/745) Article 85 f.
The developer is required to establish a post-market risk assessment and mitigation system.	There are specifics on the procedure, frequency, and identification of the individual assessing post-market data for risks, hazardous circumstances, and newly or revised hazards. The post-market risk analysis searches for use that is (foreseeable) or changes in behavior that are undesirable.	Post Market Surveillance	ISO 14971 clause 10

DISCUSSION

The integration of Artificial Intelligence in medical devices has the potential to be a game-changer in healthcare. It can lead to better patient outcomes, more efficient operations, and more accurate diagnoses. However, this integration also brings a complex set of rules and regulations that need to be carefully navigated. To make sure AI-powered medical devices are safe and effective, we need to consider a few key things. First, we need to understand the rules and regulations surrounding AI in medical devices. We also need to address the unique challenges that come with AI, like bias and transparency. And we need to develop strategies to mitigate risks, like data breaches or device malfunctions.

Regulatory bodies, industry leaders, and innovators need to work together to create rules and guidelines that balance innovation with patient safety. These rules need to be flexible and adaptable, since AI technology is constantly evolving. They also need to be consistent across the globe, so we can ensure that AI-powered medical devices are safe and effective no matter where they're used. To navigate the complex regulatory landscape of AI in medical devices, we need a team effort. We need experts in technology, medicine, and regulation to work together to ensure that AI-powered medical devices are both safe and effective.

By working together and taking a multidisciplinary approach, we can unlock the full potential of AI to transform healthcare and improve patient outcomes. We need to create rules and guidelines that support innovation while prioritizing patient safety and well-being. And we need to be transparent and collaborative, so we can maintain public trust.

Ultimately, integrating AI in medical devices requires a deep understanding of the regulatory landscape and a commitment to collaboration and innovation. By working together, we can create a future where AI-powered medical devices improve patient lives while ensuring regulatory compliance and public trust.

CONCLUSION

Artificial Intelligence (AI) has the potential to drastically enhance decision-making by accessing data and providing insights that save time, money, human effort, and even lives.

Integrating AI and Medical Devices has revolutionized healthcare, offering improved diagnosis, personalized treatment, and enhanced patient care. The additional regulatory requirements and the annotated checklist for the AI-medical devices have been given with the respected guidelines. The provisions mentioned regarding the premarket and post-market considerations give insight into the regulatory professionals involved in the regulatory compliance of AI-

medical devices. IMDRF, ISO, suitable FDA, and EMA guidelines concerning software / AI Medical Devices have been explored. Hence the Convergence of AI and Medical Devices presents a complex regulatory landscape.

ACKNOWLEDGMENT

All the authors are appreciated for their contribution and synthesis of the manuscript.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

REFERENCES

[1] Raza MA, Aziz S, Noreen M, Saeed A, Anjum I, Ahmed M, Raza SM. Artificial Intelligence (AI) in Pharmacy: An Overview of Innovations. Innov Pharm. 2022 Dec 12;13(2):10.24926/iip.v13i2.4839. doi: 10.24926/iip.v13i2.4839. PMID: 36654703; PMCID: PMC9836757.

[2] Available on https://www.dlrcgroup.com/wp-content/uploads/2023/09/Whitepaper-Artificial-Intelligence-%E2%80%93-Transforming-Regulatory-Affairs-2023.pdf [Accessed on July 15, 2024]

[3] Salas M, Petracek J, Yalamanchili P, Aimer O, Kasthuril D, Dhingra S, Junaid T, Bostic T. The Use of Artificial Intelligence in Pharmacovigilance: A Systematic Review of the Literature. Pharmaceut. Med. 2022 Oct;36(5):295-306. doi: 10.1007/s40290-022-00441-z. Epub 2022 Jul 29. PMID: 35904529.

[4] Kumar, V., & Singh, P. K. (2020). *Artificial Intelligence in Healthcare: Past, Present, and Future*. Journal of Healthcare Engineering, 2020. https://doi.org/10.1155/2020/4680680

[5] Shukla SS, Jaiswal V. Applicability of artificial intelligence in different fields of life. *IJSER* 2013;1:28–35. [Google Scholar]

[6] Bajwa J, Munir U, Nori A, Williams B. Artificial intelligence in healthcare: transforming the practice of medicine. Future Healthc J. 2021 Jul;8(2):e188-e194. doi: 10.7861/fhj.2021-0095. PMID: 34286183; PMCID: PMC8285156.

[7] Li Y, Tao W, Li Z, Sun Z, Li F, Fenton S, Xu H, Tao C. Artificial intelligence-powered pharmacovigilance: A review of machine and deep learning in clinical text-based adverse drug event detection for benchmark datasets. J Biomed Inform. 2024 Apr;152:104621. doi: 10.1016/j.jbi.2024.104621. Epub 2024 Mar 5. PMID: 38447600.

[8] Murphy RM, Klopotowska JE, de Keizer NF, Jager KJ, Leopold JH, Dongelmans DA, Abu-Hanna A, Schut MC. Adverse drug event detection using natural language processing: A scoping review of supervised learning methods. PLoS One. 2023 Jan 3;18(1):e0279842. doi: 10.1371/journal.pone.0279842. PMID: 36595517; PMCID: PMC9810201.

[9] FDA 21 CFR part 820, Quality Management System for Medical Devices. Available on https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820 [Accessed on July 12, 2024]

[10] Regulatory Framework to Artificial Intelligence / Machine Learning (AI/ML) Based SaMD. Available on https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device [Accessed on July 21, 2024]

[11] ISO 14971:2019 Available on https://www.iso.org/standard/72704.html [Accessed on July 21, 2024]

[12] IEC 62304:2006 + A1:2015, "Medical device software – Life Cycle" Available on https://www.iso.org/standard/38421.html [Accessed on July 22, 2024].

[13] MDR(2017/745) Annexes I and II Available on https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745 [Accessed on July 14, 2024]