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Global Regulatory Requirements for Software as a Medical Device (SaMD): A Comparative Review of International Regulatory Frameworks

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Abstract

Software as a Medical Device (SaMD) has transformed healthcare by enabling diagnosis, treatment planning, disease monitoring, and clinical decision support through standalone software applications. The rapid growth of artificial intelligence (AI), machine learning (ML), mobile health applications, and digital therapeutics has created significant regulatory challenges worldwide. Regulatory agencies such as the United States Food and Drug Administration (FDA), European Medicines Agency (EMA) under the Medical Device Regulation (MDR), Medicines and Healthcare products Regulatory Agency (MHRA), Therapeutic Goods Administration (TGA), and the Central Drugs Standard Control Organization (CDSCO) have developed frameworks to ensure the safety, effectiveness, cybersecurity, and clinical performance of SaMD products. This review summarizes global regulatory requirements, compares major international frameworks, and discusses emerging trends in AI-enabled SaMD regulation. The review highlights the importance of harmonization efforts led by the International Medical Device Regulators Forum (IMDRF). SaMD is generally defined as software intended for one or more medical purposes that performs these purposes without being part of a hardware medical device.

1. Introduction

Digital transformation has significantly changed healthcare delivery systems. Modern software applications perform diagnostic, monitoring, and therapeutic functions without requiring dedicated medical hardware. Such software products are classified as Software as a Medical Device (SaMD).

The IMDRF defines SaMD as software intended for one or more medical purposes that performs these purposes without being part of a hardware medical device. This

definition has been adopted or referenced by many regulatory authorities worldwide.[1]

Examples include:

- AI-based diagnostic tools
- Clinical decision support systems
- ECG interpretation applications
- Mobile health monitoring applications
- Digital therapeutics
- Medical imaging software

2. Definition and Scope of SaMD

Table 1. Characteristics of Software as a Medical Device

Parameter	Description
Medical Purpose	Diagnosis, prevention, monitoring, treatment
Standalone Nature	Operates independently of hardware medical device
Platform	Mobile, web, cloud, desktop
Clinical Use	Healthcare professionals or patients
Regulatory Oversight	Risk-based regulatory framework
Lifecycle Management	Continuous updates and post-market monitoring

SaMD differs from software embedded within medical devices because it independently achieves a medical purpose.

3. IMDRF Framework for SaMD

The IMDRF developed globally accepted guidance covering[2]:

- Key definitions
- Risk categorization
- Quality management systems
- Clinical evaluation

These documents serve as the foundation for many national regulatory systems.

Table 2. IMDRF Risk Categorization Framework

Healthcare Situation	Treat/Diagnose	Drive Clinical Management	Inform Clinical Management
Critical Condition	IV	III	II
Serious Condition	III	II	I
Non-Serious Condition	II	I	I

Category IV represents the highest risk while Category I represents the lowest risk.

4. United States FDA Requirements

The FDA regulates SaMD under its Digital Health Program.

Key Requirements

- Device classification
- Premarket submission
- Software validation
- Clinical evidence
- Cybersecurity documentation
- Post-market surveillance

Table 3. FDA Regulatory Pathways for SaMD

Pathway	Description
510(k)	Substantial equivalence
De Novo	Novel low-to-moderate risk devices
PMA	High-risk devices
Enforcement Discretion	Low-risk software categories

The FDA largely aligns its SaMD approach with IMDRF guidance.

5. European Union MDR Requirements

Under EU MDR 2017/745, standalone software intended for medical purposes is considered a medical device[4].

Major Requirements

- CE Marking

- Clinical Evaluation
- Risk Management
- Technical Documentation
- Post-Market Surveillance

Table 4. EU MDR Classification of Medical Software

Class	Risk Level
Class I	Low
Class IIa	Moderate
Class IIb	High
Class III	Highest

Software classification frequently falls under Rule 11 of MDR.

6. United Kingdom (MHRA)

Following Brexit, the UK introduced independent medical device regulations[5].

Requirements

- UKCA Marking
- Clinical Evaluation
- Software Lifecycle Documentation
- Cybersecurity Assessment

MHRA is actively developing AI-specific regulatory approaches for SaMD.

7. Australia (TGA)

Australia regulates SaMD through the Therapeutic Goods Administration (TGA)[6].

Key Principles

- Intended purpose determines classification
- Risk-based regulation
- Clinical validation[7]
- Cybersecurity controls

AI-enabled software may require increased clinical evidence and post-market monitoring.

8. India (CDSCO)

India regulates software medical devices under[8]:

Applicable Regulations

- Medical Device Rules (MDR), 2017
- CDSCO Medical Device Guidance

Requirements[9]

- Device registration
- Quality Management System
- Clinical evaluation
- Import licensing

India is gradually aligning with IMDRF principles.

Clinical evaluation demonstrates that SaMD achieves intended clinical outcomes safely and effectively.

9. Clinical Evaluation Requirements[10]

Table 5. Clinical Evaluation Components

Component	Description
Analytical Validation	Accuracy of software output
Clinical Validation	Clinical relevance
Clinical Performance	Real-world effectiveness
Benefit-Risk Assessment	Overall safety profile

IMDRF recommends a three-stage clinical evaluation model for SaMD[11].

10. Cybersecurity Requirements

Cybersecurity is increasingly important because SaMD products operate on connected platforms[12].

Table 6. Major Cybersecurity Expectations

Requirement	Purpose
Secure Coding	Reduce vulnerabilities
Data Encryption	Protect patient data
Authentication	User verification
Vulnerability Management	Continuous security updates
Incident Reporting	Post-market safety monitoring

11. AI-Based SaMD: Emerging Regulatory Challenges

Current regulatory concerns include[13]:

- Algorithm transparency
- Bias management
- Continuous learning systems
- Model drift
- Explainability
- Data privacy

Table 7. Regulatory Challenges of AI-Based SaMD

Challenge	Regulatory Concern
Black Box Algorithms	Explainability
Dataset Bias	Patient Safety
Adaptive Learning	Regulatory Change Control
Cybersecurity	Data Integrity
Privacy	Regulatory Compliance

AI-enabled SaMD products require lifecycle monitoring beyond traditional software validation.

12. Comparative Analysis of Global Regulatory Systems[14]

Table 8. Global Comparison of SaMD Regulations

Parameter	FDA	EU MDR	MHRA	TGA	CDSCO
Risk-Based Classification	Yes	Yes	Yes	Yes	Yes
Clinical Evaluation	Required	Required	Required	Required	Emerging
Cybersecurity Requirements	Extensive	Extensive	Extensive	Moderate	Developing

AI-Specific Guidance	Developing	Developing	Developing	Developing	Limited
IMDRF Alignment	High	High	High	High	Moderate

13. Future Perspectives[15]

Future regulatory developments are expected to focus on:

- AI governance
- Real-world evidence
- Continuous learning algorithms
- Global harmonization
- Digital therapeutics
- Cybersecurity assurance

IMDRF-led harmonization efforts are likely to reduce regulatory complexity and improve global market access.

14. Conclusion

SaMD has become an essential component of modern healthcare systems. Regulatory agencies worldwide are increasingly adopting harmonized, risk-based approaches to ensure safety, effectiveness, and clinical performance. Although differences remain among FDA, EU MDR, MHRA, TGA, and CDSCO frameworks, the IMDRF framework serves as a common foundation for global regulation. Future regulatory policies will increasingly address AI-enabled SaMD, cybersecurity, and continuous software learning systems to support innovation while ensuring patient safety.

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