Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED FINAL DOCUMENT

Title:	Software as a Medical Device (SaMD) Pre-Market Submission Requirement – Comparison of requirement from Key jurisdictions
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Software as a Medical Device (SaMD) Pre-Market Submission Requirement

Comparison of requirements from key jurisdictions

White Paper

GHWP TC WORK GROUP 3

For Proposed Final

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1. Preface

The objective of this whitepaper is to provide a summary of the regulatory requirements for Software as Medical Device (SaMD) pre-market submissions of a few jurisdictions. This document is intended to serve as an educational resource to promote awareness and understanding of these requirements. It is important to note that this whitepaper does not offer any guidance or recommendations, but rather aims to inform and educate stakeholders about the existing regulatory landscape. WG3 will update this document from time to time to reflect any major regulatory changes.

2. Introduction

The increasing amount of Software as a Medical Device (SaMD) as well as rapid technology evolvement leads to a great deal of complexity when applying existing medical device regulations to these devices around the world.

The manufacturer of a SaMD product, often called the "developer", has a different perspective than the manufacturer of a traditional medical device when designing, "manufacturing", and marketing the product. Regulators will need to take this into account when developing their regulatory requirements for SaMD products. Mutual understanding between the software industry and regulators is essential to ensure appropriate regulatory controls without obstructing patient's timely access to healthcare.

The first step is always the hardest. Sometimes new industry players may mis-interpret how existing regulatory requirements apply to their products, or regulatory authorities may start to regulate SaMD in a suboptimal way. Helpful material can be found in SaMD Software Qualification and Risk Categorization guidance documents, such as AHWP/WG3/F001:2015 Guidance Document on Qualification of Medical device Software and AHWP/WG3/F001:2016 Guidance document on Risk Categorisation of Software as a Medical Device.

We have collected pre-market submission requirements for some regulatory bodies and jurisdictions, such as Australia Therapeutic Goods Administration (TGA), Japan MHLW, China NMPA, Republic of Korea (South Korea) MFDS, and Singapore HSA – with reference to their published guidelines for medical software regulation and pre-market submission requirements. To ensure clarity, our focus will be exclusively on the pre-market submission requirements for SaMD, while excluding AI-based medical devices, Digital Therapeutics (DTx), and Clinical Decision Support Software (CDSS).

The main aim of this white paper is to summarize the current regulatory environment around the world, by comparing different pre-market submission requirement across jurisdictions, for next development of GHWP guidelines. These can then serve as member economies' key reference in establishing, in a consistent way, an economic and effective approach to the control of software as medical device in the interest of public health and in continuous innovation in the development of these technologies. Please note that this paper is focuses on SaMD.

2.1. Note on Terminology

This white paper does not intend to define any terms in relating to SaMD. It is noted that some of the terms adopted in regulatory guidance are different from each other even though they share the same or similar name. This is confusing when preparing regulatory (submission) documentation for multiple jurisdictions and increases the likelihood of mistakes.

3. Japan MHLW/PMDA

3.1.1. Japan SaMD Pre-Market Submission requirement

In Japan, the pre-market submission requirements for Software as a Medical Device (SaMD) are governed by the Pharmaceuticals and Medical Devices Act (PMD Act).

Scope of regulated software medical device (Yakushokukannma-hatsu #1114-5 薬食監麻発 1228-2 第 2 号) [1]**:**

"'Medical Device Programs' (which means SaMD) are used for diagnosis, treatment or prevention of human diseases or for effect on human anatomy or function by being installed into general purpose computers or mobile devices."

For Class II, III and IV Medical Device Programs pre-market application is required, but it is not required for Class I Medical Device Programs because they are not under the control of Pharmaceutical and Medical Devices Act (PMD Act). The applications for Class II Medical Device Programs are reviewed under the Certification Standard by 3rd Party Certification Bodies specified by MHLW. Most of the applications for Class III and IV Medical Device Programs are reviewed by the PMDA.

SaMD Classification in Japan

<table>
<tr><th>Non-SaMD</th><th colspan="4">SaMD</th></tr>
<tr><td rowspan="4">For health control (ex: programs which give patients advice on meal or exercise for health maintenance and promotion

Educational program (ex: training programs for health care professionals)

In-hospital business support program (ex: medical appointment system, electronic medical record)

Programs corresponded to Class I (ex: eye test, programs for color perception test)</td><td></td><td>Class II</td><td>Class III</td><td>Class IV</td></tr>
<tr><td>For treatment at home</td><td>For used exclusively at home</td><td></td><td></td></tr>
<tr><td>For diagnostics</td><td colspan="2">For computer assisted imaging diagnostics

For computer assisted diagnostics other than imaging</td><td>For gene mutation analysis</td><td></td></tr>
<tr><td>For treatment</td><td colspan="2">For therapy planning support

For Surgical Support

Application for behavioural therapy</td><td>For controlling active implantable device</td><td></td></tr>
</table>

3.1.2. PMDA submission requirement

Submission requirements (Yakushokuki-hatsu #1121-33 [2] and "Application file and STED templates with sample description for program medical device approval application" Jimurenraku 02102015).

Table 2. Submission requirement for Japan PMDA in relates to software medical device

Application file (body)		
1	Name	Category, JMDN (Japanese medical device nomenclature,) Product name
2	Purpose of use or effectiveness	Indicated patient, disease, usage condition, expected result, effectiveness
3	Shape, structure and mechanism	Concrete and detailed explanation about what the product is including following: - How to be provided (e.g. Sold by downloading, Provided by memory storage etc.) - Mechanism of operation (e.g. input, processing algorithm, output info) - Platform requirement (e.g. HDD, Memory, CPU, OS, electric safety (JIS T0601-1 or JIS C6950-1 etc.) - Devices to be used with (other medical devices (incld. SaMD,) program) If the product has an additional function, the description is also required.
4	Raw material, Mfg method Storage method & shelf-life	No description required
5	Specification related to performance and safety	Design specifications required as the product requirements as a program medical device installed in the platform from perspectives of quality, safety and effectiveness (performance and function.) Same info as the "Shape, structure and mechanism" is not required. They should be verified at development life cycle and design phase and assured as the final product quality, safety and effectiveness specification. Test methods are also required if no standards.
6	Usage method	Operation environment, preconditioning, requirement specs of combined equipment, Usage method from preparation/installation (downloading,) operation to the equipment power turning off by using flowchart or illustrations. If it is used with any other products, the usage method should include the combined products.
7	Manufacturing sites	Design mfg site name, registration # Domestic final labeling or shipping site name, registration #
8	Package insert	Draft package insert
STED (summary and attachments)		
1	Product description	Development history including needs or background and design concept, Other design and development history, summary product description including relationship between design concept and product design specifications, Approval and complaints history in foreign countries, Comparison with the existing approved medical devices.
2	Essential principles and the conformity	Reference standards, Essential principles and the evidence/explanation of conformity (EP checklist)
3	Product details	Specifications related to performance and safety and the evident data,
4	Design verification and validation summary	Declaration of conformity, Evident data of conformity to applicable product standard (Design verification and validations summary and documentations). Clinical evidence if necessary.
5	Labeling	Package insert (draft) Domestic designated labeling (draft,) Conformity to applicable JIS standard required by the applicable product standard
6	Risk analysis/management	Risk management organization, Risk analysis results (critical hazards) and risk mitigation actions taken
7	Manufacturing information	No description required

4. Australia TGA

4.1.1. Australia SaMD regulation requirements

In Australia, software based medical devices are medical devices that incorporate software or are software, including software as a medical device, or software that relies on hardware to function as intended, and are regulated in Australia by TGA. Software (including mobile apps) is a medical device if it fits within the definition of a medical device in section 41BD of the Therapeutic Goods Act 1989, unless otherwise excluded [3].

There is no specific SaMD Pre-Market submission requirement under Therapeutic Good Act 1989. However, if software is qualified as medical device, the product should go through the necessary conformity assessment and principle requirements by referencing to the Essential Principle Checklist, and ARTG listing similar to any other medical device. The TGA maintains a comprehensive SaMD guidance portal, which includes SaMD regulations (draft), FAQs, a factsheet on SaMD advertisements, among other resources.

The TGA has implemented a regulatory reform concerning SaMD by making changes to Therapeutic Goods (Medical Devices) Regulation 2002, introducing new classification rules and amending essential principles to clarify SaMD regulations. The changes under the reform is effective from 25 Feb 2021. Guidance that outlines the regulation changes [4] and draft guidance on SaMD regulatory approach [5] are available on the TGA website.

5. China NMPA

5.1.1. China SaMD regulation requirement

In China, standalone software (SaMD) refers to software that has one or more medical purposes/uses, can complete its intended use without medical device hardware, and run on a general-purpose computing platform. The general computing platform meets the safety requirements of information technology equipment (including electromagnetic compatibility, and complies with GB 4943.1, GB/T 9254 and other standards.

Both Software in a Medical Device and Software as a Medical Device are regulated in China. In 2015, the National Medical Products Administration – NMPA published the registration guidance document for software related submissions. Technical Evaluation of submissions will be performed by the Centre for Medical Device Evaluation (CMDE) under the NMPA. The guidance was revised in 2022, any medical device software registration shall follow the latest NMPA software guidance. Furthermore, NMPA CMDE already setup digital health regulation framework, including general software technical review guidance, which is mentioned above, the cybersecurity review guidance, AI medical device review guidance, mobile medical device review guidance and specific software product review guidance, like PACS [6].

5.1.2. China NMPA Submission Requirements

NMPA request manufacture to provide a software study report for new and change medical device product registration submission. The structure of the software study report can be found in table 3. In addition, the NMPA general software guidance also indicate the requirement about the software version, measurement function, interoperability, UDI, quality management software, IFU and etc.

The study report shall cover self-development software and off-the-shelf (OTS) software and cloud computing. Since the manufacture won't manage the OTS software and cloud computing through full software lifecycle, the submission requirements are tailored and focus on the verification, maintenance and risk management.

Table 3: Submission Requirement for Medical Device Software Description DocumentationReport Clauses		**Software Safety Class**		
		Minor	**Moderate**	**Major**
Basic information	Software identification	Describe software name, model, version No., HASH (#) value, registration applicant and manufacturing address		
	Level of Safety Class	Indicating the Level of safety class and a description of the rationale for that level.		
	Architecture and function	The functions, uses, interfaces of component module and function module and the prerequisite software shall be explained according to the architecture diagram, user interface relationship diagram and main interface diagram.		
	Physical Topology	Describe the physical connection relation among software/composition module, general computer platform and medical device hardware/component, prerequisite software according to the physical topological diagram.		
	Operating environment	Identify the typical operating environment required for the normal operation of the software, including the hardware configuration, external software environment, prerequisite software, and network conditions.		
	Registration history	Identify the registration status of software in China and the country of origin.		
Realizati	Development overview	Describe development language, tool, method, model, personnel, time, workload, number of code line and controlling documents		
	Risk management	Provide the risk management process workflow chart and describe the software risk management activities . The risk analysis report, risk management summary report of software update shall be provided.		

	Software Requirement specification (SRS)	The SRS documents shall be provided		
	Software Lifecycle process	The software development process, software maintenance process, and software configuration management process shall be summarized.	Provide the software development process workflow chart, software maintenance process workflow chart, software configuration management process workflow chart and describe activities in the software development process, software maintenance process and software configuration management process.	Provide the software development process workflow chart, software maintenance process workflow chart, software configuration management process workflow chart and describe activities in the software development process, software maintenance process and software configuration management process. The index table of software design history files and software coding rule document shall be provided.
	Verification and validation	Provide the plan and report of system test and user test	Summarize the quality assurance activities at various stages of software development process and provide the plans and reports for system testing & user testing.	Provide the software development quality assurance workflow chart and describe the quality assurance activities for software development process, the plan and report of integration testing, system testing, user testing shall be provided.
	Traceability Analysis	Provide the software traceability analysis process workflow chart. Describe the activities in the software traceability analysis process. The traceability analysis report of software update shall be provided.		
	Defect Management	Summary of software defect management process, and product the total number of known defects and the number of residual defects.	Provide the software defect management process workflow chart, describe the activities in the software defect management process. Indicate the total number of known defects and the number of residual effects of the software subject version shall be specified. The contents, impacts, risks of known residual defects shall be listed, ensuring that the risks are acceptable.	
	Change history	The software version naming rules, software release version and software integral version shall be specified; the integral version, date, type and details of all previous software updates since the previous registration shall be listed.	The software version naming rules, software release version and software integral version shall be specified; the integral version, date, type and details of all previous software updates since the previous registration shall be listed.	The software version naming rules, software release version and software integral version shall be specified; the integral version, date, type and details of all previous software updates since the initial registration shall be listed.
Core functions		The name of core functions, core algorithms used and intended uses of the software shall be listed, and the type shall be noted.	The name of core functions, core algorithms used, intended uses of the software shall be listed and the type shall be noted. The study data of safety and effectiveness shall be provided for the brand-new core functions, core algorithms and intended uses.	
Conclusion		The standardization of the implementation process of software update and the correctness of the corresponding core functions shall be summarized. And whether the safety and effectiveness of the software of subject version meet the requirements shall be determined.		

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6. South Korea MFDS

6.1.1. MFDS SaMD regulation requirements

In South Korea, “Medical device software” refers to software developed and manufactured for the purposes specified in Article 2 of the Medical Device Act, including embedded software, standalone software, and mobile medical apps.

There are multiple specific guidance documents that have been published under the existing Medical Device Act over the past 10 years, such as the Guidance on Review and Approval of Medical Device Software, Guidance for Medical Device Software Validation, Guidance for Mobile Medical Apps, Guidance for General Wellness Devices, Guidance for Software requirements for Big Data and AI Medical Device Registration and the recent Guide on Regulation on Review and Approval of Medical Device Software (2023) [7].

6.1.2. MFDS Guidance for Software requirement for Medical Device Registration

Form No.14 under the Revised Regulation for approval, notification, review of medical device, is described and explained by this guidance as published in June 2018 [8]. The table below (unofficial translation) shows the key documents and information required for submission.

Table 4. Form No. 14 of Revised Regulation for approval, notification, review of medical device

Medical Device Software Compliance Verification Report			
Item name (Item classification number)		Software name and version	
Software Usage type	□Built-in	□Standalone	
Software functional characteristics (Multiple selection possible)	□ Control □ Diagnosis □ Receive Data	□ Measure □ Data Conversion □ Display	□ Analysis □ Data transmission □ Other
Software Safety Class	□ A	□ B	□ C
Software Intended Use			
Software Operation Environment (Standalone software only)			

Software Development	Software Development Plan	e.g. Software Development Plan
	Software Requirement Analysis	e.g. Software Requirement Specification
	Software Implementation	e.g. Software Architecture; Software Design Specification
	Software Verification and Validation	e.g. Software Verification and Validation
	Software Distribution	e.g. Software Release
Software Maintenance and Troubleshooting	e.g. Software Maintenance; Software Problem Resolution	
Software Risk Management	e.g. Software Risk Management	
Software Configuration Management	e.g. Software Configuration Management	

7. Singapore HSA

In Singapore, Standalone software (also known as SaMD in IMRDF context) is a software and/or mobile applications that is intended to function by itself and are not intended for use to control or affect the operation of other hardware medical devices.

7.1.1. HSA SaMD regulation requirements

As mentioned, SaMD is classified as a medical device based on the first schedule of the *Health Products Act 2007* as it is used for humans for one or more of the specific purposes of:

I. diagnosis, prevention, monitoring, treatment or alleviation of disease;
II. diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury;
III. investigation, replacement, modification or support of the anatomy or of a physiological process, mainly for medical purposes;
IV. supporting or sustaining life;
V. control of conception;
VI. disinfection of medical devices; or
VII. providing information by means of in-vitro examination of specimens derived from the human body, for medical or diagnostic purposes.

Singapore HSA's approach to medical device classification was revised and updated in their "Guidelines on Risk Classification of Standalone Medical Mobile Applications and Qualification of Clinical Decision Support Software (CDSS)" updated in April 2022. Per the updated guidelines, HSA leverages the risk-based classification framework described by IMDRF (ref IMDRF/SaMD WG/N12) and takes into consideration the significance of the information provided to the healthcare decision as well as the state of healthcare situation or condition in determining risk classification. Lower risk software is classified as Class A, while more regulatory oversight is provided to higher risk software. Of note, this guidance also clarifies that lower risk CDSS would be considered Class A if it met certain criteria outlined in the guidance. The Act and its Regulations prescribe the regulatory controls for all medical devices including SaMD. The Health Sciences Authority also published guidance documents to provide guidance on product registration, dealer's licensing, change notification and amendments, special access routes, advertisement and sales promotion, safety monitoring, and technical references.

7.1.2. HSA Guidance for Software requirement for Medical Device Registration

The Act and its subsidiary Regulations require Class B and C SaMD to be registered with HSA prior to placing them on the Singapore market. Although Class A SaMD are exempted from the product registration, manufacturers and importers are required to submit a list of their Class A SaMD electronically to HSA as part of the licensing requirements.

GN-15: Guidance on Medical Device Product Registration [9] provides general guidance to local registrants on the types of evaluation route for SaMD. The details of each route are summarized in the tables below:

Type	Risk Class	Eligibility Criteria
Full	B, C	A SaMD that has not obtained any prior approval from any of HSA's reference regulatory agencies
Abridged	B, C	A SaMD that has obtained at least one reference agency approval for a labelled use identical to that intended for marketing in SG.
Immediate Class B Registration (IBR) / Immediate Class C Registration (ICR)	B, C	A Class B or C SaMD may qualify for registration via the IBR/ ICR route if it fulfils specific conditions: ***IBR-1/ ICR*** • Obtained approval from at least one of HSA's independent reference regulatory agencies for a labelled use identical to that intend for marketing in SG. **(IBR-1 and ICR)** • Marketed for at least three years in the above independent reference regulatory agency's jurisdiction **(IBR-1 only)** • No safety issues globally. **(IBR-1 and ICR)** ***IBR-2*** • Obtained approvals from at least two of HSA's independent reference regulatory agencies for a labelled use identical to that intended for marketing in SG • No safety issues globally.

For more details and requirements, please refer to the GN-15. Exclusion criteria may apply to certain routes.

Under the Verification and Validation documents, software verification and validation studies are required for standalone medical mobile applications; and traceability analysis is required for full evaluation route. Software version indicated in the report should tally with the version to be supplied in Singapore.

All software medical device manufacturers are recommended to adopt a Total Product Life Cycle (TPLC) [10] approach to manage and adapt to the rapid changes, including

a. quality management system
b. pre-market registration
c. dealer's licensing requirements
d. change notification
e. post-market management
f. cybersecurity
g. Artificial Intelligence

8. Summary of SaMD Pre-Market Submission requirements, similar or difference

The following is a summary of key requirement for the jurisdictions compared:

SaMD required

1. Level of Concern / Risk Categorization#
2. Software Description including Platform and Operation Environment#
3. Device Hazard Analysis / Risk Assessment#
4. Software Requirement Specifications (SRS) #
5. Architecture Design Chart#
6. Software Design Specification (SDS) #
7. Traceability Analysis#
8. Software Development Environment Description#
9. Verification & Validation Documentation#
10. Software Version/Revision level History#
11. Unresolved Anomalies (Bugs or Defects) #
12. Software Configuration Management#
13. Medical Device - Software Development Life Cycle (SDLC) standards

Other requirements, emphasized in certain regulatory guidance

1. Labelling (Product Label & Instruction For Use)
2. Intended Use & Indication for Use
3. Contra-indications
4. Market History
5. Registration History (Product Approval in Country of Origin)
6. Clinical Evaluations / Clinical Trial / Clinical Studies
7. Essential Principal / Essential Requirements
8. Unique Device Identification (UDI)
9. Cloud computing
10. OTS software

A table below compares and summarizes the requirements in different jurisdictions.

Also part of the IEC 62304:2015 requirements.

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Doc \ Economy	Japan PMDA	Australia TGA	China NMPA	South Korea MFDS	SG HSA
Level of Concern / Risk Categorization	Not Part of Premarket Submission Requirements	Incorporate into Medical Device classification	Yes	Yes	Incorporate into Medical Device classification
Software Description including Platform and Operation Environment#	Yes	No SaMD Specific submission guidance published as of Oct 2019.	Yes	Yes	Yes
Device Hazard Analysis / Risk Assessment#	Yes		Yes	Yes	Yes
Software Requirement Specifications (SRS)#	Not Part of Premarket Submission Requirements		Yes	Yes	Yes
Architecture Design Chart#	Not Part of Premarket Submission Requirements		Yes	Yes	Yes
Software Design Specification (SDS)#	Not Part of Premarket Submission Requirements		Yes	Yes	Yes
Traceability Analysis#	Not Part of Premarket Submission Requirements		Yes	Not Part of Premarket Submission Requirements	Yes
Software Development Environment Description#	Not Part of Premarket Submission Requirements		Yes	Yes	Yes
Verification & Validation Documentation#	Yes		Yes	Yes	Yes
Revision level History#	Not Part of Premarket Submission Requirements		Yes	Yes	Yes
Unresolved Anomalies (Bugs or Defects)#	Not Part of Premarket Submission Requirements		Yes	Not Part of Premarket Submission Requirements	Yes
Software Configuration Management#	Not Part of Premarket Submission Requirements		Not Part of Premarket Submission Requirements	Yes	Yes
Medical Device - Software Development Life Cycle (SDLC) standards	Yes. IEC62304:2015 / JIS T 2304	Not Part of Premarket Submission Requirements	SDLC summary is required. IEC 62304 (YY/T 0664) checklist is recommended.	Yes. IEC62304:2015	Yes. IEC62304:2015

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Other Requirements					
Doc \ Economy	**Japan PMDA**	**Australia TGA**	**China NMPA**	**South Korea MFDS**	**SG HSA**
Instruction for use	Yes	Yes	Yes	Yes	Yes
Intended Use & Indication for Use	Yes	Yes	Yes	Yes	Yes
Contra-indications	Yes	Yes	Yes	Yes	Yes
Market History	Yes	Yes	Yes	Not Part of Premarket Submission Requirements	Yes
Registration History (Product Approval in Country of Origin	Not Part of Premarket Submission Requirements	Not Part of Premarket Submission Requirements	Yes	Not Part of Premarket Submission Requirements	Yes (for immediate & Abridged registration path)
Clinical Evaluations / Trial / Studies	Yes	Yes	Yes	Yes	Yes
Labelling	Yes	Yes	Yes	Yes	Yes
Essential Principles / Essential Requirements	Yes	Yes	Not Part of Premarket Submission Requirements	Not Part of Premarket Submission Requirements	Yes
Unique Device Identification (UDI)	UDI applies to SaMD since 2019	Under discussion for guidance and implementation. No timeline yet	Yes, required for Class III SaMD.	Yes. Starting from 2019 by phase	Yes. Starting from 2024 by phase

 # Also the requirements of IEC 62304:2015.

9. Summary

There is a trend to require a common set of information in order to compile SaMD pre-market submissions, although some jurisdictions do have unique requirements. However, most of these requirements are closely related to the Medical Device Software Development Life Cycle - in the traditional medical device manufacturing point of view it is similar to an integrated Design, Development and Manufacturing process. A more harmonised approach to SaMD regulatory requirements, beginning with terminology, is very important. Not only for "manufacturers" but also for reviewers and users of SaMD, especially when the same product is made available in multiple jurisdictions.

10. References

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