Medical Software Regulation

IMDRF/SaMD WG/N23 FINAL: 2015

Management of Equipment Technology - GQUIP

General Management of Health Product Technology - GGTPS

Brasília, October 2022

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Motivation

- The IMDRF documents highlights the use of quality management as a general consideration towards the safety, effectiveness, and performance of SaMD and as key to ensuring the predictability and quality of SaMD.
- In the medical device sector it is generally accepted that following QMS requirements is one of the controls used to minimize and manage unintentional outcomes related to patient safety.
- In the software industry, good software quality and engineering practices are used to control the quality of software products.

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Scope

- Inform the reader of SaMD specific practices.
- Provide guidance for the application of QMS.
- Highlight clinical environment, technology and systems environment considerations that should be addressed.
- Help attain a common understanding and vocabulary QMS requirements to SaMD.
- Complement the IMDRF SaMD framework for risk categorization.
- Not intended to provide guidance on how to undertake good software quality and engineering practices or how to implement QMS

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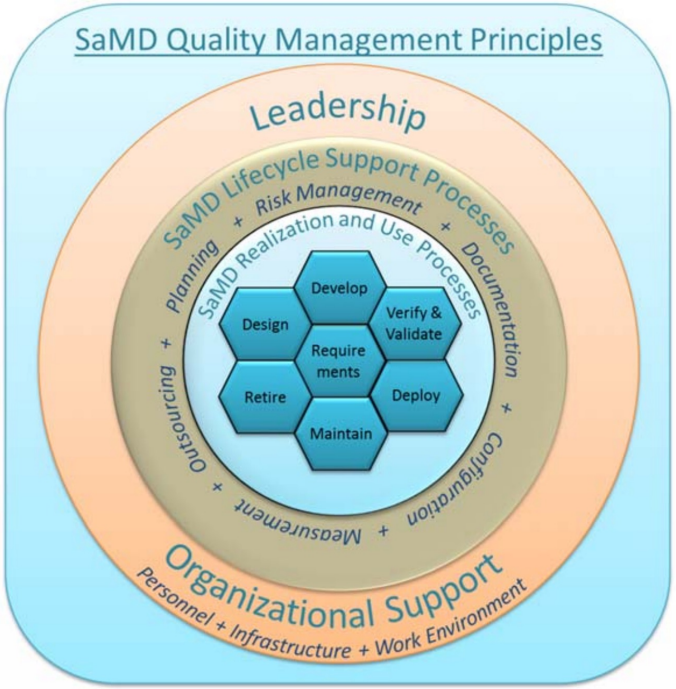
SaMD Quality Management Principles

- An organizational structure that provides leadership, accountability, and governance…
- A set of SaMD lifecycle support processes that are scalable for the size of the Organization…
- A set of realization and use processes that are scalable for the type of SaMD....



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SaMD Leadership and Organizational Support

- The organization's leadership is responsible for implementing the QMS, ensuring:
  - Resource and Infrastructure Management, including people that must have competencies in technology and software engineering including an understanding of the clinical aspects;
  - Resources should be made available throughout SaMD lifecycle processes.

SaMD Lifecycle Support Processes

- QMS should be built and managed around processes that support the lifecycle activities of SaMD.
  - Product Planning;
  - Risk Management;
  - Document and Record Control;
  - Configuration Management and Control;
  - Measurement, Analysis, and Improvement;
  - Managing Outsourced.

SaMD Realization and Use Processes

- SaMD lifecycle support processes should be applied throughout the SaMD realization and use processes considering Patient Safety/Clinical Environment and Technology/Systems Environment.
  - Requirements Management - satisfy the needs across the socio-technical environment;
  - Design - define the software based on user and performance requirements;
  - Development - should be adequately captured and communicated;

SaMD Realization and Use Processes

- Verification and Validation - targeted towards the criticality and impact to patient safety;
- Deployment - support a controlled and effective distribution;
- Maintenance - tasks to modify a previously deployed SaMD, risk assessment should be performed;
- Decommissioning - terminate maintenance, support, and distribution of SaMD in a controlled and a managed fashion.

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Mapping of applicable clauses, articles, and subsections of the regulations for a QMS for SaMD for the jurisdictions represented in the current IMDRF SaMD WG members.

N23	Topic	ISO 13485:2003	Australia	Brazil RDC 16/2013	China MD GMP ([2014]64)	Japan MHLW QMS Ordinance	US 21 CFR
5.0--SAMD QUALITY MANAGEMENT PRINCIPLES	Quality management strategy	4	All	2.1	3,24	5	820.5
	Management responsibility	5			5-7,78		
6.0--SAMD LEADERSHIP AND ORGANIZATIONAL SUPPORT							
6.1--LEADERSHIP AND ACCOUNTABILITY IN THE ORGANIZATION	Management responsibility	5	All				
	Management commitment	5.1		2.2.5, 2.2.6	6	10	820.20b
	Customer focus	5.2				11	
	Quality policy	5.3		2.2.1	6	12	820.20a
	Quality planning	5.4			6	13, 14	820.20d
	Responsibility and authority	5.5		2.2.3	5	15	820.20b1
	Management representative	5.5.2		2.2.5	7	16	820.20b3
	Internal communication	5.5.3		2.2.1		17	
	Management review	5.6		2.2.6	78	18, 19, 20	820.20c
	Internal audit	8.2.2					
6.2--RESOURCE AND INFRASTRUCTURE MANAGEMENT	Resource Management	6	All				

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Conclusion

- Is a essential guide to understand how to apply ISO 13485:2003 in a SaMD driven environment.
- Uses didactic language but is generic enough to apply to any venture involving SaMD
- It is easily compliant with QMS requirements already required in various regulatory environments, as well as those required for traditional medical devices.

Thank you

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