Software as a Medical Device (SaMD)

Application of Quality Management System
IMDRF/WG/N23FINAL:2015

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NWIP – Quality Management System for Software as Medical Device (SaMD)

Scope

- Translate and adapt existing quality management system (QMS) requirements to common software development practices.
- Illustrate how QMS applies to software lifecycle processes.

Rationale

The scope and complexity of existing QMS requirements are influenced by widely varying risks of physical medical devices. There is no clear guidance on how a SaMD manufacturer, often new to regulations, should apply and meet QMS requirements.

Proposed Timeline

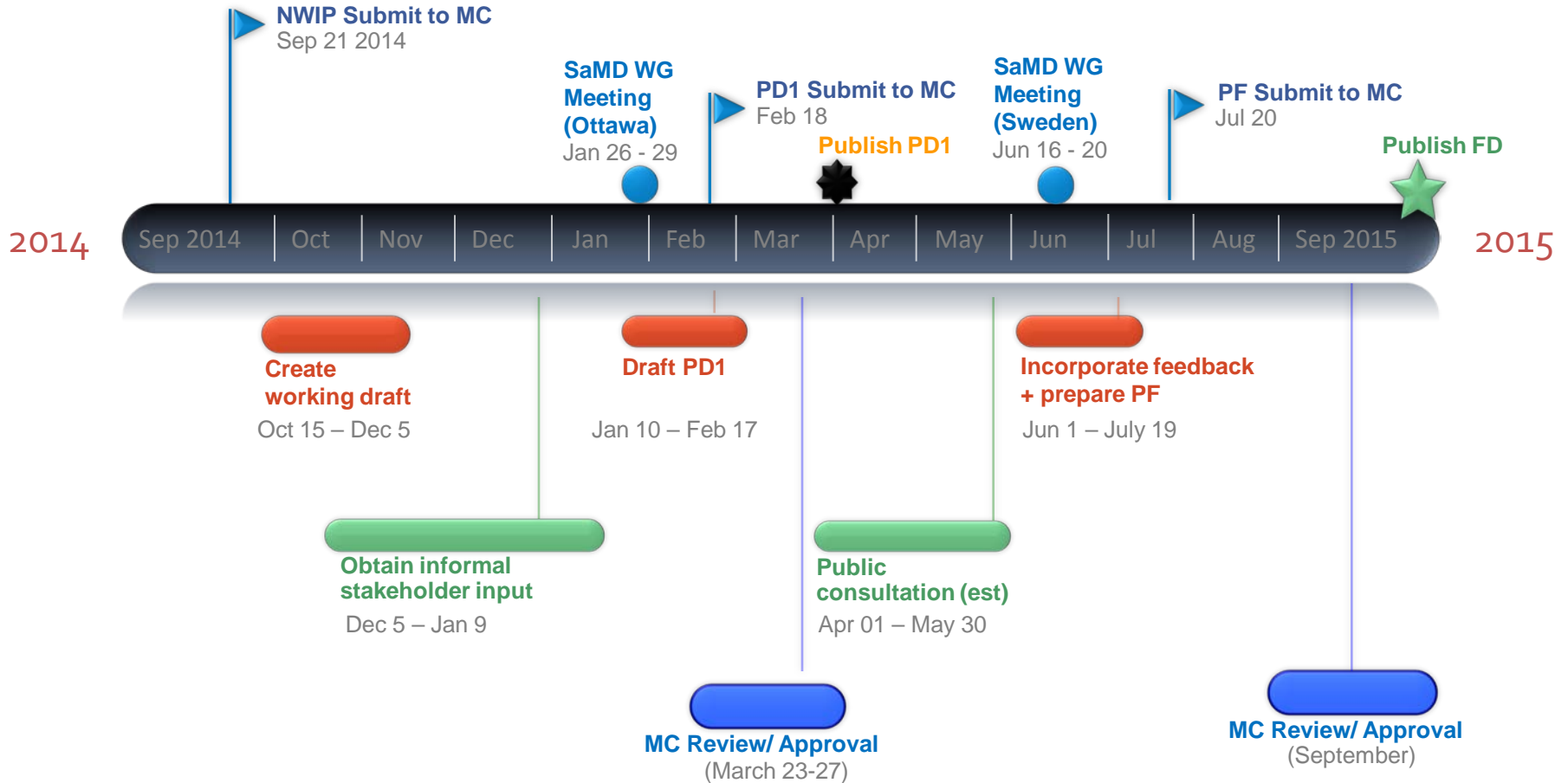Publish Final Document – October 2015

Goals

- International convergence and common understanding of how existing medical device QMS regulations and standards apply to Software as a Medical Device (SaMD).

- Provide guidance to SaMD manufacturers, often new to medical device regulations, on how to apply medical device quality management principles for safe and effective SaMD.

- Help software manufacturers advance the safety, performance and effectiveness of SaMD by highlighting certain QMS requirements from a clinical and technological perspective.

Timeline

IMDRF — International Medical Device Regulators Forum

NWIP Submit to MC
Sep 21 2014

SaMD WG Meeting (Ottawa)
Jan 26 - 29

PD1 Submit to MC
Feb 18

Publish PD1

SaMD WG Meeting (Sweden)
Jun 16 - 20

PF Submit to MC
Jul 20

Publish FD

2014 — Sep 2014 | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep 2015 — 2015

Create working draft
Oct 15 – Dec 5

Draft PD1
Jan 10 – Feb 17

Incorporate feedback + prepare PF
Jun 1 – July 19

Obtain informal stakeholder input
Dec 5 – Jan 9

Public consultation (est)
Apr 01 – May 30

MC Review/ Approval
(March 23-27)

MC Review/ Approval
(September)

PD1 Development Process

Proposed Draft Feedback → **Stakeholders** → **Feedback Themes**

Proposed Draft Feedback

- ~500 comments received

- 34 organizations

- Increased feedback from software developers, clinicians and software researchers

- Increased global feedback

Stakeholders

Regulators

- Australia
- Brazil
- Canada
- China
- EU
- Japan
- USA

Thank You

Industry

- AdvaMed
- Coach
- DITTA
- Eucomed/EDMA
- ITAC
- GMTA
- Medec
- ABIMED/ABIMO
- Standards
- SW Developers

Feedback Themes

- ✓ Clarify document objective, scope, target audience, not a QMS or software practice tutorial

- ✓ Use 13485 as a reference and not regulations

- ✓ Provide roadmap to existing QMS

- ✓ Provide clear lines to patient safety

- ✓ Provide additional clarity and content for outsourcing and cybersecurity

- ✓ Align concepts between section content and examples

Key Changes to Final N23

- Consistent use of "process" and "activities" terminology

- Revised examples to align concepts with section content

- Added emphasis on cybersecurity considerations in relevant QMS processes

- Changed names of example companies from ACME and J&M to *Magna* and *Parva*

- Appendix expanded to include mapping of N23 sections to ISO13485:2003 to WG member country regulations

Target Audience

The document targets software development organizations that apply good software quality and engineering practices but may not be familiar with "medical device QMS" principles.

| Organizations New to SaMD and New to MD QMS	⟷	Organizations Experienced in MD QMS and New to SaMD

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SaMD Quality Management Principles
Model for QMS activities from a Software perspective

- **An organizational structure –** that provides leadership, accountability, governance, and an organization with adequate resources to assure the safety, effectiveness and performance of SaMD;

- **SaMD lifecycle support processes –** a scalable set of quality processes that apply commonly across the SaMD lifecycle realization and use processes;

- **A set of key realization and use processes –** that is scalable for the type of SaMD, the size of the organization and takes into account important elements required for assuring the safety, effectiveness and performance of SaMD.
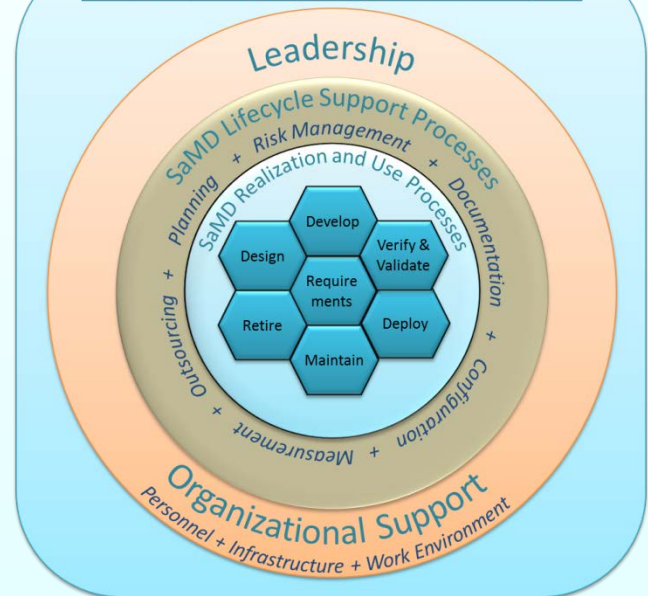
- Leadership and organizational support provides a **foundation** for SaMD lifecycle support processes

- SaMD lifecycle support processes **apply across** the SaMD realization and use processes.

Document Key Points

"*overview of scope and approach*"

- <u>Not</u> a new QMS

- Not in conflict with current QMS requirements

- Assumes developers are using good software engineering practices

- Not a tutorial for software practices or QMS

- Uses common software quality terminology and practices

- Groups QMS principles from a software perspective

- Reinforces medical device quality principles that should be appropriately incorporated for an effective SaMD QMS

- Highlights clinical and technological considerations of medical device QMS in elements of software practices

- Links to IMDRF N12 SaMD risk framework document (SaMD types and general and special considerations of SaMD)

"*reinforces medical device quality principles and how they apply to SaMD lifecycle processes*"

- Highlights key medical device QMS points for effective SaMD QMS
  - *Patient Safety and Clinical Environment Considerations*
  - *Technology and Systems Environment Considerations*

- Uses examples to Illustrate how SaMD QMS principles can be applied from two different perspectives (two fictitious companies):
  - *Magna — a large organization*
  - *Parva — a small start-up*

- Uses ISO13485:2003 as the QMS reference.

Aligning software industry practices with medical device QMS

Terminology

Document uses terminology common in the software industry to illustrate how typical software-engineering activities translate to equivalent activities in a medical device QMS

Examples

Software Industry		Medical Device QMS
Software requirements	⇔	Product requirements
Testing	⇔	Verification & Validation (V&V)
Configuration Management	⇔	Configuration Identification and Traceability

Processes

Document organizes QMS principles based on processes commonly found in software engineering lifecycle approaches with leadership and management of the organization as the foundation

Examples

Document Sections		Medical Device QMS
Product Planning (Section 7.1)	⇔	Planning, Planning of Product Realization, Design and Development Planning
Managing Outsourced Processes, Activities, and Products (Section	⇔	Purchasing Process, Purchasing Information
Maintenance	⇔	Customer Communication, Production and Service Provision, Servicing Activities, Feedback

Aligning regulations to software practices

Appendix A — Maps Medical Device Regulations to IMDRF/SaMD N23
for the jurisdictions represented by the current IMDRF SaMD WG members

N23	Topic	ISO 13485:2003 [13, 14]	Australia [15]	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

Applicability to Health Canada regulations:

- The Medical Devices Regulations require class II, III and IV medical devices to be manufactured **…**

Applicability to Europe Union regulations:

- EU legislation foresees the QMS to be assessed by third parties only for certain classes of **…**

Special thanks to all working group members and stakeholders for engaging and providing valuable input towards N23/FINAL