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International Medical  
Device Regulators Forum

# Software as a Medical Device (SaMD)

Application of Quality Management System

IMDRF/WG/N23 Proposed Document (PD1)R3



# NWIP - Quality Management Systems for Software as a Medical Device (SaMD)

## Scope

- Translate and adapt existing quality management system requirements to common software practices
- Explain how quality system requirements are applicable and adapted to typical software development, maintenance and management practices.

**Rationale** -- The scope and complexity of the quality management system are influenced by the range of different SaMD types, software development practices, maintenance practices, and other quality processes that are unique to software. There is no clear guidance on, how should a developer of SaMD follow and comply QMS requirements, examples of issues include:

- software quickly using modules, how should a developer comply with regulatory expectations?
- some of the processes used to develop SaMD are automated, what expectations are reasonable for the principles outlined in the quality systems regulations and standards?

## Proposed Timeline

- Publish Proposed Document for Public Comment in April and May 2015.
- Publish Final Document in October 2015



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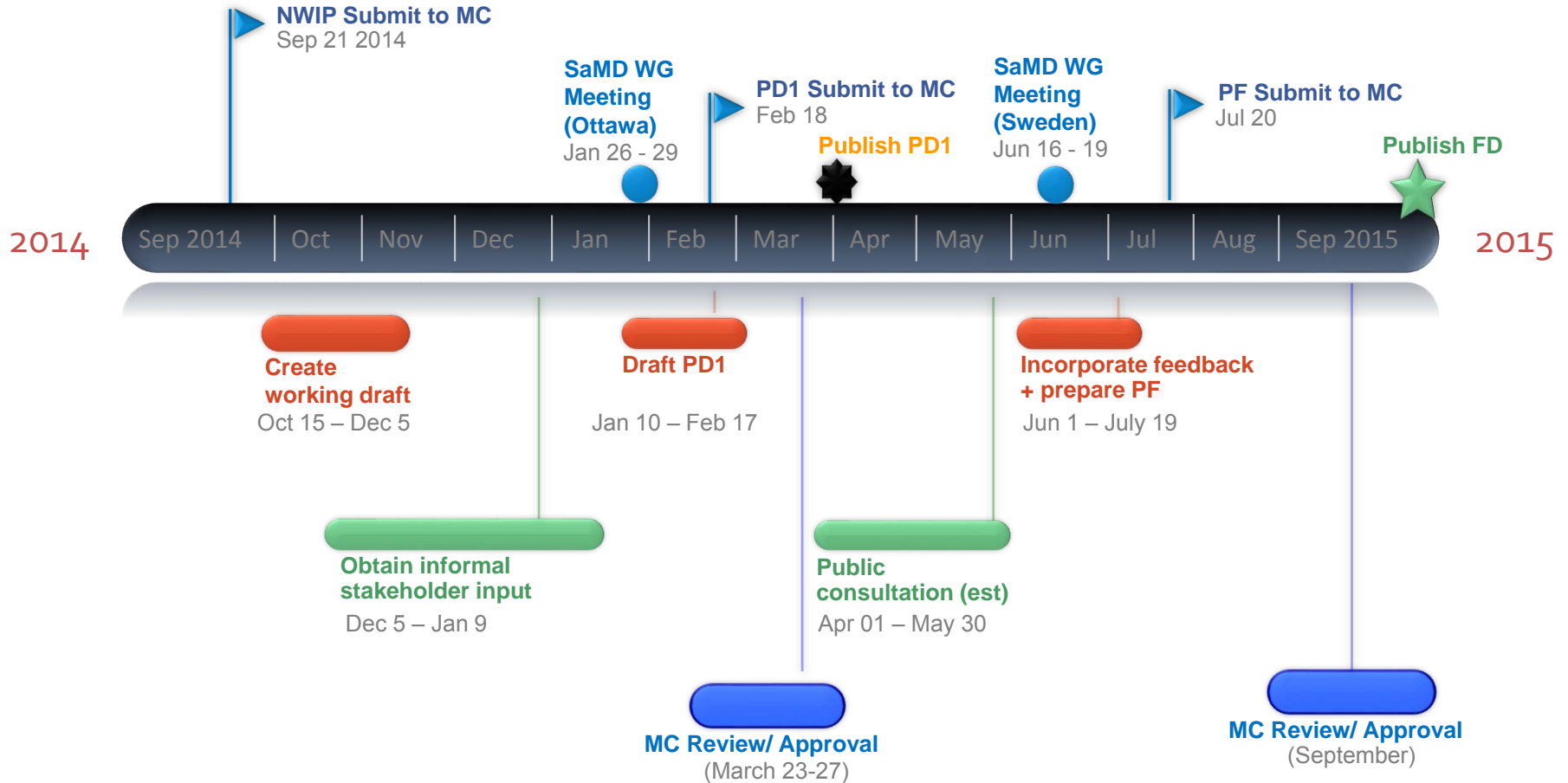
## Goals

- International convergence and common understanding of how existing medical device QMS and standards apply to Software as a Medical Device (SaMD).
- Provide guidance on application of medical device quality management principles for SaMD developers.



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## Timeline





## PD1 Development Process

### Pre working Draft & Informal Feedback

- Aligning to software vocabulary
- Introduction of QMS from the perspective of software lifecycle processes and activities
- Highlighting good practices



### Stakeholders

#### Regulators

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

#### Industry

- AdvaMed
- Coach
- DITTA
- Eucomed
- ITAC
- GMTA
- Medec
- Standards
- SW Developers

**Thank You**



### Feedback Themes

- ✓ Identified need for this document - General buy-in
- ✓ Clarify scope, target audience not a new QMS
- ✓ Illustrate concepts by figures and tables
- ✓ Maintain consistent terminology
- ✓ Should not be a tutorial
- ✓ Include missing concepts
- ✓ Use 13485 as a reference and not regulations
- ✓ Link this document to previous IMDRF SaMD docs



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## Target Audience

The document targets the software developer who is already experienced with using mature software engineering quality practices but is not familiar with “medical device QMS” principles.



## PD1 – Application of QMS to SaMD

### *“overview of scope and approach”*

- Not a new QMS
- Not in conflict with current QMS requirements
- Assumes developers are using good s/w 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
- Highlight clinical and technological considerations of Medical device QMS in elements of s/w practices
- Link to IMDRF SaMD risk framework document (SaMD types and general and special considerations of SaMD)



## SaMD Quality Management Principles

: A grouping of QMS activities from a Software perspective

- **A governance structure** provides leadership, accountability and an organization with adequate resources that assures the safety, effectiveness and performance of SaMD;
- **SaMD lifecycle processes** -- A scalable set of quality processes that apply commonly across lifecycle activities;
- **A set of key lifecycle activities** that is scalable for the type of SaMD, the size of the organization 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 processes
- SaMD lifecycle processes support and apply across the SaMD lifecycle activities.







## Converging on a common terminology and understanding of QMS principles

Terminology common in the software industry is used in the document 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*



*Identification and Traceability*



## Converging on a common understanding on governance, processes and activities

Sections are organized based on processes and activities commonly found in software engineering lifecycle approaches as well as the leadership and management of the organization as a whole.

### Examples

#### Document Sections

#### Medical Device QMS

*Product Planning (Section 7.1)*



*Planning, Planning of Product Realization, Design and Development Planning*

*Configuration Management and Control (Section 7.4)*



*Control of Documents, Records, Design and Development Changes, Production and Service Provisions, Identification and Traceability*

*Managing Outsourced Process and Products (Section 7.6)*



*Purchasing Process, Purchasing Information, Improvement*

*Deployment (Section 8.5)*



*Customer Communication, Production and Service Provision, Installation Activities, Servicing Activities*

*Maintenance (Section 8.6)*



*Customer Communication, Production and Service Provision, Servicing Activities, Feedback*



## Reinforcing medical device quality principles on SaMD lifecycle

- Highlight aspects for effective SaMD QMS
  - *Patient Safety and Clinical Environment Considerations*
  - *Technology and Systems Environment Considerations*
- Illustrates using examples how SaMD QMS principles can be applied from two different perspectives (*two fictitious companies*):
  - *ACME — a large organization*
  - *J&M — a small start-up*
- ISO13485:2003 is used as the reference material.



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## Summary and Next Steps

- Publish IMDRF/WG/N23 R3/PD1 for public commenting
- Solicit feedback on PD1
- SaMD WG meet in Sweden in June 2015 to review/resolve public comments
- Finalize IMDRF/WG/N23/PF in July 2015
- Publish Final Document in October 2015



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Special thanks to all working  
group members and stakeholders  
for engaging and providing  
valuable input towards N23/PD1