Studying IMDRF SaMD QMS document, N23, along with ISO 13485

Marcelo Antunes

Regulatory Affairs Strategy Consultant - SQR Consulting

DITTA Workshop on Medical Software
9th meeting of IMDRF in Brasilia, Brazil
March 7th, 2016

Marcelo Antunes

- Regulatory Affairs Strategy Consultant
  - SQR Consulting

- Chairman
  - ABNT CB 26 - CE 26:150.01 - Brazilian ISO TC 210 mirror (Quality management)

- Expert member
  - ISO TC 210 - Quality management and corresponding aspects for medical devices
  - Joint WGs of SC 62A and ISO TC 210

- IMDRF
  - SaMD working group member representing Brazilian industry

SQR Consulting

Summary

How the need for a QMS fits into medical device regulations

Problems in applying current medical device regulations to SAMD

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

IMDRF/SaMD WG/N23 FINAL:2015 - Scope

IMDRF/SaMD WG/N23 FINAL:2015 - Intended audience

IMDRF/SaMD WG/N23 FINAL:2015 - Relationships

IMDRF/SaMD WG/N23 FINAL:2015 - SaMD Quality Management Principles

IMDRF/SaMD WG/N23 FINAL:2015 - SaMD Leadership and Organizational Support

IMDRF/SaMD WG/N23 FINAL:2015 - SaMD Lifecycle Support Processes

IMDRF/SaMD WG/N23 FINAL:2015 - Realization and Use Processes

How the need for a QMS fits into medical device regulations

The conformity assessment elements that the RA may make available to the manufacturer will include: a quality management system, a system for post-market surveillance, summary technical documentation, a declaration of conformity and the registration of manufacturers and their medical devices by the RA

The requirements for a quality management system that is accepted by RAs for regulatory purposes and based on international recognised standards, combined with the other conformity assessment elements are intended to ensure that medical devices will be safe and perform as intended by the manufacturer

A manufacturer needs to demonstrate its ability to provide medical devices that consistently meet both customer and regulatory requirements. Manufacturers demonstrate compliance through an established and effectively implemented quality management system that meets the regulatory requirements

From GHTF SG1/N40:2006 - GHTF SG1 - Principles of Conformity Assessment for Medical Devices

How the need for a QMS fits into medical device regulations

From GHTF SG1/N40:2006 - GHTF SG1 - Principles of Conformity Assessment for Medical Devices

	Conformity Assessment Element	Manufacturer Responsibility	RA / CAB Responsibility
Conformity assessment of the QMS	Quality Management System (QMS)	Establish and maintain a QMS.	Be satisfied that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization.
	Post Market Surveillance	Establish and maintain an adverse event reporting procedure according to GHTF SG2 guidance.	Be satisfied that a current and appropriate adverse event reporting procedure is in place as part of the QMS.
Conformity assessment of device safety & performance	Technical Documentation	Prepare and submit a STED for review.	Conduct a review, normally premarket, of the STED sufficient to determine conformity to Essential Principles.
	Declaration of Conformity	Prepare, sign and submit.	Review and verify compliance with requirements.
Registration	Registration of manufacturers and their devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.

SQR Consulting

Problems in applying current medical device regulations to SAMD

- Current medical devices regulations are somewhat old (20-30 + years) and/or based on older regulations

- Software (and the use of software) as we know it today did not exist even in the recent past

- Regulations had a focus on physical devices (problems related to physical hazards such as leakage current, explosion, contamination and mechanical hazards) and not topics which are important to SaMD, such as cybersecurity and privacy, rapid design changes, and the like

- To include SaMD, some regulations and requirements (such as standards) just included a definition of SaMD and/or said that they were medical devices; however, this ends up creating interpretation problems

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

SQR Consulting

Scope

Translate and adapt existing quality management system (QMS) requirements to common software development practices

Illustrate how QMS applies to software lifecycle processes

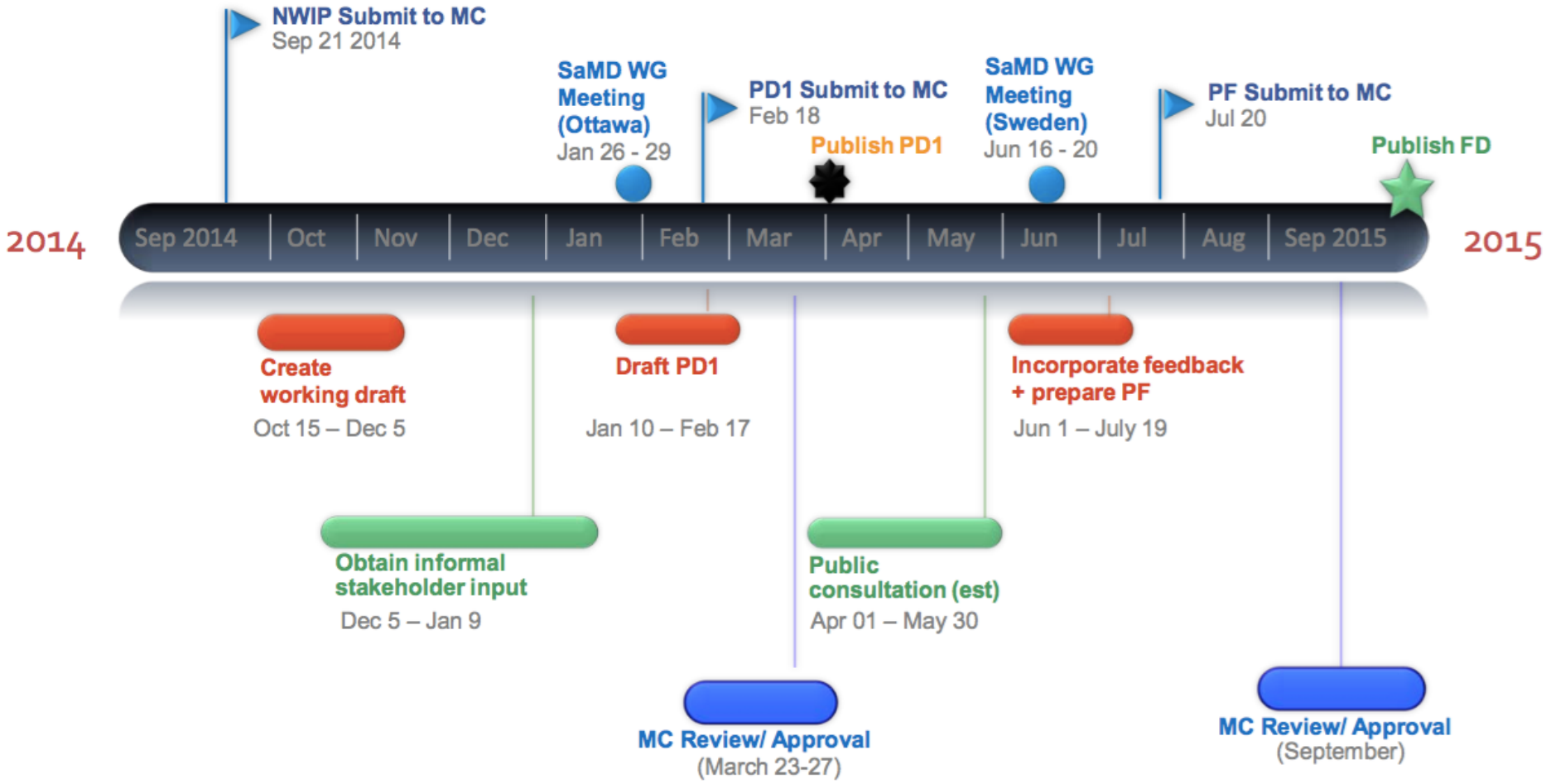
Rationale

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

SQR Consulting

Presentation from Bakul Patel

Timeline



SQR Consulting

IMDRF/SaMD WG/N23 FINAL:2015 - Scope

IMDRF/SaMD WG/N23 FINAL:2015 - Software as a Medical Device (SaMD): Application of Quality Management System

Guidance on the application of existing **standardized and generally accepted QMS practices** to SaMD

Inform the reader of SaMD specific practices, assuming the reader is following **generally accepted software lifecycle processes** and **may not** be familiar with medical device QMS

Highlight SaMD realization and use processes from the perspective of **patient safety and clinical environment considerations** as well as technology and systems environment considerations that should be addressed to ensure the safety, effectiveness, and performance of SaMD

Help manufacturers and regulators attain a **common understanding and vocabulary** for the application of medical device quality management system requirements to SaMD

IMDRF/SaMD WG/N23 FINAL:2015 - Intended audience

Groups and/or individuals who are or want to become **developers of SaMD**

Software development organizations (large or small) that **apply good software quality and engineering practices** and that may **not necessarily be familiar with medical device QMS requirements**

Organizations (divisions/departments) working within established medical device quality systems that intend to **communicate** the linkage between medical device quality system practice and software development practices

IMDRF/SaMD WG/N23 FINAL:2015 - Relationships

Relationship to regulatory requirements and to technical standards:

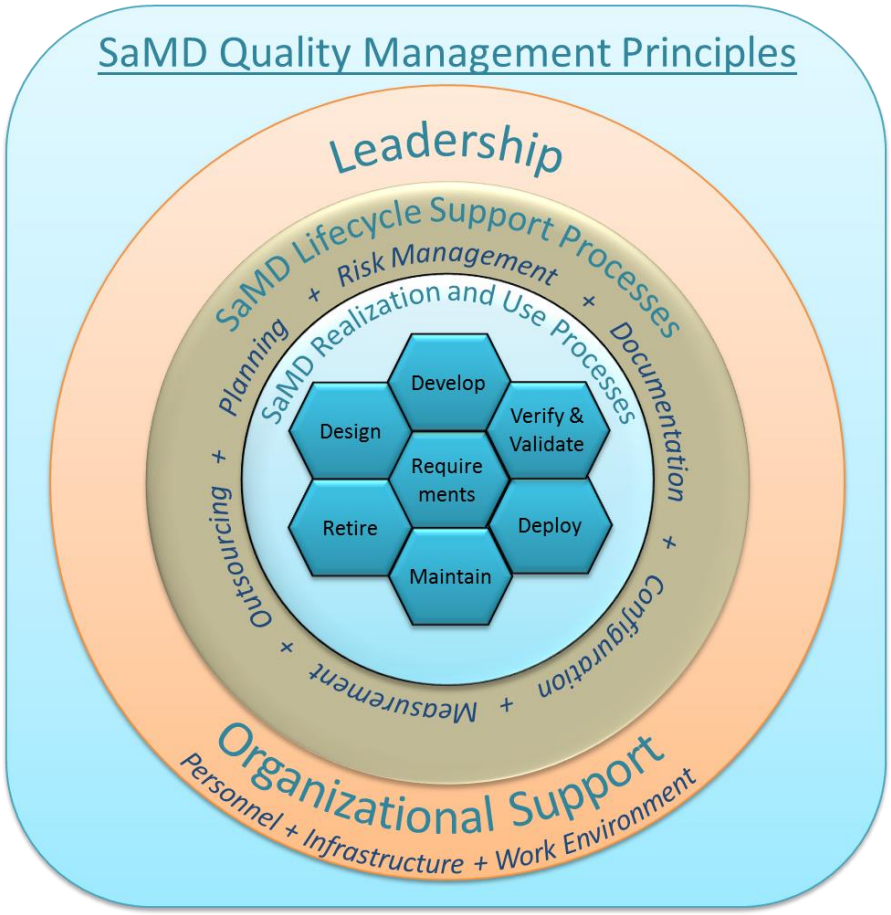
Does not replace or create new QMS standards, software quality and engineering practices, or regulations

Not intended to replace or conflict with medical device legislation, regulations, or procedures required in individual regulatory jurisdictions

Not a tutorial on risk management practices for software

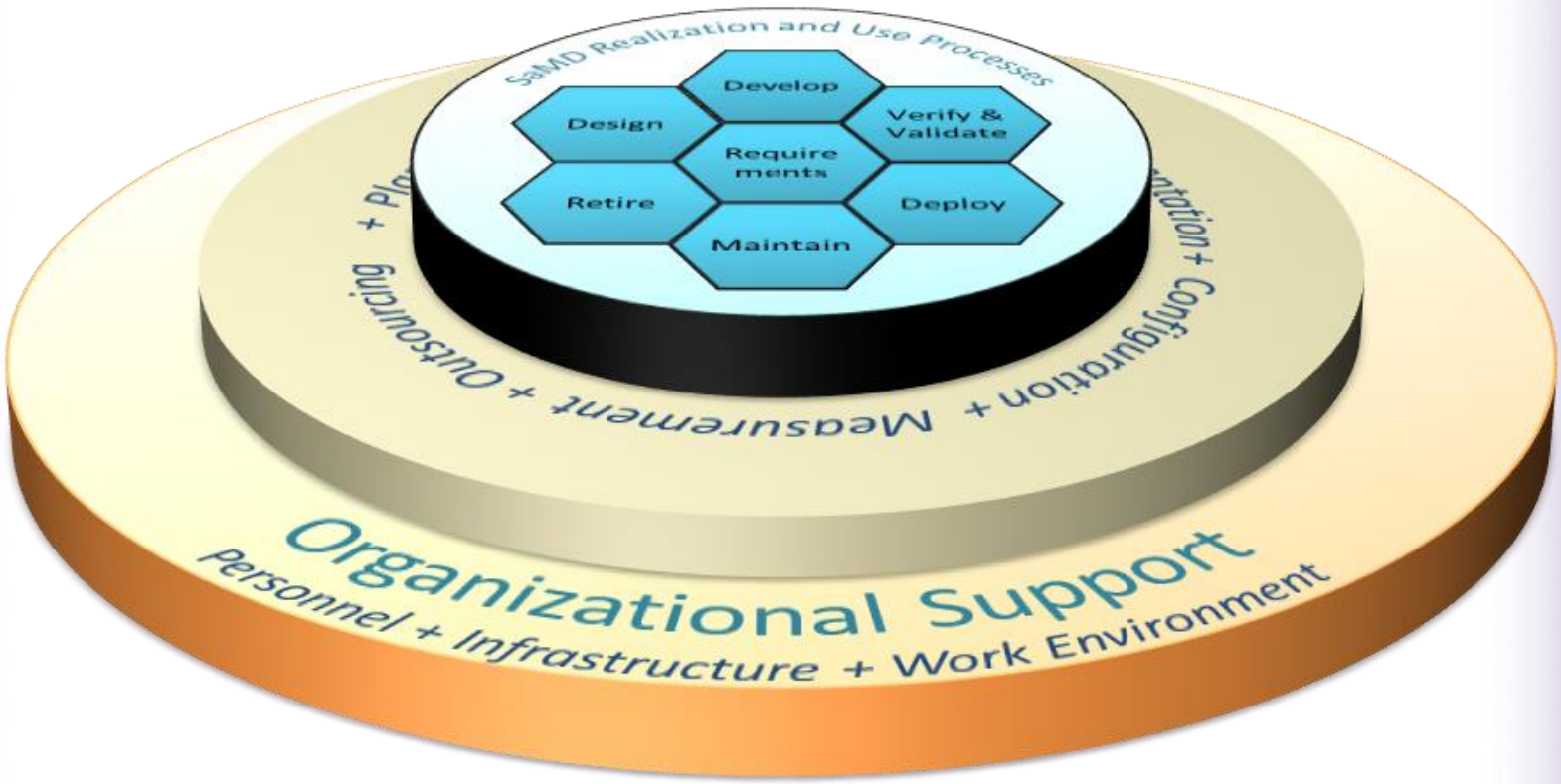
Activities highlighted are not meant to replace or conflict with the content and/or development of technical or process standards related to software risk-management activities or software-development practices but may provide input to these processes and activities

IMDRF/SaMD WG/N23 FINAL:2015 - SaMD Quality Management Principles



The concepts presented relate to clauses 4 *and* 5 *in ISO 13485:2003*

IMDRF/SaMD WG/N23 FINAL:2015 - Relationship between QMS principles



The concepts presented relate to clauses 4 *and* 5 *in ISO 13485:2003*

Management of the organization

- Provides the leadership and governance of all activities related to the lifecycle processes of SaMD

- Is responsible for implementing the QMS

The governance structure should provide support for creating and establishing appropriate processes

Resource and Infrastructure Management provide the appropriate level of resources (including people, tools, environment, etc.)

People who are assigned to SaMD projects should be competent in performing their jobs, with competencies in technology and software engineering including and understanding of the clinical aspects of the use of the software

The concepts presented relate to clauses 5, 8.2.22, 6, 6.1 and 6.2 in ISO 13485:2003

SQR Consulting

Infrastructure and work environment

Such as equipment, information, communication networks, tools, and the physical facility, and others

May include identifying and providing the software development and test environment, including providing a test environment that simulates the intended environment of use and tools that support managing various software configurations during the lifecycle processes, e.g., version management for source code during development

As work environments become increasingly virtual, the reliability and dependability of the collective infrastructure environment is an important consideration (e.g., dependence on 3rd party networks and equipment)

The concepts presented relate to clauses 6.3 and 6.4 in ISO 13485:2003

Product planning

Includes the definition of phases, activities, responsibilities, and resources for developing the SaMD, needs to be updated as required

Understanding of clinical perspective and software perspective) is important in planning

Risk Management

Focus on risks to patients and users

Hazards dimensions

- User-Based
- Application-Based
- Device-Based
- Environment-Based
- Security-Based

The concepts presented relate to clauses 5.4, 7.1 and 7.1.3 in ISO 13485:2003

Document control and records management

Makes it easier for the users of those documents and records, both within and outside) the organization, to share and collaborate in the many activities related to the SaMD lifecycle processes

Serves to help communicate and preserve the rationale for why certain decisions were made, such as those related to patient safety or risk management

Configuration Management and Control

Control of configurable items, including source code, releases, documents, software tools, etc., is important in order to maintain the integrity and traceability of the configuration

Important consideration to enable the correct installation and integration of the SaMD into the clinical environment

The concepts presented relate to clauses 4.2.3, 4.2.4, 7.3.7, 7.5.1, and 7.5.3 in ISO 13485:2003

Measurement, Analysis, and Improvement of Processes and Products

An effective measurement of key factors, often associated with issues related to risk, can help identify the capabilities needed to deliver safe and effective SaMD

Monitoring to demonstrate through objective measurement that processes are being followed does not itself guarantee good software, just as monitoring software quality alone does not guarantee that the objectives for a process are being achieved

After the product is in the market, it is important to maintain vigilance for (between other aspects) vulnerability to intentional and unintentional security threats as part of post market surveillance

The concepts presented relate to clauses 7.2.3, 7.3.7, 7.5.1.1, 8.1, 8.2, 8.3, 8.4, and 8.5 in ISO 13485:2003

Managing Outsourced Processes, Activities, and Products

Understand the capabilities and competencies of potential outsourcing suppliers

Clearly communicate the roles and responsibilities of the outsourcing supplier

Extensively define the quality requirements for the outsourced process, activity, or product

Clearly establish upfront the criteria for and review of deliverables, frequency of intermediate inspections, and relevant audits of the supplier; and

Select and qualify the appropriate outsourcing supplier to deliver safe and effective SaMD

Also, take care with COTS product

The concepts presented relate to clauses 7.4, 7.4.1, 7.4.2, 7.4.3, and 8.5.1 in ISO 13485:2003

Key lifecycle processes (based on IEC 62304:2006)

Activities commonly found in software engineering lifecycle approaches (process, activities, tasks, etc.) that are important for an effective SaMD QMS

Elements to be addressed as part of any development methodology employed (not necessarily in serial fashion or as discrete phases)

Requirements Management

Clinical needs should be clearly articulated and the requirements captured in line with the intended use of SaMD

Requires clear, and often repeated, customer interaction to understand the user needs. These user needs are then translated into requirements

The concepts presented relate to clauses 7, 7.2.1, 7.2.2, 7.2.3, 4.2, *and* 7.1d *in ISO 13485:2003*

SQR Consulting

Design

Process to create a clear and concise design solution that is an effective, well described (e.g., captured in software requirements specifications) logical architecture that best meets the user needs and that enables other lifecycle processes and activities such as development, verification, validation, safe deployment, and maintenance of the SaMD

Building quality into SaMD requires that safety and security should be evaluated within each phase of the product lifecycle and at key milestones

Development

Transforms the requirements, architecture, design (including interface definition), recognized coding practices (secure), and architecture patterns into software items and the integration of those software items into a SaMD

The concepts presented relate to clauses 7.3, 7.3.2, 7.3.3, 7.3.4, 7.3.7 and 7.3.1b in ISO 13485:2003

Verification and Validation

The verification and validation (V&V) activities should be targeted towards the criticality and impact to patient safety of the SaMD

V&V activities should include scenarios that cover the clinical user/use environment (usability, instructions for use, etc.). This can be accomplished, in part, through structured human factors testing using a subset of patients/clinicians

Confirmation of acceptable failure behavior in the clinical environment should be established

Deployment

Activities include aspects of delivery, installation, setup, and configuration,including any planned risk mitigation for hazards identified

The concepts presented relate to clauses 7.2.3, 7.3.5, 7.3.6, *7.*4.3, 7.5, 7.5.1.2.1, 7.5.1.2.2, 7.5.1.2.3 *in ISO 13485:2003*

SQR Consulting

Maintenance

Activities and tasks to modify a previously deployed SaMD

The SaMD manufacturer should take into account implications and introduction of patient safety risk as a result of changes to architecture and code

The concepts presented relate to clauses 7.2.3, 7.5, 7.5.1.2.3, 7.5.4, 7.6 *and* 8.2.1 *in ISO 13485:2003*

Decommissioning (Retirement or End-of-Life Activity)

Decommissioning activities are important to minimize the impact to patient and public health safety as a result of retiring the SaMD

The concepts presented relate to clauses 4.2, 7, *and* 7.5.1.1 *in ISO 13485:2003*

SQR Consulting

I would like to thank the SaMD WG for the great work and fun!

And thank you for watching this presentation!

Contact information: marcelo@sqrconsulting.com.br