

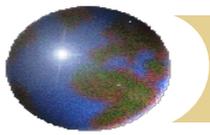
ISO 13485 Update

Presenter:

Scott Sardeson RAC US/EU

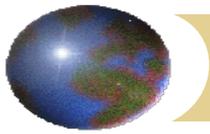
3M Health Care

St. Paul, MN USA



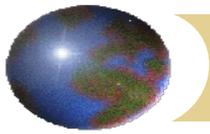
Background of Revision

- ✚ ISO 13485 has been “revised” and is out for public comment as a DIS
 - ❏ Revision was necessary due to changes in ISO standard template requirements for all quality system standards
 - ❏ The revisions was an opportunity to converge US, Japan, and Brazil unique requirements with ISO 13485 text
 - ❏ Timing for final document is thought to be Q1, 2015 with 3 year transition



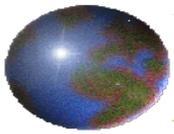
Goal of the New ISO 13485 Text

- ✦ Provide a easily understood QMS standard that is designed for REGULATORY purposes
 - ✦ Clarify how to use the standard and some requirements
 - ✦ Update to current best practices based on previous GHTF SG3 documents
 - ✦ Improve convergence of US FDA, Japan, and ISO QMS requirements
 - ✦ Modify to align better with EU Medical Device Directive (MDD) needs
 - ✦ Support future Medical Device Single Audit Program (MDSAP) goals
 - ✦ Incorporate risk-based decisions and principles throughout the QMS



Presentation Goal

- ✦ We could spend a whole day on the new text discussing the intent
- ✦ Today the goal is to just give awareness of the types of changes that the new text will add
- ✦ Detailed review of the DIS individually is necessary for full understanding
 - ✦ The presentation gives a good outline of where to study the differences from ISO 13485:2003



Expansion of Scope

The principles can now be included to other parties beside the manufacturer

1 Scope

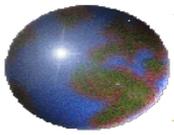
1.1 General

This International Standard specifies requirements for an organization that needs to demonstrate that its quality management system has the ability to manage the life-cycle of medical devices and associated activities consistently to meet customer and appropriate regulatory requirements. It may also be used by suppliers or external parties that provide goods and quality system related services to medical device organizations.

Stronger REGULATORY focus throughout the new text

NOTES

- 1) *Throughout this standard, statutory, regulatory and legal requirements are encompassed in the term "regulatory requirements".*



Revision Overview

- Revision was done under a New Design Specification (ISO Guide 72)
- Maintains current ISO 13485 format and will NOT use the new ISO standardized template required for future standards

DRAFT INTERNATIONAL STANDARD
ISO/DIS 13485

ISO/TC 210

Secretariat: ANSI

Voting begins on:
2014-02-20

Voting terminates on:
2014-07-20

Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires
[Revision of second edition (ISO 13485:2003) and ISO 13485:2003/Cor 1:2009]

ICS: 11.040.01, 03.120.10

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the ISO lead mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

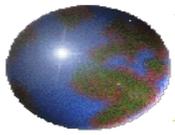
IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

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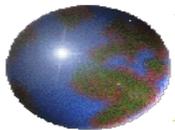
Reference number
ISO/DIS 13485:2014(E)

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Changes to Introduction & Scope

- ✦ Added storage and distribution
- ✦ Added “associated activities”
- ✦ “May” be used by suppliers
- ✦ Option to “not apply” clauses 6, 7, and 8 if not preformed as part of the organizations processes
- ✦ Scope to include the “life-cycle” of the product
- ✦ Allowance for required processes not performed (exclusions)



Changes in References & Definitions

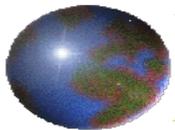
- ✦ Updated to ISO 9000:2005

- ✦ Definitions

- ✦ **Removed**: Supply Chain explanation

- ✦ **Modified**: Active Medical Device, Complaint, Labeling, and Medical Device

- ✦ **Added**: Clinical Evaluation, Distributor, Life-cycle, Manufacturer, Medical Device Software, Post Market Surveillance, Performance Evaluation, Pre-clinical Evaluation, Risk, and Risk Management



Changes to Quality Management Systems

✚ General (Section 4/4.1) - Re-organized this entire clause

✚ Document organization's role

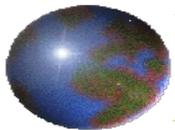
Several jurisdictions have regulatory requirements for the application of quality management systems by organizations with a variety of roles in the supply chain for medical devices. Consequently, this standard expects that the organization

- identifies its role(s) under appropriate regulatory requirements,*
- identifies the regulatory requirements that are appropriate for its activities under these roles, and*
- incorporates these appropriate regulatory requirements within its quality management system.*

✚ Establish risk based decisions within processes

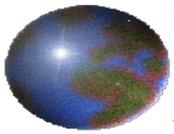
4.1.2 *The organization shall*

- a) determine the processes needed for the quality management system and their application throughout the organization taking into account the roles and responsibilities of the organization,*
- b) consider a risk based approach when developing the processes needed for the quality management system*
- c) determine the sequence and interaction of these processes.**



Changes to Quality Management Systems

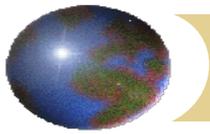
- ✦ Documentation (4.2)
 - ✦ Re-organized paragraphs
 - ✦ Added numerous items to the contents of product information file
(Added as a note and not mandatory or exclusive)
 - ✦ Added security of records—prevention of loss
 - ✦ Control of records – Added changes shall be identifiable



Changes to Management Review (5.6)

- ⊕ Assurance that QMS is meeting regulatory requirements
- ⊕ Management Review
 - ⊞ Predefined intervals, rationale for interval
- ⊕ Documentation of review must include the input

ISO 13485:2003	ISO 13485:201x
<p>5.6.3 Review output The output from the management review shall include any decisions and actions related to</p> <ul style="list-style-type: none"> a) <i>improvements needed to maintain the effectiveness of the quality management system and its processes,</i> b) improvement of product related to customer requirements, and c) resource needs. 	<p>5.6.3 Review output <i>The output from the management review shall be recorded (see 4.2.4) and include the input reviewed and any decisions and actions related to</i></p> <ul style="list-style-type: none"> a) <i>improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes,</i> b) improvement of products related to customer requirements, c) <i>improvement needed to respond to appropriate new or revised regulatory requirements, and</i> d) resource needs.
6 Resource management	6 Resource management

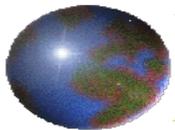


Changes to Resource Management

- ⊕ Competency of work and require to “maintain” competency
- ⊕ Consider risk of associated work (in note see below)
- ⊕ Specified requirement for documenting maintenance of equipment
 - ⊞ Used in production
 - ⊞ For control of the work environment
- ⊕ Environmental control inspection
- ⊕ Health, cleanliness and clothing

NOTES

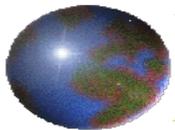
- 1) *Appropriate regulatory requirements might prescribe the organization document procedures for identifying training needs (see 4.2.1)*
- 2) *The methodology used to check effectiveness is commensurate with the risk associated with the work for which the training or other action is being provided.*



Changes to Product Realization

✚ 7.1 Planning

- ✚ Include “customer-related” processes including regulatory requirements
- ✚ Risk Management records required
- ✚ Work environment/infrastructure emphasis for resources
- ✚ Including considerations for traceability for post market requirements



Changes to Product Realization

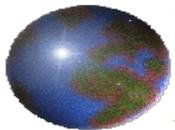
7.2 Customer Related Processes

- ❑ Identification of user training
- ❑ Protection of confidential health information
- ❑ Note added for post delivery activities and requirements

ISO 13485:201x

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.



Changes to Product Realization

7.2.3 Communication

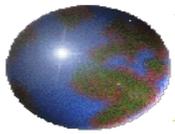
❏ Requirements related to communications with regulatory authorities in relation to

- Product information
- Regulatory enquiries
- Complaints meeting specified reporting criteria
- Advisory notices

7.2.3.2 Communication with regulatory authorities

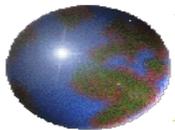
As applicable, the organization shall document arrangements for communicating with regulatory authorities in relation to

- a) Product information*
- b) Regulatory enquiries*
- c) Complaints meeting specified reporting criteria*
- d) Advisory notices*



Changes to Product Realization -

- ✦ Design & Development added much more text on:
 - ✦ Maintenance of planning documents
 - ✦ Reviews with decision point documented
 - ✦ Added design transfer, traceability (inputs/outputs) and resource competency to planning
 - ✦ Usability requirements (note to see standard) and ability to verify/validate to inputs
 - ✦ Note added for independent reviewer (specialist)



Changes to Product Realization

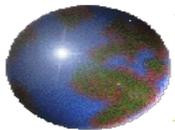
✚ Design & Development (cont.)

☒ Verification

- Plan includes: Method, acceptance criteria and sample size
- Connection to other devices
- Report includes: Traceability, rationale for sample sizes/deviations and conclusion
- Notes: additional requirements and examples

☒ Validation Plans

- See above
- Use of production units/document equivalency
- Notes: Delivery and clinical evaluation



Changes to Product Realization

✚ Design & Development (cont.)

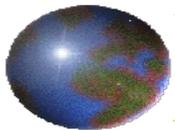
☒ Change Control

- Review of effect
- Throughout product life-cycle

☒ Records—long note on content

☒ Purchasing

- Controls—risk based
- Verification of conformance—risk based
- Communication



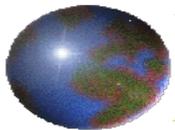
Changes to Product Realization

✚ Design & Development (cont.)

☒ Production & Service

- Analysis of data—complaint and improvement
- Validation proportionate to risk
- Validation of sterile barrier/sterilization
- Identification (UDI) & Traceability
- Customer Property
- Preservation of product—packaging validation, record of conditions if it impacts product, can include raw component or other assemblies.

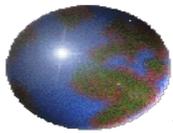
☒ Monitoring & Measurement Equipment-note on software verification and configuration management



Changes to Measurement, Analysis & Improvement

✚ 8.2.1 Feedback

- ✚ Production & Post-production
- ✚ Input to risk management with application of statistical methodology



New Section on Complaint Handling (8.2.1.2)

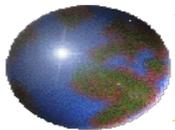
- ❏ Procedure required for requirements and responsibilities
- ❏ Maintain complaint records
- ❏ Information exchange to external party
- ❏ Adverse event reporting

8.2.1.2 Complaint handling

The organization shall document procedures for timely complaint handling.

These procedures shall include at a minimum requirements and responsibilities for the following activities:

- *Receiving information*
- *Evaluating information to determine if the feedback constitutes a complaint*
- *Investigating complaints*
- *Considering regulatory reporting*
- *Handling of complaint related goods*
- *Determining and initiating corrections and/or corrective actions if applicable on the basis of risk.*
- *Defining requirements for complaint records*
- *Feedback to review risk management file*



Changes to Measurement, Analysis, & Improvement

✚ Nonconforming Product

- ✚ Determine the need for investigation
- ✚ Before Delivery and After Delivery requirements

✚ Rework

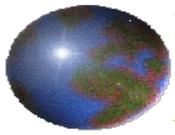
- ✚ New section for rework with requirement for procedure

8.3.4 Rework

Rework is a form of correction. The manufacturer shall establish and maintain procedures for rework, to include determination of any potential adverse effect of rework on the product.

After rework, the product shall be retested to ensure that the product meets its current approved specifications. Records shall be maintained.

NOTE The extent of procedures for rework should be proportional to the risk.



Changes to Measurement, Analysis & Improvement



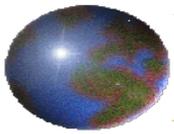
Analysis of Data

- ❑ Added audits and service reports as input
- ❑ Statistical techniques



Improvement

- ❑ General—Evaluate product safety and effectiveness and use of post market surveillance added
- ❑ Corrective Action section
 - In a "timely manner"
 - Update of documentation
 - Part of management review
- ❑ Preventive Action section = corrective action section with add of "potential" (except no "correction" evaluation)



Where to Get More Information

- ✦ DIS/ISO 13485

- ✦ ISO web site for TC210

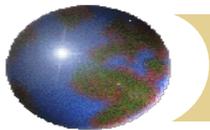
 - ✦ <http://isotc.iso.org/livelink/livelink/open/tc210>

- ✦ IMDRF website

 - ✦ <http://www.imdrf.org>

- ✦ Notified Bodies

- ✦ Local experts



Vocabulary

- ✦ ISO TC210—Technical Committee charged with revision of several standards including ISO 13485 and ISO 14971
- ✦ WG1—Working Group One—charged with drafting revisions to ISO 13485 (for TC210)
- ✦ QMS—Quality Management System
- ✦ MDD—Medical Device Directive
- ✦ JPAL—Japan Pharmaceutical Affairs Law