ISO 13485 Update

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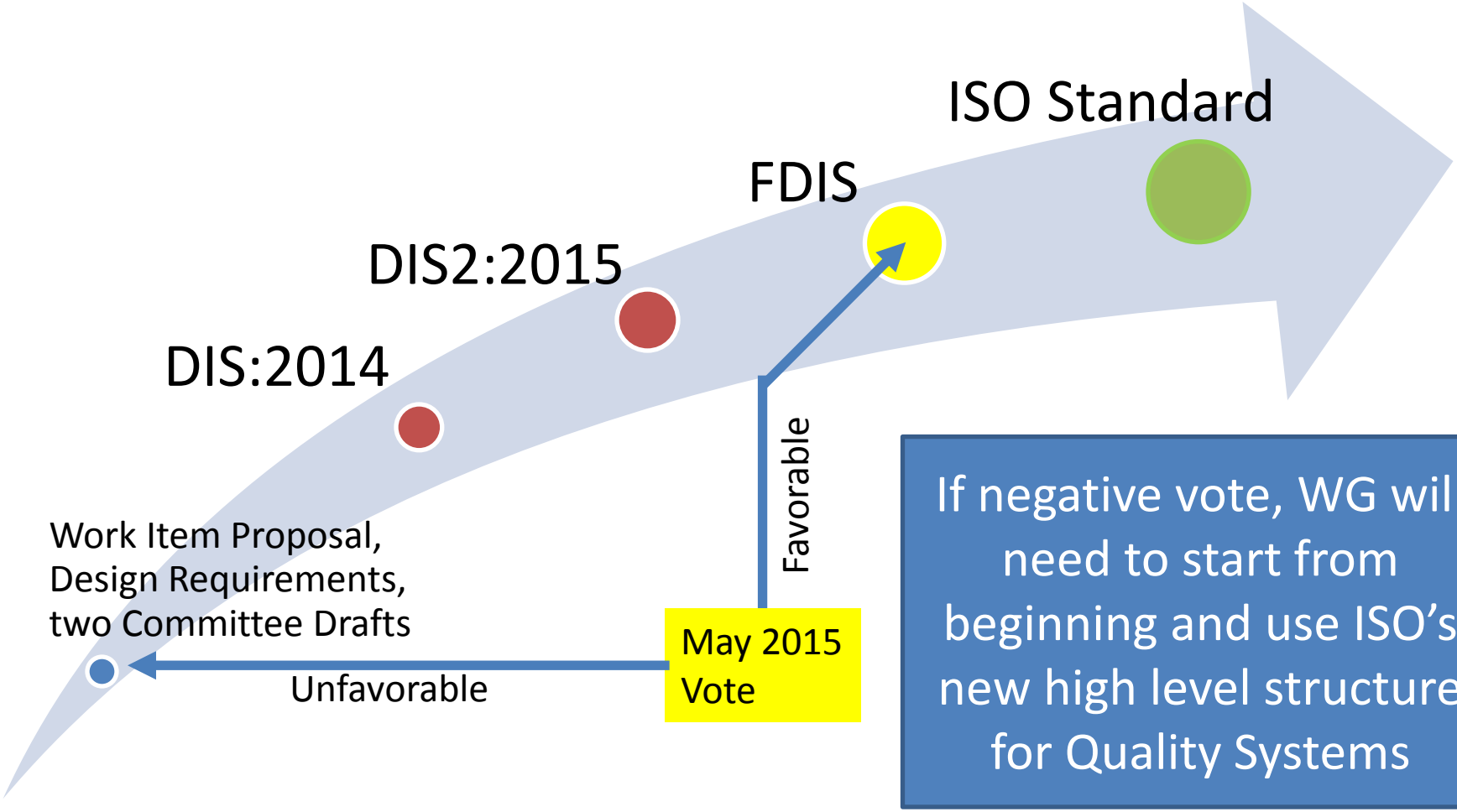
Background of Revision

- ISO 13485 has been “revised” and is out for public comment as a second DIS
  - Revision was necessary due to mandatory changes in the ISO standard template requirements for ALL quality system standards
    - By revising the ISO 13485 industry and regulators bought some time to see the impact the new template has on other quality systems
    - The revisions was an opportunity to converge US, Japan, and Brazil unique requirements with ISO 13485 text
  - Goal for the for final document to be approved for implantation by Q1, 2016 with 3 year transition

How does the ISO process work?

- Working Group (WG1) submits a work item proposal to the ISO Technical Committee responsible – ISO TC210
  - Includes rationale for the work and creation of design requirements specification
- Working group creates Committee Drafts (CD)
- When ready for public comment submits a Draft International Standard (DIS) for votes (2 rounds allowed)
- If favorable vote on DIS standard is released as Final Draft International Standard (FDIS) for final ratification

ISO 13484:XXXX Status



If negative vote, WG will need to start from beginning and use ISO's new high level structure for Quality Systems

Goal of the ISO 13485:20XX

- Provide an easily understood Quality Management System (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 Global Harmonization Task Force (GHTF)- Study Group 3 documents
  - Improve convergence of US FDA, Japan, and ISO QMS requirements
  - Modify to align better with EU Medical Device Regulations (MDR) needs
  - Support future Medical Device Single Audit Program (MDSAP) goals
  - Incorporate risk-based decisions and principles throughout the QMS

Work Item Approval

- Revision was done under a New Design Specification (ISO Guide 72)
- Agreed that it should maintain current ISO 13485 format and would NOT use the new ISO standardized template required for future standards

Compatibility with other QMS models

- **0.4 Compatibility with other management systems**
- This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

1.0 Expansion of Scope

ISO 13485:20XX Introduction - device manufacturer

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stage(s) of the life-cycle of a medical device including the design and development, production, storage and distribution, installation or servicing of medical devices, and the design, development, or provision of associated activities (e.g. technical support). The requirements in this standard may also be used by suppliers or other external parties providing product (e.g., sterilization services, calibration services, distribution services) to such organizations. Such a supplier or external party may voluntarily choose to conform to the requirements of this standard or may be required by contract to conform.

Stronger REGULATORY focus throughout the new text

1.2 Application

- This area was significantly rewritten in DIS 2 ISO 13485 and very important to revisit as one reads the standard's text.
  - Provisions for exclusions and exemptions based on regulatory requirements and scope of work done by the organization
  - Defines what is meant by documented - required to be established, implemented and maintained.
  - Explains the use of the term risk within the standard and the application as it pertains to:
    - safety or performance requirements or
    - meeting applicable regulatory requirements.
  - Regulatory requirements encompasses statutory, regulatory and legal requirements. … limited to requirements for the quality management system and the safety or performance of the medical device.
  - Note - meant for guidance in understanding or clarifying the associated requirement.

3.0 Terms and Definitions

- Updated to ISO 9000:2005
- Definitions
  - **Removed**: Active Medical Device, Active Implantable Medical Device,
  - **Modified**: Complaint, Labelling, and Medical Device
  - **Added**:
    - GHTF Definitions – Manufacturer, Distributor,
    - ISO 14971 Definitions – Risk, Risk Management
    - Others - Authorized Representative, Clinical Evaluation, Importer, Performance Evaluation, Post Market Surveillance, life-cycle

4.1 General requirements

- Re-organized this entire clause
- Document organization's role
- Establish risk based approaches within processes
- Manage and evaluate changes within the QMS
- Outsourced processes – monitor and ensure control, written quality agreements
- Document procedures for validation of software used in the QMS

4.2 Documentation requirements

- Documentation (4.2)
  - Re-organized paragraphs
  - New section (4.2.1.2) – list of what information should be in the product information file
  - Added security of records— prevent deterioration and loss to list (g)
  - Control of records – Added changes shall be identifiable (4.2.4)

5.0 Management Responsibility

- 5.4.1 Quality Objectives
  - Define quality objectives to ensure that regulatory requirements and requirements for product are met
- 5.6.1 - Management Review
  - Documented planned intervals
  - Predefined intervals,
  - Rationale for interval
- 5.6.3 Review Output
  - Added - changes needed to respond to new or revised regulatory requirements

6.2 Human Resource & 6.3 Infrastructure & 6.4 Work Environment

- Competency required for workers that could affect product safety or performance (6.2.1)
- Document the process for establishing competency
- Former NOTE concept is now part of the Section normative text
- Specified requirement for documenting work environment
  - Equipment used in production that could effect product safety or performance (6.3.2)
  - to control of the work environment (6.4.1.1)
- More detail on health, cleanliness and clothing requirements for controlled areas (6.4.1.3)
- Particular requirements for sterile medical devices (6.4.2)

7.0 Product Realization

- Design & Development added much more text to clarify this complex area of a QMS:
  - Maintenance of planning documents
  - Reviews with decision point documented
  - Added design transfer, traceability (inputs/outputs) and resource competency to planning
  - Usability requirements and ability to verify/validate to inputs
  - Note added for independent reviewer (specialist)

7.2 - Customer Related Processes

- 7.2 - Customer Related Processes
  - Include “customer-related” processes including regulatory requirements
    - Determine user training needed to ensure safe use (7.2.1 d)
    - Ensure user training is identified (7.2.2 d)
  - Identification of user training
  - Note added for post delivery activities and requirements

7.2 - Customer Related Processes

- 7.2.3.2 - Communication
  - Requirements related to communications with regulatory authorities

- 7.3.2 - Design and Development Planning
  - Review decisions at each stage (b)
  - Methods to ensure traceability of design and development outputs (e)
  - Resources needed including competency (f)

7.0 Product Realization

- 7.3.5 - Design and Development Review
  - Requirements of participants
- 7.3.6 - Design and Development Verification
  - Verification plans and detailed requirements
  - Documentation and record requirements
- 7.3.7 - Design and Development Validation
  - Documentation requirements
  - Representative product
  - Interface with other devices

7.0 Product Realization

- 7.3.8 - Design and Development Transfer - NEW
  - Document transfer plans considerations
- 7.3.9 - Control of Design and Development Changes
  - Requirements for the evaluation of the change on
    - Constituent parts and product in process or already delivered
    - Output of risk management, and
    - Product realization processes
  - Record requirements
  - Design file requirements

7.4 Purchasing

- 7.4.1.2 - Supplier approval – NEW
- 7.4.1.3 - Monitoring of supplier - NEW
- 7.4.2 - Purchasing information
  - more details and requirements on what documents shall include (i.e. specifications, change notices, and QMS requirements)
- 7.4.3 - Verification of purchased products
  - activities based on results and proportional to the risk associated with the purchased product
  - Evaluation on purchased product changes

7.5 Production and Service Provisions

- Production and service provisions shall be planned, carried out, monitored and controlled to ensure medical device conformity
  - New list identifying some production controls (7.5.1.1)
  - Specific requirements for cleanliness of product including aspects of cleaning before sterilization
- Documentation requirements for process validation plans including revalidation (7.5.2.1)
- Specific sections on sterile products and sterile barrier systems (7.5.1.3&7.5.2.2)

7.5 Production and Service Provisions

- 7.5.3 - Identification and Traceability
  - If required, a system for assigning unique device identifiers
  - Traceability requirements as defined by regulatory requirements
- 7.5.5 - Preservation of product new details and list

8.2 Monitoring and Measurement

- 8.2.1- Feedback
  - Production & Post-production
  - Active gathering of information as a process
  - Input to risk management with application of statistical methodology
  - Input into product realization processes

8.0 Measurement, analysis, and improvement

- 8.2.1.2 - New Section on Complaint Handling - NEW
  - Procedure required for requirements and responsibilities to include different process requirements such as:
    - Receiving information
    - Investigation
    - Justify when not investigated
    - Adverse event reporting
    - Maintain complaint records
- 8.2.1.2.2 - Reporting to Regulatory Authorities NEW

8.3 Control of nonconforming product

- 8.3.2 - Nonconforming Product
  - Determine the need for investigation
  - Before Delivery and After Delivery requirements
- 8.3.4 - Rework
  - New section for rework with requirement for procedure

8.4 Analysis of Data & 8.5 Improvement

- 8.4 - Analysis of Data
  - Added audits and service reports as input
  - Statistical techniques
- 8.5 - 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)

Thank You!

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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