ISO 13485:201x

What is in the new standard?

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Presentation Slides

- This slide deck is the presentation performed on 2015-09-10.
    - A more detailed slide deck will be posted with expanded information in a number of the slides, and additional references and resources added within the next few weeks.
    - Please check back on the ASQ Baltimore website for the expanded version
    - Alternatively, email efinegan@asqbaltimore.org to get a notice when the slide deck is posted.

ISO 13485

- What is ISO 13485?
    - ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. (ISO)

ISO 13485

- What is ISO 13485?
    - The primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. (ISO)

ISO 13485

- Who is working on ISO 13485?
  - ISO 13485:2003 is being developed by ISO Technical Committee 210 Working Group 1 (ISO TC 210 WG1).
  - Standards work is not as public as the ISO 9001 work that is on-going.

ISO 13485 vs ISO 9001

- Comparisons are performed on the current standards
  - ISO 13485:2003 (unchanged in 12 years).
  - ISO 9001:2008 (about to change).
- New ISO 13485 will NOT align with the new ISO High Level Structure
  - ISO 13485 still mimics the sections 4, 5, 6, 7, 8 of the current ISO 9001 standard.

ISO 13485 vs ISO 9001

- Clause structure (old vs new)

New clauses (Annex SL of ISO 9001:2015)	Existing clauses (ISO 13485:2003/201x)
1 Scope	1 Scope
2 Normative Reference	2 Normative Reference
3 Terms and Definitions	3 Terms and Definitions
4 Context of the Organization	**4 Quality management system**
5 Leadership	**5 Management responsibility**
6 Planning	**6 Resource management**
7 Support	**7 Product realization**
8 Operation	**8 Measurement, analysis and improvement**
9 Performance evaluation	
10 Improvement	

ISO 13485 vs ISO 9001

- Due to regulatory focus, there are more requirements specified within ISO 13485.
    - Rather than leave it to the manufacturer to determine the need for a documented procedure or a record, ISO 13485 details required documents/records.

ISO 13485 vs ISO 9001

- Documentation requirements (ISO 9001):
  - Documents needed by the organization to ensure the effective planning, operation and control of its processes.
  - Procedures that are required are:
    - » Document Control (4.2.3)
    - » Records (4.2.4)
    - » Internal Audits (8.2.2)
    - » Control of Nonconforming Product (8.3)
    - » Corrective Action (8.5.2)
    - » Preventive Action (8.5.3)

ISO 13485 vs ISO 9001

- Documentation requirements (ISO 13485):
  - 31 Documents required are called out specifically.

- Document Control (4.2.3)
- Records (4.2.4)
- Risk Management (7.1)
- Design and development (7.3.1)
- Purchasing process (7.4.1)
- Product identification (7.5.3.1)
- Product return identification from normal production (7.5.3.1)
- Product traceability (7.5.3.2)
- Product Conformity preservation (7.5.5)
- Control of monitoring and measuring equipment (7.6)
- Feedback system (including customer complaint) (8.2.1)
- Internal Audits (8.2.2)
- Monitoring and measurement of product (8.2.4.1)
- Control of Nonconforming Product (8.3)
- Analysis of data (8.4)
- Advisory notice (8.5.1)
- Vigilance system (8.5.1)
- Corrective Action (8.5.2)
- Preventive Action (8.5.3)
- Maintenance Activities (6.3)
- Health, cleanliness and clothing (6.4)
- Work environment conditions, monitoring and control (6.4)
- Control of contaminated products (6.4)
- Control of production and service provision (7.5.1.1)
- Product cleanliness (7.5.1.2.1)
- Installation activities (7.5.1.2.2)
- Servicing activities (7.5.1.2.3)
- Validation of the application of the computer S/W (7.5.2.1)
- Sterilization process validation (7.5.2.2)
- Control of limited shelf life products (7.5.5)
- Post-production phase experience (8.2.1)

ISO 13485 vs ISO 9001

- Record requirements:
  - Records determined by the organization to be necessary to ensure effective planning, operation and control of processes.
  - ISO 9001 requires specifically 20 records if created in the course of producing product.
  - ISO 13485 requires specifically 37 records if created in the course of producing product.

ISO 13485 vs ISO 9001

- Most differences between the two standards are clarifications due to documentation requirements:
  - The organization shall **identify**… vs
    The organization shall determine …
  - … where applicable …
  - … defined **and documented**…

ISO 13485 vs ISO 9001

- Other than minor clarifications of text and regulatory-specific changes, the following items are different:
  - Maintaining effectiveness of the system versus Continual improvement
  - Replace Customer Satisfaction with Regulatory requirements
  - Work environment requirements are expanded
  - Verification, validation, design output and design transfer more detailed
  - Risk management is addressed
  - Complaint management is addressed

ISO 13485:2016 – What's New?

- Many additions.
- Some new requirements.
- Some expansion / clarification.
- Increased clarification of interrelationship between clauses and requirements.

ISO 13485:2016 – What's New?

- Increase in Regulatory requirements
  - Makes sense, standard revolves around a regulatory framework.
  - "Regulatory"/"regulations" are mentioned 16 times in ISO 13485:2003.
  - Terms are mentioned at least 80 times in latest draft.

ISO 13485:2016 – What's New?

- Expansion of Scope
    - Moving from Medical Device manufacturers to organizations involved in any aspect of the product life-cycle (from design through distribution and support)

ISO 13485:2016 – What's New?

Note that the content of the changes in the clauses throughout the remainder of the presentation are based on documents that are still being reviewed and updated by TC210/WG1, so these requirements may be changed prior to the publication of the (proposed) ISO 13485:2016 standard.

General Requirements – Changes

- Clause 4.1 General Requirements
  - Role(s) undertaken by organization under regulatory requirements are now required to be documented
    - In addition to "The organization shall ensure the availability of resources…"
  - Calls out using a risk based approach for developing QMS processes.
    - Anything that affects the quality system needs to be viewed from that risk perspective (and documented)

General Requirements – Changes

- Clause 4.1 General Requirements
  - Records to meet regulatory requirements specified
    - more detailed than existing
  - Control of outsourced processes based on risk and ability.
    - beyond “Control of such outsourced processes shall be identified within the quality management system ”

General Requirements – Changes

- Clause 4.1 General Requirements
  - Requirement to validate the computer software used for QMS prior to initial use and after changes
    - Expansion of 7.5.2 (validation of the application of computer software)
    - Called out specifically by the FDA in 21 CFR 820.70(i);
    - Software used for, but not limited to, product design, testing, production, labeling, distribution, inventory control, data management, complaint handling, equipment calibration and maintenance, and corrective and preventive action.
    - If software involves or affects the quality system, you need to validate it.

General Requirements – Changes

- Clause 4.2 Documentation Requirements
  - Detailed list of documented items that can be included in a product or technical file to meet regulatory requirements
    - Useful checklist, but since each “technical file” is different for each market, will never be able to be comprehensive
    - Existing standard states “any other documentation specified by national or regional regulations”
    - May have been more useful in an Annex, easily updated in future, but that is not how the committee decided to go
    - Good example of the new standard’s style to be more prescriptive

General Requirements – Changes

- Record Requirements
    - Unfortunately doesn't specifically address record retention, so regulatory / quality / documentation personnel will still need to make themselves aware of the various international retention requirements.

Management Responsibility – Changes

- General Requirements
  - Regulatory requirements are addressed throughout the standard, rather than trickle down through Sections 4 and 5

Management Responsibility – Changes

- Clause 5.4.2 QMS planning
  - A note is to be added clarifying what quality systems planning normally includes
    - quality objectives should be consistent with be quality policy,
    - action items to accomplish objectives, monitor progress, and revisions
  - There has been some debate as to whether an actual “plan document” is required
    - FDA requires “establish a Quality plan” versus “ensure the planning of the quality management system”

Management Responsibility – Changes

- Clause 5.5.1 Responsibility and authority
  - Responsibilities and authorities for regulatory requirements are being specified.
    - how specific individuals are nominated as responsible for activities having to do with monitoring of the product, and also for post-production activities
    - competency of regulatory and quality personnel to be defined

Management Responsibility – Changes

- Clause 5.5.2 Management representative
  - Focus on documentation of the quality management system and the removal of customer requirements from bullet c)
    - Regulatory bodies are concerned with safe and effective devices, not customer requirements
    - "promotion of awareness of **regulatory *and customer* requirements** " to "promotion of awareness of **regulatory requirements** "

Management Responsibility – Changes

- Clause 5.6 Management review
  - Organization to record rationale for frequency for management review
    - Justification required moving forward
  - Improvement clarified for new or revised regulatory requirements
    - Management review outputs changed from "improvement needed to **maintain the effectiveness** of the quality management system and its processes" to "improvement needed to **maintain the suitability and adequacy** of the quality management system and its processes"

Resource Management– Changes

- Clause 6.2.1 Human resources – General
  - Personnel requirements defined at all levels across product, process, regulatory requirements and QMS
    - Personnel who are involved with fulfilling process requirements, regulatory requirements, and quality system compliance
    - Will require the organization to define what education, skills, and training those individuals need to have to perform each role
    - More prescriptive than “Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience”

Resource Management– Changes

- Clause 6.2.2 Competence, awareness and training
  - New standard requires personnel to maintain competency
    - detailed requirements and risk evaluation of training effectiveness to be provided
    - effectiveness of the training is to be commensurate with the risks associated with the work that an individual is performing
    - controversial, as still relatively subjective

Resource Management– Changes

- Clause 6.3 Infrastructure
  - Documented procedures for production and any controlled work environment are required.
  - Maintenance requirements to be implemented
    - how those activities are being performed,
    - planned intervals for maintenance
    - how records associated with how those activities are being maintained
  - Information systems are now included (exist in ISO 9001, but not in current ISO 13485).

Resource Management– Changes

- Clause 6.4 Work environment
  - Significant additional detail to clarify requirements to work environment
    - will help to reduce auditor subjectivity
    - conditions to be considered such as noise, temperature, humidity, lighting, or weather
    - areas of infrastructure such as inspection areas, storage areas, and distribution areas, and any other area involved with product manufacture
  - New section added (6.4.2) that will address particular requirements for sterile medical devices (special work environment case)

Product Realization – Changes

- Clause 7.1 Planning of product realization
  - Greater focus on risk management
  - Requires planning and risk management incorporation for verification, validation, revalidation, monitoring, measurement, inspection, test activities, handling, storage, and traceability
  - Note added for organizations to look at IEC/ISO 62304 (software lifecycle processes)

Product Realization – Changes

- Clause 7.2 Customer-related processes
  - User training to ensure that the product will be used in a safe and effective manner now required
  - Organizations must protect confidential health information from their customers
    - however received (customer requirements, customer servicing, post-market surveillance)

Product Realization – Changes

- New clause 7.2.3.2 Communication with regulatory authorities
  - Under current 7.2.3 Customer communication
  - As appropriate, the organization shall communicate with regulatory authorities in accordance with planned arrangements.
    - product information, regulatory inquiries, complaints, and advisory notices
    - documented procedure will be required

Product Realization – Changes

- Clause 7.3.1 – Design and development planning
  - Previous version required planning, now organizations will be required to document planning and results
  - Design traceability from inputs through outputs required

Product Realization – Changes

- Clauses 7.3.5 Design and development verification
  7.3.6 Design and development validation
  - More emphasis on planning design and development verification and validation activities
    - documented methods, acceptance criteria and sample sizes that you will utilize, along with the rationale behind selecting them
  - Validation on production units or (documented) equivalents
    - Added to match FDA requirement 21 CFR 820(g) “Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents”

Product Realization – Changes

- Clause 7.3.8 Design and development transfer
  - New clause requiring a documented plan if you are going to transfer your design to another facility or an outsourcing partner
    - ensure that your design and development outputs are suitable for production
  - Aspects the organization should consider
    - supplier quality and capability, manufacturing personnel capability and training, manufacturing process and process validation, materials, manufacturing tools and method, manufacturing environment, installation, and service.
  - New emphasis on supplier control for design transfer

Product Realization – Changes

- Clause 7.3.10 Design and development records
  - New clause that defines the records that are to be clearly identified and maintained in the design and development file.
    - more prescriptive as to the types of documentation (align with FDA/EU)
    - Examples include (as appropriate):
      - » Results of preclinical tests, biocompatibility studies, clinical evaluation
      - » Postmarket clinical follow-up plan and evaluation report
      - » Electrical safety and electromagnetic compatibility
      - » Software verification and validation

Product Realization – Changes

- Clause 7.4 Purchasing
  - Emphasis on risk analysis.
  - Clause 7.4.1 broken out and documentation requirements clarified
    - 7.4.1.1 Supplier approval
    - 7.4.1.2 Monitoring of suppliers
    - 7.4.1.3 Supplier documentation
  - Criteria for selection, evaluation and re-evaluation consistent with risk, along with evidence of review

Product Realization – Changes

- Clause 7.4.2 Purchasing information
  - Purchasing information to include, where possible, suppliers agreement to notify the organization of any changes
    - Align with FDA 21 CFR 820.50(b) “Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device. ”

Product Realization – Changes

- Clause 7.4.3 Verification of purchased product
  - Clause updated to add that the extent of verification must be commensurate with product risks and the result of evaluation and re-evaluation are to be documented

Product Realization – Changes

- Clause 7.5.2 Validation of processes for production and service provision
  - Validate processes for production and service provision where output cannot be or is not verified
  - Required to document validation plans and procedures, including procedures for validation of sterilization and packaging processes

Product Realization – Changes

- Clause 7.5.3 Identification and traceability
  - Unique device identification (UDI) where required by national or regional regulations will need to be performed
  - Requirement added for procedures for separation of returned products from conforming products

Product Realization – Changes

- Clause 7.5.4 Customer Property
    - Customer property can include intellectual property or confidential health information, based on the regulatory requirements of the market the device is sold into.

Product Realization – Changes

- Clause 7.5.5 Preservation of product
  - Organization needs to evaluate packaging and shipping containers to ensure they are designed to protect the device from contamination and
    - during the processing, handling, storage, and distribution
  - A note is added that sterile barrier systems of sterile medical devices are a constituent part of a medical device.
  - A new clause (7.5.5.1) Particular requirements for sterile medical devices has been added.

Measurement/Analysis/Improvement – Changes

- Clause 8.2 Monitoring and measurement
  - Documented processes for gathering data from production and post-production activities are now required.
  - Trending data based on this review will be required to be reviewed, analyzed and determine if applicable to enter CAPA process.
  - This data is now required to become an input to the organization's risk management program.

Measurement/Analysis/Improvement – Changes

- Clause 8.2.1.2.1 Complaint Handling
  - A new clause that requires procedures for complaint handling, investigation, regulatory notification and how this information relates to other processes within the QMS
    - Aligns with the FDA 21 CFR 820.198, Complaint files

Measurement/Analysis/Improvement – Changes

- Clause 8.2.1.2.2 Reporting
  - A new clause that requires procedures and records for reporting to regulatory authorities
    - documents explicitly what has been assumed under 4.2.1

Measurement/Analysis/Improvement – Changes

- Clause 8.2.4 - Monitoring and measurement of product
  - This section now includes a note that says, "Records shall identify the test equipment used to perform measurement activities and the person(s) authorizing release of product."
    - This applies traceability to the test equipment used during release

Measurement/Analysis/Improvement – Changes

- Clause 8.3 Control of nonconforming product
  - Non-conforming product shall be considered for corrective action.
  - Records associated with nonconforming product management are required.
  - Section 8.3 has been broken down in several different subsections
    - 8.3.1 – Control of nonconforming product (general)
    - 8.3.2 – Actions in response to nonconforming product before delivery
    - 8.3.3 – Actions in response to nonconforming product after delivery
    - 8.3.4 – Rework

Measurement/Analysis/Improvement – Changes

- Clause 8.5.2 Corrective action
  - Additional requirement to plan corrective actions commensurate with risk (device safety and performance)

Measurement/Analysis/Improvement – Changes

- Clause 8.5.3 Preventive action
  - Preventive actions are to be reviewed in a timely manner.
  - When addressing preventive actions, the impact to the QMS and the organization's regulatory requirements
    - ISO 13485 is still going to call out preventive action, rather than incorporating it as risk-based thinking throughout the standard (as done in ISO 9001:2015)
    - One of the reasons is that the FDA QSR specifically requires preventive action as part of the organization's CAPA process

ISO 13485:2016 Changes

- Although a significant set of changes, most of them are clarifications of the existing standard (against existing regulations)
    - Regulatory requirements.
    - Risk Management (not simply risk-based thinking).
    - Verification, Validation and Transfer activities defined.
    - Improved supplier control.

ISO 13485:2016 Changes

- For manufacturers who have medical devices in international markets, these should not be significant changes
- Audits will be clearer for both auditor and auditee, with less “interpretation” of the deliverables (especially for regulatory requirements).
- Suppliers of medical devices will now have a standard that is clearer for what is expected of them.
    - Not every supplier will be required to follow every requirement.

Standards News

- ISO 9001
  - ISO 9001:2015 projected to be release this month.
- ISO 14001
  - ISO 14001:2015 projected to be released soon.
- ISO 13485:201x FDIS
  - Scheduled to be released after the August 2015 meeting, but information is showing that one more meeting may be necessary due to the number of comments to be addressed.

Questions ?

Thank you

ISO 13485:2003 vs EN ISO 13485:2012

- EN ISO 13485:2012
  - Not a “new version” of ISO 13485
  - European harmonized standard
  - Adds interpretative Annexes at the end of the standard to allow mapping to the Medical Devices Directive and the European interpretation of how the standard is to be used
  - Only applies to manufacturers who wish to place medical devices on the EU market