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What is a Quality Management System?

- People
- Equipment
- Processes
- Components/Materials
- Documentation
- Products/Service
ISO13485:2016

- “Voluntary” standard—sort of
- Generic in nature due to wide audience
- This version was published in March 2016, there is a 3 year transition period for organizations registered to 2008 version
- Applicable to finished medical device manufacturers, component manufacturers, and service providers
Any Similarities Between ISO 13485 and ISO 9001? Yes

- Emphasis on management support—the buck stops at the top
- Define the quality management system
- Need for documentation
- Risk—more on that in a minute
- Monitor and measurement of processes
- Development of a quality policy and quality objectives
- Employees must be trained
- Processes: CAPA, internal audits, calibration (not all inclusive)
Differences

- **Industries**
  - ISO 9001 is not industry-specific
  - ISO 13485 is specific to the medical device industry
    - There are specific requirements for some types of medical devices (sterile or implantable)
    - Requirements for devices requiring installation
    - Requirements for devices requiring servicing
Differences

- Management Representative
  - No longer required by ISO 9001

- Quality Manual
  - No longer required by ISO 9001
Differences

- Format of the Standards
  - ISO 9001 has 10 sections
  - ISO 13485 has 8 sections
- Section Headings
Differences

- **ISO 9001 Terminology and Requirements**
  - Interested Parties
  - External Providers
  - Documented Information
  - Internal and External Issues
  - Opportunities (risk can be positive)
  - Eliminated “preventive action”
Differences

• ISO 13485 Terminology and Requirements
  • Medical Device File
  • Risk Management (reference to ISO 14971—Risk Management standard for medical devices)
    • Definition of “risk” differs as well as context. In this standard, risk cannot be positive
    • Specific risk management records must be maintained
  • Sterile medical devices
  • Implantable medical devices
  • Complaint—related to product
In A Nutshell...

- ISO 9001—focus on continual improvement and customer satisfaction, consideration of business needs, customer needs
- ISO 13485—QMS “shall meet customer and applicable regulatory requirements for safety and performance”
- Regulatory agencies don’t care about customer satisfaction—they care that medical devices are safe and effective
- ISO 13485 is more stringent than ISO 9001
Regardless of the standard, avoid this.
A Closer Look at ISO 13485
General Comments

- Again, this is a voluntary standard, it is not a regulation
- Not a lot of significant changes from 2003 version
- Clarifying text—removed ambiguity
- Stronger linkage to regulatory requirements
- Requirements are similar to FDA Quality System Regulation—not identical
- Note: If a company does not place a medical device in commercial distribution, many regulatory requirements do not apply. For example, a machine shop who provides a plastic component for a ventilator which their customer places on the market.
Section 4: Quality Management System

- Determine and implement processes, establish controls so that processes are effective
- Monitor, measure, and analyze processes
- Risk-based approach
- Changes to processes must be evaluated for their impact on QMS and the medical devices
- Software used in the QMS must be validated for their application—risk based determination
Section 4: Documentation Requirements

- Quality Manual
- Medical Device File
- Control of Documents
  - Unlike ISO 9001, there are numerous required procedures.
- Control of Records
  - Protect confidential patient information
  - Retention times can be driven by regulatory requirements or the lifetime of the device
Section 4: Documentation Requirements

Avoid This:
Section 5: Management Responsibility

- Top management is responsible for the implementation and effectiveness of the QMS—activities can be delegated, responsibility for the QMS cannot
- Appoint a management representative who reports to top management
- Conduct management reviews at planned intervals (this is a comprehensive review of the QMS) Inputs and outputs are prescriptive
- Quality planning—maintain the effectiveness of the QMS in spite of changes
Management engagement/support is key!
Section 6: Resource Management

- Provide appropriate resources
- Employee competent to perform their job functions
- Provide and document training
- Evaluate the effectiveness of training

- Appropriate infrastructure to perform QMS activities
- Document work environment controls necessary to achieve product requirements
- Monitor and control environment when it can impact product quality
Section 6: Resource Management

• Control contamination
  • Sterile devices—control particulate, maintain cleanliness during packaging and labeling activities
  • Sterile devices are typically manufactured in a cleanroom or otherwise environmentally controlled area
  • Consider ESD controls
Section 7: Product Realization

- Risk management during product realization—cradle to grave
- Production planning
  - Required documents/records
  - Validation activities
- Customer related requirements
  - What are the customer needs?
  - Can the organization meet these needs?
  - Identify user training needs
Section 7: Product Realization

- Design and development activities:
  - Control the design activities
  - Define Responsibilities and authorities
  - Beefed up design inputs, must be able to verify
    - Consideration of human factors
  - Beefed up requirements for verification and validation—statistically valid sample sizes
  - Ensure design outputs are traceable to design inputs
  - Satisfy regulatory requirements
  - Maintain records (design file)
Section 7: Product Realization

- Control suppliers
  - Evaluate and approve for use—responsible for outsourced processes
  - Controls over supplier based on risk of what they provide
  - Monitor performance
  - Ensure adequacy of specified requirements (supplier agreement, purchase order, etc)
  - Notification of changes by supplier so impact can be evaluated

- Control of manufacturing and servicing requirements
  - Activities shall be planned, carried out, monitored and controlled to ensure product meets specifications
  - Records maintained, traceability identified
  - Requirements for sterile devices
  - Requirement for specific record for manufacturing history
Section 7: Product Realization

- Installation and Servicing Activities
- Validation of sterile devices and sterile barrier systems
Section 7: Product Realization

- Validation of processes whose output cannot be fully verified.
  - Includes computer software—level of validation dependent upon risk
  - Requirements for sterilization validation

- Product Identification, product status, and traceability requirements
- Control customer property, this includes IP
- Controls for the preservation of product
- Control of measuring and test equipment
Section 8: Measurement, Analysis, and Improvement

- Establish feedback process
  - Production and post-production
  - Feed info into risk management process

- Complaint handling process—complaints may need to be reported to regulatory agencies
- Conduct internal audits, corrective actions timely
- Monitor and measure processes
- Monitor and measurement of product (QC activities)
- Recall requirements—may need to be reported to regulatory agencies
Section 8: Measurement, Analysis, and Improvement

- Nonconforming Material
  - Specific requirements for rework, impact on finished device
  - Justification for Use As Is
Section 8: Measurement, Analysis, and Improvement

- Analysis of data to determine that the QMS is functioning effectively
  - Defined inputs: product conformity, supplier data, internal audits, service reports, etc.

- Implement changes (improvements) so that the QMS maintains effectiveness
- Corrective/preventive actions to address QMS issues (can be processes or products)
Closing Thoughts/Questions?

• ISO 13485 takes a risk-based approach to the controls needed within your QMS
• Generic but prescriptive
• Focus is different than ISO 9001
• Hard requirement for procedures throughout the standard
• Bottom line—meet regulatory requirements
Thanks for your time!
How to Reach Me

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