ISO 13485:2016

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What is a QUALITY SYSTEM?

- A Quality System is a set of documented policies and related processes and procedures that describe how your organization performs specific tasks ….
  - Examples:
    - Quality Management Systems for Medical Devices: ISO 13485:2016
    - Quality Management System: ISO 9001:2015
    - Environmental Management System: ISO 14001:2015
    - QMS for Automotive: ISO/TS 16949:2009
    - ISO 17025:2005 Testing and Calibration Laboratories

ISO 13485:2016

Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

- ISO 13485 outlines QMS requirements for the lifecycle of medical devices
- Used globally by many Regulatory Authorities as the requirement for GMPs for medical device manufacturers
  - Canada, Japan, S. Korea, EU, Australia, etc.
- Foundation of the Medical Device Single Audit Program (MDSAP) audit model

Why Require a QMS?

- Quality system requirements are the base requirement for medical device life cycle. *Not ONLY Manufacturing*

- Quality systems assure that products are designed, manufactured and provided consistently by focusing on safety, performance and regulatory requirements.

- Quality system requirements are designed with flexibility to accommodate the diversity and complexity of medical devices, manufacturing processes, supply chains, etc.

US FDA AND ISO 13485

FDA's Intention

FDA intends to harmonize and modernize the Quality System regulation for medical devices. The revisions will supplant the existing requirements with the specifications of an international consensus standard for medical device manufacture, ISO 13485:2016. The revisions are intended to reduce compliance and recordkeeping burdens on device manufacturers by harmonizing domestic and international requirements. The revisions will also modernize the regulation.

Rationale for Use of ISO 13485: 2016

- Many similarities between the requirements of the QS regulation (21 CFR 820) and the clauses of ISO 13485:2016
  - Differences between the QS regulation and standard are minor
- ISO 13485:2016 is already used in many countries to meet jurisdictional QMS requirements
- Moving to ISO 13485 allows for:
  - More opportunities to work closer with regulatory authorities around the globe and facilitate regulatory convergence on QMS.
  - Opportunities for medical device manufacturers to have a more globally harmonized QMS system.

Questions?