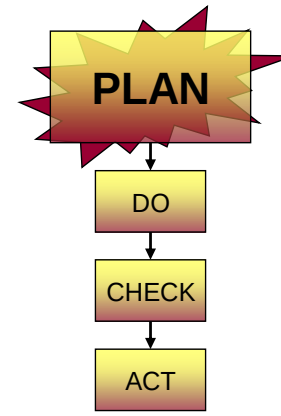
ISO 13485 Internal Auditor

PLAN: Determine the Requirements and Prepare for the Audit

"What Should Be"



Determine the Requirements

What Is ISO 13485:2016?

A set of quality management system requirements used in the medical device industry to *demonstrate* an organization's ability to *consistently* provide safe and effective product that meets customer and regulatory requirements.

It's intent is to facilitate global alignment of appropriate regulatory requirements for quality management systems applicable to organizations involved in one or more stages of the life-cycle of a medical device.

Reference: *ISO 13485:2016 Introduction, 0.4 Relationship with ISO 9001*

The Standard can be summarized in this common-sense approach:

- Develop a good understanding of your QMS processes
- Document QMS processes based on current best practices
- Deploy documented best practices throughout the organization
- Establish and deploy measurable objectives
- Ensure best practices are followed (Internal Audits)
- Identify opportunities to correct and prevent systemic problems from occurring or reoccurring
- Ensure Changes are Controlled
- Establish a strong foundation for maintaining effectiveness of your systems and processes

What Is ISO 13485:2016?

Background

- Medical QMS model can be used by an organization for the design and development, production, storage and distribution, installation and/or servicing of medical devices, and the design, development and provision of associated activities.
- 1st edition 1996, as companion to ISO 9001/02:1994
- 2nd edition 2003, as an unique individual Standard, aligned with ISO 9001:2000
- 3rd edition 2016 to align with ISO 9001:2008 and maintain consistency with latest cGMP/regulatory requirements.
- Can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements.
- Internationally recognized and accepted
- Uses a process approach

Full title: *ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes*

3rd edition 2016–03–01, Reference number ISO 13485:2016(E)

The associated regulation in the United States is *FDA Title 21 CFR Part 820: Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*. The term "cGMP" gets used as well, and stands for Current Good Manufacturing Processes.

Other helpful documents:

- *ISO 13485:2016 - Medical devices — A Practical Guide (2017 Ed. 1),* replaces the former *ISO-TR 14969:2004 Medical devices — Quality management systems — Guidance on the application of ISO 13485:2003,* which was withdrawn.
- *ISO 14971:2007 Medical devices — Application of risk management to medical devices*

Guidance: Normative Reference

ISO 9000:2015 is a normative reference for definitions.

Additional Definitions in ISO 13485:2016:

1. Advisory Notice
2. Authorized Representative
3. Clinical Evaluation
4. Complaint
5. Distributor
6. Implantable Medical Device
7. Importer
8. Labelling
9. Life-Cycle
10. Manufacturer
11. Medical Device
12. Medical Device Family
13. Performance Evaluation
14. Post-Market Surveillance
15. Product
16. Purchased Product
17. Risk
18. Risk Management
19. Sterile Barrier System
20. Sterile Medical Device

Definitions increased from 8 in the 2003 version to 20 in the 2016 revision.

Product is defined as the "result of a process." Generic categories are given as services, software, hardware and processed materials along with the following text: *"Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element."-3.15 ISO 13485:2016*. Additional examples and Notes are also provided.

The definition of "implantable medical device" now includes active implantable medical devices.

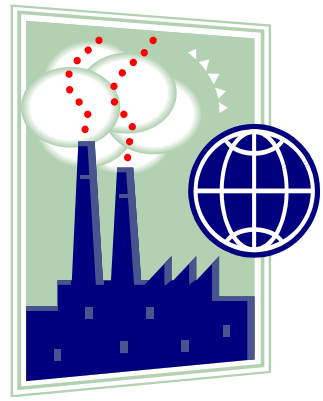
Guidance: “Appropriate”

- Always assumed to be appropriate
- When used in the Standard, exclusion must be justified
- *Meaning* — if it is necessary for:
  - product to meet requirements;
  - compliance with applicable regulatory requirements;
  - the organization to carry out corrective action;
  - the organization to manage risks.

ISO 13485:2016, *Introduction*, section *0.2 Clarification of concepts* was modified to add the criteria for regulatory requirements and risk management.

This section 0.2 also clarifies meanings regarding the use of the following terms: risk, documented, product, regulatory requirement, shall, should, may and can.

ISO 9001…The Commercial Model



CUSTOMER SATISFACTION
&
CONTINUAL IMPROVEMENT

ISO 13485…The Medical Regulatory Model

Safety and Efficacy

How Does It Differ from ISO 9001:2015?

- **Product Specific:** focus on maintaining the effectiveness of the QMS to consistently produce safe and effective products.
- **Regulatory**: emphasis on complying with regulatory requirements, and as such, customer satisfaction and continual improvement are not considered appropriate to include.
- **Documented**: Much greater emphasis on documented procedures and with detailed records requirements.
- Adds medical device-specific requirements in relation to:
  - Medical device file requirement
  - Risk Management – follows both ISO 14971 and ISO 31000
  - Controls for work environment and production processes related to contamination, cleanliness, sterilization and sterile barrier systems.
  - Nonconforming Material (rework of product)
  - Identification of product status, traceability, labeling and packaging
  - Installation activities
  - Design Control, stricter on documentation, records and validation
  - Feedback processes (as opposed to customer satisfaction)

ISO 13485:2016 contains 51 places where a specific documented procedure (including policies, objectives, plans, system, etc.) is required (some of these are "if applicable").

ISO 9001:2015 requires specific documents in just three places: scope of the QMS, quality policy and quality objectives.

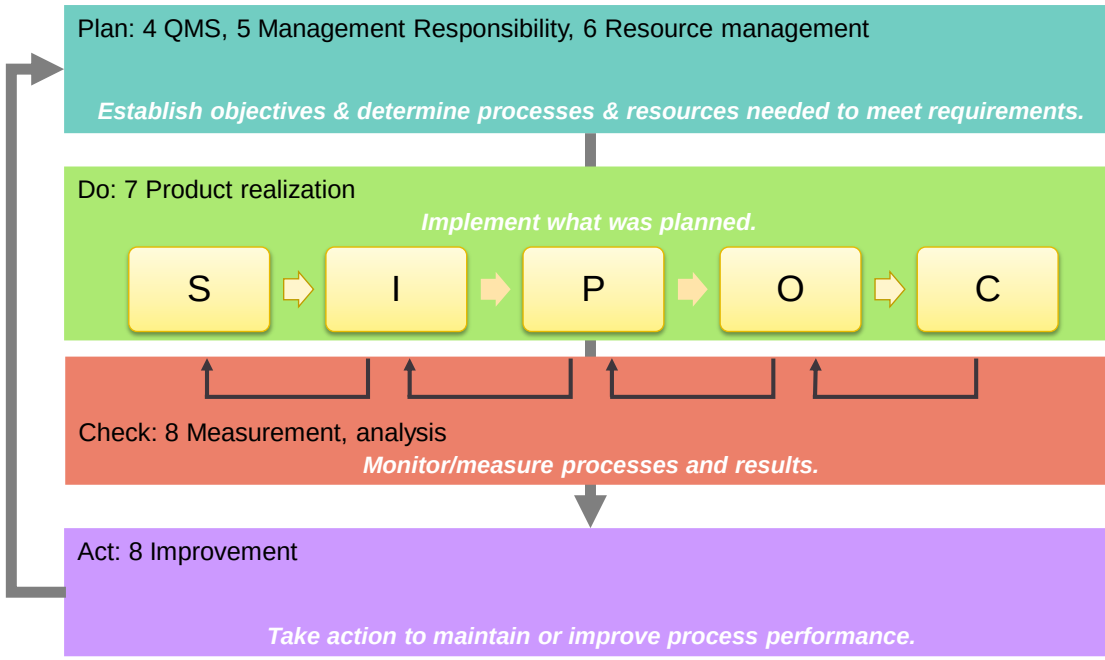
Both Standards contain many requirements for records.

ISO 13485:2016 did not adopt the new high-level Management System Structure for titles and numbers used in ISO 9001:2015; it does provide the correspondence between the current versions of ISO 13485 and ISO 9001 in Annex B.

ISO 14971 addresses risk related to product/patient safety (a regulatory compliance perspective).

ISO 31000 addresses risk to meeting organizational objectives (a business perspective).

PDCA in ISO 13485



The Notes in this section will overview the changes to the Standard for each of the sections of the ISO 13485:2016 Standard.

The Standard has been modified throughout to refer to "applicable" regulatory requirements. The clarification in the *Introduction, section 0.2* states:
"When the term 'regulatory requirements' is used, it encompasses requirements contained in any law applicable to the user of this International Standard (e.g. statutes, regulations, ordinances or directives). The application of the term 'regulatory requirements' is limited to requirements for the quality management system and the safety or performance of the medical device."

8.2.4 Internal Audit: "Must Do" Requirements

- Conduct audits at planned intervals
- Determine if QMS:
  - Conforms to:
    - Planned and documented arrangements (yours)
    - Requirements of the Standard
    - Requirements set by the organization (you)
    - Applicable regulatory requirements
  - Is effectively implemented & maintained
- Plan audits considering:
  - Status & importance of processes and areas
  - Prior results
- Define and record audit criteria, scope, interval and methods
- Audit records to include processes and areas audited and the conclusions

- 8.2.4 modifies wording to clarify that "arrangements" are those that are documented (as is seen in other parts of the Standard), along with some other wording modifications. More detail is given on what should be contained in the audit records, with an emphasis on providing evidence of both conformance and nonconformance.

8.2.4 Internal Audit: “Must Do” Requirements

- Ensure objectivity and impartiality in auditor selection and conduct
- Cannot audit own work
- Define responsibilities in documented procedure
  - Planning and conducting audits
  - Reporting results
  - Keeping records of audit results
- Management shall ensure necessary corrections and corrective actions are taken “without undue delay” to eliminate nonconformities and their cause(s)
- Must follow up to verify actions taken and reporting of results
- Audit results will be one input to management review (sub-clause 5.6.2)