



ISO 13485:2003 Training

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ISO 13485:2003 – QMS Requirements Training for Medical Devices



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The ISO 13485:2003 module is ideal for those organizations looking to achieve certification to the ISO 13485 standard and/or meet global quality management system requirements for medical devices (e.g. FDA's QSR, Canada's Medical Devices Regulation, Annex II of the European Union's Medical Device Directive).


Management commitment is essential to implementing an effective quality management system. As a result, it is critical that an organization's management team show its commitment to quality through its actions as well as its words. Management must be willing to provide the resources needed to implement and maintain the system as well as be knowledgeable of the requirements that pertain to their area(s) of responsibility and authority.

The ISO 13485:2003 Training module was designed to provide participants with a comprehensive understanding of the ISO 13485 quality management system requirements for medical devices. The requirements are presented in a simple and easy to understand manner with supplemental guidance and practical examples provided through Instructor Notes pages.

Each module includes a CD ROM of the Adobe Acrobat® formatted presentation, an Instructor's Manual, a comprehension exam and a 3-per-page master presentation handout. Unlimited copies of the comprehension exam and 3-per-page presentation handout may be made, however the CD-ROM and Instructor's Manual may not be reproduced or copied. Completion of the comprehension exam provides a record of training and measure of effectiveness.

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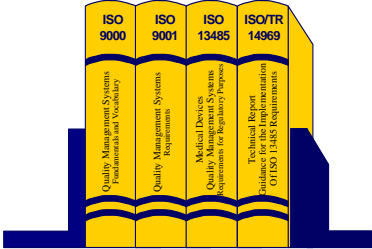
Course Objectives

- ✓ To review the ISO QMS series of standards
- ✓ To provide background on the ISO 13485 standard
- ✓ To discuss the eight quality management principles from which ISO 13485 is founded
- ✓ To review the process approach to quality management
- ✓ To identify the benefits of applying the process approach
- ✓ To discuss the differences between ISO 13485 and ISO 9001
- ✓ To discuss the meaning of "exclusion" and "non-applicable"
- ✓ To review key terms and definitions
- ✓ To review the ISO 13485:2003 requirements

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Related Standards




ISO 9000 Quality Management Systems Fundamentals and Vocabulary
ISO 9001 Quality Management Systems Requirements
ISO 13485 Medical Devices Quality Management Systems Requirements for Regulatory Purposes
ISO/TR 14969 Technical Report Guidance for the Implementation of ISO 13485 Requirements

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Introduction

- ISO 13485 is based on quality management system requirements currently contained in medical device regulations around the world as well as those appropriate requirements contained in ISO 9001:2000.
- ISO 13485 provides a good base model for compliance with the EU CE Marking Medical Device Directives (Annex II, V, VI) and Health Canada CMDCAS (class II, III, & IV devices) requirements.
- ISO 13485 is considered to be compatible with the FDA QSR codified under Title 21 CFR Part 820.



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4 Quality Management System

4.2 Documentation Requirements

4.2.2 Quality manual

Establish and maintain a quality manual that includes:

- QMS scope
- Justification for exclusions or non-applicability
- Documented procedures established or reference to them
- Process interaction description
- Outline of the QMS documentation structure

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Each presentation page has “train-the-trainer” notes, as needed. (See Figure 1 & 2) The notes page clarifies and/or emphasizes the slide contents and may provide an example of how a particular requirement might be satisfied. The notes are included in the Instructor’s Manual and provide a unique and invaluable training aid.

4.2 Documentation Requirements

4.2.2 Quality Manual

Notes Pages

- 1 The scope of the quality management system needs to be defined in the quality manual. The scope typically includes reference to this ISO standard, other applicable requirements (industry, statutory, regulatory, etc.) and field of application.
- 2 Any justification for “exclusions” shall be defined and justified. Exclusions are limited to the requirements of clause 7 of this standard. Any requirements that are “not applicable” shall also be identified.
- 3 The quality manual shall document the procedures the organization has established for the quality management system, or refer to these documented procedures. If these procedures are not listed or identified directly in the manual, a supporting document/procedure index is often referenced or included as an appendix.
- 4 You must describe the interaction between the processes of the quality management system. For example, what are the key processes? How do they relate to each other – i.e. sequence or linkage of processes? What are the inputs and outputs of each?
- 5 The quality manual needs to outline the documentation structure for your quality management system. For example, the quality manual is typically the top level document. It then references lower level procedures which may reference other documentation such as quality plans, work instructions, etc.

Figure 1 ↑

Figure 2 ↓



5 Management Responsibility

5.2 Customer focus

Ensure customer needs and expectations are determined and met.

Goal = a happy and satisfied customer



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5.2 Customer Focus

Notes Pages

Customer focus is a new requirement and reinforces the need for top management to clearly understand and define customer requirements.

- It is important to determine customer needs and expectations. To do this you need to ask:
 - Who are your customers and potential customers?
 - What are their needs and expectations? e.g. conformance, dependability, availability, delivery, price, life cycle, etc.
 - Who are your competitors?
 - What is the customer’s perception of quality?

There are various sources of data which can be tapped to uncover the answers to these questions. Sources include market research studies, literature reviews, customer surveys/questionnaires, clinical studies, market evaluations, customer feedback/complaints, returns, service/repair reports, etc.

- Once this is done, these needs and expectations need to be translated or converted into requirements and fed back into the quality management system. The requirements can then be addressed and implemented (met).

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