

QMS Requirements Training

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Manufacturer's of medical devices are often faced with meeting multiple standards or regulations for regulatory compliance. However, existing training products often fall short and only address FDA Quality System Regulation requirements or ISO 13485 requirements. QARACC's "QMS Requirements Training" module was designed to meet both needs by offering organizations a training program for employees that addresses both FDA QSR and ISO 13485 quality management system requirements.

Management commitment is essential to implementing an effective quality management system. As a result, it is critical that management provide the resources needed to implement and maintain the system as well as ensure that personnel not only understand their particular job function but also the quality management system requirements that pertain to their area(s) of responsibility and authority. Education and training is key to accomplishing this objective.

The QMS Requirements Training module was designed to provide employees with a basic understanding of the quality management system requirements that pertain to the design, manufacture and distribution of medical devices. It is ideal for employee orientation or annual refresher training as it provides employees with an overview of the requirements in clear, easy to understand language. A sample of some of the training slides is provided below.

Each module includes a CD-ROM of the Adobe Acrobat® formatted presentation, an Instructor's Training Manual, a comprehension exam, and a 3-per-page master presentation participant handout. The Instructor's Manual includes presentation notes, as needed, to further clarify and/or explain the slide contents. The notes may also include an example of how a particular requirement may be satisfied. This document provides a unique and invaluable training aid. Further, completion of the comprehension exam provides organizations with a record of training and measure of effectiveness. Unlimited copies of the comprehension exam and 3-per-page handout made be made, however the CD-ROM and Instructor's Manual may not be reproduced.

QMS Standards and Regulations

- The FDA's cGMP's were initially published in 1978 and revised in 1997.
- The ISO 9001 standard was initially published in 1987, revised in 1994, and revised again in 2000.
- The ISO 13485 standard was initially published in 1996 and revised in 2003.
- The Canadian Medical Devices Regulation was initially published in 1998 and revised in 2003.
- The Medical Device Directive was initially published in 1995, was revised in 2003 and again in 2007.

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ISO 9001 ≠ FDA QSR

Enforcement Concerns:

- Assuring Customer Satisfaction
- Engaging in Continuous Improvement
- Documentation
- Process Model Approach

ISO 13485 is considered to be compatible with the FDA's QSR

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Process Management

To function effectively you need to identify and manage numerous linked processes

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Required QMS Documentation

Documented quality policy and quality objectives
Quality manual
Documented procedures (e.g. SOP's, WI's)
Documents needed to ensure effective planning, operation and control of processes (e.g. quality plans, project plans)
Records (e.g. completed forms, minutes)
Device Master Records

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Management Responsibility

Overall business goals, quality objectives and the quality policy are all interrelated and must work together to achieve business improvement. As a result:

- The quality policy should provide a framework for reviewing the company's quality objectives
- Objectives must be measurable
- QMS processes must be designed to meet objectives and maintain QMS integrity

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Design and Development Planning

Establish a procedure and plan for design control
Determine and document:

- What activities are required?
- Who needs to do them and what resources are needed?
- How will activities be performed and what constitutes success – i.e. method and acceptance criteria?
- When do activities need to be done and results reviewed?

Update the design plan as the design evolves

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Review of Product Requirements

Review customer order/contract requirements prior to acceptance to ensure:

- Requirements are defined and documented
- Ambiguities or changes are addressed
- Requirements can be met

Ensure relevant personnel are made aware of any changes
Maintain records of customer orders and/or contracts and any changes

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Measurement, Analysis & Improvement

Implement systems needed to:

- Demonstrate product conformity
 - Acceptance/verification activities
 - Complaint handling processes
 - Control of non-conforming product
- Ensure QMS conformity
 - Internal audits
- Maintain the effectiveness of the QMS
 - Analysis of data
 - CAPA

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Analysis of Data & CAPA

- Document procedures for analyzing data and implementing corrective and preventive action
- Analyze quality data sources for existing and potential problems

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