



ISO 13485:2003 Executive Understanding

The Executive Understanding program is a series of individual courses that an organization can pick and choose what is covered to fit their customized needs. There are 5 independent modules including: *Executive Briefing, Describing the System, Factors for Successful Implementation, QMS Requirements Overview, and Planning for Implementation*. Choose which modules fit your needs and time allowance, and Plexus will provide a highly experienced consultant to explain the benefits and necessary resources for your company's commitment to ISO 13485:2003.

Length: Variable

CEUs: Variable

Prerequisites: *None*

AVAILABLE MODULES

Module 1: Executive Briefing (2 hours)

- Top management responsibilities
- Quality Management Systems
- Process Mapping
- Purpose and intent of the Standard

Module 2: Describing the System (4 hours)

- Planning responsibilities
- Mapping the organization utilizing a process based approach
- Analysis of a system of processes through the identification and analysis of individual processes
- Turtle diagrams
- The Process Approach

Module 3: Factors for Successful Implementation (1 hour)

- Executive commitment
- Organizational culture
- Conflict resolution
- Problem solving, communication, team and cross functional management skills

Module 4: QMS Requirements Overview (1-2 hours)

- Brief overview of the standard and related requirements

Module 5: Planning for Implementation (1-2 hours)

- Strategic Planning
- Tactical Planning
- Operational Planning
- Analyzing the mission
- Setting objectives to achieve the vision

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PLEXUS LEARNING MODEL

Learning is maximized through participation. That is why Plexus training avoids lecture-based teaching and focuses on group activities, case studies and hands-on applications. *Learn by doing.*

WHO SHOULD ATTEND

- Executives and Upper Level Management

INSTRUCTORS

Plexus Master Trainers. Plexus Master Trainers train and evaluate:

- ISO 9001:2008, ISO/TS 16949:2009, AS9100, ISO 14001:2004 Environmental Management Systems, ISO 22000:2005 Food Safety, ISO 9001:2008 for Healthcare and ISO 13485:2003 for Medical Devices.
- Plexus trains 3rd party auditors and wrote the materials used to certify all of them
- Supplier Auditors