



## Understanding ISO 13485:2003

# ISO 13485:2005

Learn the concepts of ISO 13485:2003 and how the standard can become a valuable part of your business management system. Participants engage in activities that create an understanding of each standard element and the benefits of each element for their organization and for them as participants in a business management system.

Length: 2 days

CEUs: 1.4

Prerequisites: *None*

### WHAT YOU WILL LEARN

- Obtain invaluable insights into the benefits the process approach of ISO 13485:2003 can deliver to any business management system.
- The purpose and intent of the ISO 13485 standard
- The process approach and how it impacts the use of ISO 13485:2003.
- How to identify and understand the process within your organization.
- The 8 quality management principles upon which the ISO 9000 family of standards were based.
- The purpose of ISO 14971 and ISO/TR 14969 and their relationship with ISO 13485:2003
- Terminology and exclusion requirements in ISO 13485:2003
- A practical application of each of the standard's clauses and how it relates to the intent of the standard
- Create a basic business model for elements of the standard – with inputs, transformations, and outputs as any business would have.
- “Reflect and Connect” exercises compare the model to your organization's model — and confirm insights gained into the process.
- Relate key elements of the standard to your own company. Clause-by-clause review of the standard ensures understanding — and each clause is applied to your own company.

### 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

- Any member of an ISO 13485:2005 implementation team
- Risk managers
- Quality managers
- New internal auditors and experienced auditors that have not attended training in over three years
- Representatives from key functional groups involved in an organization's quality management system

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## **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 3<sup>rd</sup> party auditors and wrote the materials used to certify all of them
- Supplier Auditors

## **AGENDA**

Day 1:

- ❖ Purpose and Objectives
- ❖ Process Approach and Impacts
- ❖ Clause by clause review of ISO 13485:2003

Day 2:

- ❖ Clause by clause review of ISO 13485:2003 (continued)
- ❖ Quality Management Principles
- ❖ Closure and Planning: Opportunities, roadblocks and implementation planning