

# **Understanding ISO 13485:2003 for Medical Devices (Plexus Curriculum) – SC-325**

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Learn the concepts of ISO 13485:2003 and how the standard can become a valuable part of your business management system.

CEUs: 1.4    RU's: 1.4    Required for ISO 13485:2003 Internal Auditing, SC 326

## **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 processes 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 of ISO 13485:2003
- A practical application of each of the standard's clauses and how it relate 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 to 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.

## **WHO SHOULD ATTEND**

- Any member of an ISO 13485:2003 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

## **PREREQUISITES**

None

## **SCHEDULE**

- 2-Day session, 8:30AM-4:30PM, Course Fee: \$ 700.00.
- Lunch and refreshments included