



5550 Nicollet Ave.  
Minneapolis, MN 55419  
www.plexusintl.com  
Phone: 612-238-1200  
Fax: 612-238-1218



## ISO 9001:2008 Internal Quality Auditing For Healthcare

This course is designed for both new auditors and those looking to sharpen their current auditing skills. Participants will acquire the necessary skills to become a leader in preparing and conducting 1<sup>st</sup> and 2<sup>nd</sup> party audits through interactive methods and avoiding lecture based learning. This course includes a simulated audit, based on documentation from an actual organization, so participants can develop and refine their newly acquired knowledge and skills.

Length: 2 days    CEUs: 1.4    Prerequisites: *Understanding ISO 9001:2008* highly recommended

### WHAT YOU WILL LEARN

- ISO 19011:2002 Standard on performing audits
- Comply to the ISO 9001:2008 Standard by applying the Process Approach to your quality management system
- Form an audit team
  - Who needs to be on it
  - Determine roles & responsibilities of each individual
- Conduct an audit meeting
  - Who needs to be there from the audit team
  - Who needs to be there from the organization receiving the audit
  - Agenda
  - What reports are needed and how to form them
- Documentation
  - What is needed
  - How to organize according to the ISO 19011:2002 Standard
- Nonconformities
  - How to classify, record and resolve
  - How to implement preventative measures to avoid future nonconformities

### 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 9001:2008 implementation team
- 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

# ISO 9001:2008 for Healthcare

## **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

- ❖ A brief review of ISO 9001
- ❖ Quality System Terminology
- ❖ What is an Audit? Types, objectives and relation to a standard
- ❖ Internal Auditors: attributes, roles and responsibilities
- ❖ Communication Skills: verbal, nonverbal and conflict situations

Day 2

- ❖ Plan For The Audit
- ❖ Prepare For The Audit
- ❖ Perform the Audit
- ❖ After The Audit