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Transitioning to ISO 9001:2008 and Lessons Learned from the Process Approach 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 1st and 2nd 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: *Participants must be familiar with ISO 9001:2000 (there will not be a clause by clause review of all sections of the standard)*

WHAT YOU WILL LEARN

- Understand the changes from ISO 9001:2000 to ISO 9001:2008 and what that means to your organization in the healthcare industry
- Obtain valuable insights into the benefits the process approach of ISO 9001:2008 can deliver to any business management system
- Provide Lessons Learned about the Process Approach
- Identifying the different levels of processes within an organization and how they link to maximize effectiveness and efficiency in the organization
- Basic quality system terminology
- Effective communication skills and techniques
- Conflict management
- The process of auditing – plan, prepare and perform and after an internal quality audit
- The process approach impact upon auditing technique and methodology
- A simulated audit using documentation from an actual organization

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 3rd 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