Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Effective and Efficient Internal and Supplier Quality System Auditing for Medical Devices

Jersey City, NJ

November 10th & 11th, 2016

9:00 AM to 6:00 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees (With stay)

Price: **$4,485.00** You Save: $2,990.0 (40%)*

~~$7,475.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

Betty Lane

Founder and President,
Be Quality Associates, LLC

Betty Lane has over 30 years experience in Medical Device quality assurance and regulatory affairs. She is the founder and President of Be Quality Associates, LLC, a consulting company helping small and medium sized medical device and diagnostic companies implement and improve their quality systems. Her work enables companies to manage their business in compliance with FDA and ISO 13485 requirements, as well for quality system requirements for other geographic area such as Europe and Canada. Her background in digital systems engineering enables her to facilitate quality system processes for design controls and software validation.

Overview :

Do you want to understand how to do efficient and effective internal and supplier audits that meet all the requirements of your external auditors, but also add value to your company? Are you confused by all the requirements and guidance documents for medical device quality management systems and are tired of wading through all the regulatory language they contain. This course is for those who will do internal or supplier audits, manage an audit process for these or other company audits. This course will provide you with an easy to understand presentation on the auditing process as well as the requirements you will need to audit under ISO 13485 and the FDA Quality System Regulation (cGMP)

Agenda:

Day One

Requirements of ISO 13485

Lecture 1: Course Overview

Lecture 2: Introductions - interview exercise

Lecture 3: Overview of ISO 13485 and FDA Quality System Regulation (cGMP)

Lecture 4: General Quality system requirements for Medical Devices

Lecture 5: Document and Records Control

Lecture 6: Management's Responsibilities including Management Review

Lecture 7: Provision of Resources including human resources, training, facilities and work environment

Lecture 8: Provision of Products and Services: How do you provide products and services to your customers

Lecture 9: Exercise on Provision of Product and Services - what issues has you company had

Lecture10: Monitoring, Measurement and Improvement: How to we make sure everything is running well or fix it if it is not (including product and process monitoring, complaints, Corrective and preventive action and internal audits)

Lecture11: Exercise on application of requirements

Lecture12: Q&A

Day Two

Lecture 1: The purpose of auditing

Lecture 2: The difference between internal and external audits

Lecture 3: Audit Planning
- •The Audit Manager
- •How to create an audit schedule
- •Tracking audit performance

Lecture 4: The audit process and our procedures
- •Audit Preparation & Planning
- •Check lists
- •Audit Notice
- •Opening Meeting
- •The audit
- •Specific items to check in various areas
- •Comments and nonconformities
- •Audit Report

Lecture 5: How to say things properly on audit paperwork

Lecture 6: Exercise on writing nonconformities
- •Corrective Actions
- •Closing the audit

Lecture 7: Practice Audits

Lecture 8: What the FDA can ask for concerning internal and supplier audits

Lecture 9: Q&A

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
2. Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
3. PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
4. Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry's top notch professionals

Contact Information: Event Coordinator

NetZealous LLC, DBA GlobalCompliancePanel
161 Mission Falls Lane, Suite 216,
Fremont, CA 94539, USA
Toll free: +1-800-447-9407
Fax: 302 288 6884
Email: support@globalcompliancepanel.com

www.globalcompliancepanel.com

Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

GlobalCompliancePanel