Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Supplier Management for Medical Device Manufacturers

Zurich, Switzerland

November 13th & 14th, 2017

9:00 AM to 6:00 PM

Price

Price: **$1,895.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$5,685.00** You Save: $3,790.0 (40%)*

~~$9,475.00~~

Register for 10 attendees

Price: **$10,422.00** You Save: $8,528.0 (45%)*

~~$18,950.00~~

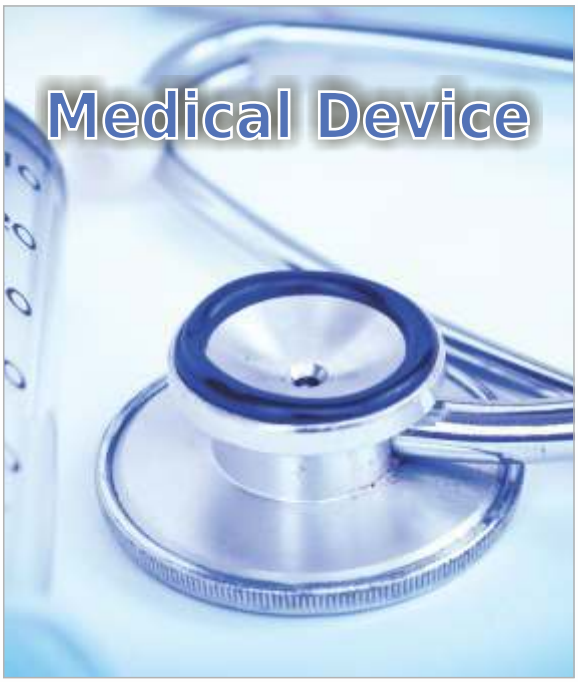
ENROLL

***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.



Overview:

Supplier selection and management is one of the critical issues for medical device manufacturers. Suppliers provide materials and services to the device manufacturer, which means that they can be critical to performance and delivery of your device. Neither the FDA nor your notified body regulates your suppliers (with a few exceptions). They expect you to have an effective process to ensure your suppliers perform in the regulatory environment.

How well do you understand the requirements for supplier management?

Could you pass a regulatory audit or inspection without any issues?

This course delivers the tools, templates, and methods to help participants implement an effective and efficient supplier management

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Agenda:

Day One

Lecture 1: Introductions

Lecture 2: Fundamentals Regulatory Requirements

- FDA Requirements
- ISO 13485 requirements
- Understanding the role of the Global Harmonization Task Force Guideline
- Understanding NBOC Guideline and why it should be used

Lecture 3: Planning the Supplier Management Program

- Supplier Classification
- Supplier QA agreements what are they and why are then

Day Two

Lecture 1: Planning Supplier Selection

Lecture 2: Potential Suppliers

Lecture 3: Supplier Selection

Lecture 4: Implementing Supplier Controls

Lecture 5: Monitoring, Measuring, and Evaluation

- Periodic Monitoring
- Re-evaluations

Lecture 6: Supplier Audits - where do they add value

- Planning your supplier audit schedule
- How Notified Body unannounced audits affect your contract manufacturer
- What you should do to prepare yourself and your contract manufacturer for unannounced Notified body audits

Lecture 7: Feedback and Communication

- Supplier meetings: Partnering with Key suppliers
- Supplier Corrective Actions

Lecture 8: Evaluating your current program to see how it measures up to regulatory Expectations

Why you should attend:

Since FDA regulations do not allow them to audit your suppliers unless they make finished medical devices, they require that you have sufficient control over them. But from time to time the FDA makes a reinterpretation of what this means. This happened within the last f 5 years, so if you supplier management program is older than that, you need to make major changes in you supplier management program. This is why the Good Manufacturing Practice (aka Quality System Regulations) is called cGMP. The C stands for current, meaning what the FDA considers the current state of the art in the areas they regulate. Also European Notified Bodies also periodically update their expectations, and for suppliers this happened with the publication of a guidance document by the Notified Body Operations Group (NBOG).

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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

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

Look forward to meeting you at the seminar

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