Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

FDA Concepts for Medical Device Companies – Regulations, Myths, Challenges, and Best Practices

Baltimore, MD

December 1st & 2nd, 2016

9:00 AM to 6:00 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees

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.*

Susanne Manz

Susanne Manz MBA, MBB, RAC, CQA is an accomplished leader in the medical device industry with emphasis on quality, compliance, and six sigma. She has an extensive background in quality and compliance for medical devices from new product development, to operations, to post-market activities. While at GE, J&J, and Medtronic, Susanne worked in various world-wide roles including Executive Business Consultant, WW Director of Quality Engineering and, Design Quality, and Director of Corporate Compliance. Susanne has a BS in Biomedical Engineering and an MBA from the University of NM.

Overview :

This webinar will show you how to structure and optimize your QMS. It all starts with Management Responsibility and a commitment to quality. We'll discuss the concepts of management responsibility, a culture of quality, and continuous improvement. We'll discuss tools and metrics for understand the state of your QMS and how to identify and prioritize opportunities for improvement. We'll discuss the 4 major Quality System elements that are emphasized by the FDA in their QSIT (Quality Systems Inspection Technique) inspections.

Global CompliancePanel

2-day In-person Seminar:
FDA Concepts for Medical Device Companies - Regulations, Myths, Challenges, and Best Practices

Agenda:

Day One

Lecture 1:

- Intro to Quality System Regulations
- Management Responsibility
- Culture of Quality
- Metrics for monitoring and improving your Quality System
- Internal Audit is a secret to success

Lecture 2:

- Structuring your Quality Management System
- Document and Change Controls

Lecture 3:

- Writing Excellent SOPs

Lecture 4:

- Corrective and Preventive Action
- Root Cause Analysis

Day Two

Lecture 1:

- Complaints and Medical Device Reporting

Lecture 2:

- Design Controls
- Intro to Risk Management

Lecture 3:

- Production and Process Controls

Lecture 4:

- Inspection Readiness

Why should you attend:

An efficient and effective Quality Management System (QMS) is a critical success factor for all Medical Device Companies and is necessary for you to meet the needs of all of your stakeholders. A QMS needs to be effective to ensure your products are safe and effective for your customers. It needs to ensure compliance to the regulations and enable you to successfully demonstrate that compliance to the regulators. But, a QMS system also needs to be efficient to allow you to meet the needs of your business stakeholders and shareholders. This seminar will introduce you to the Quality System Regulations and how to translate them into a QMS that can be both nimble and rigorous in ensuring safe and effective products.

Who Will Benefit:

- Quality Engineers
- Process Engineers
- Design Engineers
- Compliance Specialists
- Quality and Compliance Managers
- CAPA Specialists
- Auditors
- Senior Management wanting an overview of Quality Systems and Management Responsibility
- Anyone wanting an introduction to Quality Management Systems

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