Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Death by CAPA – Does your CAPA Program need a CAPA?

Boston, MA

April 18th & 19th, 2019

9:00 AM to 6:00 PM

Price

Price: **$2,000.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees

Price: **$10,000.00**

Register for 10 attendees

Price: **$20,000.00**

ENROLL

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

Susanne Manz

Quality and Compliance Expert /
Auditor for Medical Devices, Manz Consulting, Inc.

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, Worldwide Director of Quality Engineering, Worldwide Director of Design Quality, and Director of Corporate Compliance. Susanne is a Presidential Scholar and has a BS in Biomedical Engineering and an MBA from the University of NM. She earned her Black Belt and Master Black Belt certifications while at Johnson and Johnson.

Overview :

This 2-day seminar will help you establish an efficient and effective CAPA (Corrective and Preventive Action) process leading to improved quality and compliance for your company. You'll learn how to streamline and monitor your process to ensure compliance and improved performance. If your CAPA process needs a CAPA, this seminar is for you.

Agenda:

Day One

- FDA expectations for CAPA
- Lessons Learned from 483s and warning letters
- Common problems with CAPA
- Elements of a CAPA program
- How to structure your CAPA process
- How to use IT tools to monitor and maintain your CAPAs
- Metrics to ensure your CAPAs are timely and effective
- A toolkit for CAPAs
- Sources of Data
- Analysis of Data
- Failure Investigation
- Root Cause Analysis

Why you should attend :

Corrective and Preventive Action (CAPA) is the cornerstone of a strong Quality Management System. And yet, many medical device manufacturers struggle to establish and maintain an effective CAPA process. An ineffective CAPA process leads to disastrous consequences like complaints, recalls, 483s, and warning letters. Additionally, an inefficient CAPA system leads to wasted time and resources.

CAPA is so important that it is always emphasized in FDA inspections. It is consistently one of the top reasons for 483 and Warning Letter observations. It is critical that your company establishes a compliant, effective process. This seminar will also provide tools and checklists to ensure your program is inspection ready.

Day Two

- CAPA Project Management
- Problem Solving and Improvement techniques
- Effectiveness Checks
- Control, Monitoring, Dissemination of Information
- Connections within your Quality Management System
  - Non-conforming Product
  - Corrections and Removals
  - Change Control
  - Statistical Techniques
  - Risk Management
- Bullet-proof Reports
- Inspection Readiness and Checklists
- Best Practices

Objectives :

- Understand the regulatory requirements
- Elements of creating an efficient and effective program
- CAPA process, tools, and techniques
- Linkages to your Quality Management System
- Myths, Challenges, and Best Practices
- Inspection preparedness

Who Will Benefit:

- Quality Systems Specialists
- Document Control Specialists
- Quality and Compliance Specialists
- Quality Engineers
- Internal Auditors and Managers

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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

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

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