Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Quality by Design – Essential Techniques for Medical Devices

San Diego, CA

November 12th & 13th, 2018

9:00 AM to 6:00 PM

Price

Price: **$1,295.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees

Price: **$3,885.00** You Save: $2,590.0 (40%)*

~~$6,475.00~~

Register for 10 attendees

Price: **$7,122.00** You Save: $5,828.0 (45%)*

~~$12,950.00~~

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

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 industry leaders like GE, J&J, and Medtronic, Susanne worked in various world-wide roles including Executive Business Consultant, Worldwide Director of Quality Engineering, Design Quality, and Director of Corporate Compliance. She has traveled extensively throughout the world conducting audits and helping companies to understand and improve their Quality Management Systems. 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. Susanne also holds Regulatory Affairs Certification (RAC) from RAPS and is a Certified Quality Auditor by the American Society

Overview :

Design Controls are essential for producing safe and effective medical devices. And Design Controls are considered a critical process by the FDA. Yet, Design Controls are still one of the most frequent areas for 483 and Warning Letter observations. This 2 day seminar will help you understand, develop, and implement design controls processes and tools that are a competitive strength for your company. You will learn how to incorporate design controls into your product development process to help streamline development and ensure quality and compliance.

Agenda:

Day One

Lecture 1 (90 Mins):

Overview and Expectations

Background of FDA regulations

Design Controls as an integrated part of New Product Development

Lecture 2 (90 Mins):

Design Planning

Project Management

Design Inputs

Lecture 3 (90 Mins):

Design Outputs

Tools, forms, documents

Lecture 4 (90 Mins):

Design Verification and Validation

- Concepts
- Strategies
- Statistical techniques

Day Two

Lecture 1 (90 Mins):

Design Review

Design History File

Documentation Requirements

Lecture 2 (90 Mins):

Design Transfer

Design for manufacturability concepts

Design Changes

Change Control and configuration management

Lecture 3 (90 Mins):

Linkages to other quality sub-systems

- Risk Management
- Failure Investigation
- CAPA

Inspection Preparedness and Compliance Strategy

Lecture 4 (90 Mins):

Lessons Learned

Myths

Challenges

Best Practices

Why you should attend:

The intrinsic quality, safety, and effectiveness of medical device are established during the design phase. Yet, statistics show that a significant percentage of all medical device recalls are due to design problems. And those design problems can have disastrous results for your customer and for your company. A rigorous and efficient design control process can help avoid these quality and compliance problems. Issues that are identified early are more easily and quickly resolved. This seminar will help you avoid design problems and their impact on quality, cost, speed to market, and customer satisfaction.

Design Control is one of the critical areas covered by the FDA in inspections of Medical Device Companies. Design issues can also result in complaints from your customers and in medical device reports. Design issues can even create issues with manufacturability for your company including low yields and excessive scrap and rework.

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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