




2-day In-person Seminar:

Design Controls for Medical Devices – Regulations, Myths, Challenges, and Best Practices

-  Los Angeles, CA
-  November 17th & 18th, 2016
-  9:00 AM to 6:00 PM



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 :

Design Controls are essential for producing safe and effective medical devices. And Design Controls are considered a critical process by the FDA. Yet is still one of the most frequent areas for 483 and Warning Letter observations. This 2 days seminar will help you understand and develop design controls processes and tools that are a competitive strength for your company.

Intrinsic quality, safety, and effectiveness of a device are known to be established during the design phase. Yet, statistics show that a significant percentage of all medical device recalls are due to design problems. And design problems can have disastrous results for your customer and for your company.

Price

Price: **\$1,295.00**

(Seminar for One Delegate)

Register now and save \$200. (Early Bird)

Register for 5 attendees (With stay)

Price: **\$3,885.00** You Save: \$2,590.0 (40%)*
~~\$6,475.00~~

ENROLL

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



Agenda:

Day One

Lecture 1:

- Overview and Expectations

Lecture 2:

- Design Planning
- Design Inputs

Lecture 3:

- Design Outputs

Lecture 4:

- Design Verification and Validation

Why should you attend:

Poor design of medical devices accounts for a significant number of recalls. Design issues can result in complaints and medical device reports. Design issues can even create issues with manufacturability for your company including low yields and excessive scrap and rework. Finding and fixing issues early on in design provide much more leverage than trying to fix problems for products already in production. This webinar can help you learn from past issues and improve your next generations of product.

Day Two

Lecture 1:

- Design Review

Lecture 2:

- Design Transfer and Design Changes

Lecture 3:

- Design History File
- Linkages to Other Quality Sub-systems
- Inspection Preparedness

Lecture 4:

- Myths
- Challenges
- Best Practices

Who Will Benefit:

- R&D Engineers
- R&D Managers and Directors
- Individuals participating in Product Design and Development
- Individuals participating in design changes and failure investigations
- Regulatory Affairs
- Design Quality Engineers
- R&D engineers and scientists
- Compliance Specialists
- Auditors
- Senior Management

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
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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.
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- 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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