




2-day In-person Seminar:

Strategies for Improving Effectiveness and Efficiency of your Quality Management System

-  Salt Lake city, UT
-  October 15th & 16th, 2018
-  9:00 AM to 6:00 PM



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 :

This 2-day seminar will cover the essentials of an effective yet efficient quality management system for medical device companies. An efficient and effective quality system can be a competitive advantage for companies by leading to improved quality and compliance as well as optimizing the cost of quality. This seminar will get you started in setting up just such a Quality System. We'll discuss the "case for quality" and how you can use compliance, not as an end itself, but as a means to improved quality and reduced cost of non-compliance.

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~~

Register for 10 attendees

Price: **\$8,222.00** You Save: \$6,728.0 (45%)*
~~\$14,950.00~~

ENROLL

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

Agenda:

Day One

- Overview
- Introductions
- Regulatory expectations
- Quality Systems requirements for medical devices
- Quality System structure and writing SOPs

Break

- Roles and Responsibilities
- Management Responsibility and a Culture of Quality
- Management Review

Lunch Break

- Key Capabilities for Success
- Metrics and performance monitoring
- An effective auditing program is a key to self-awareness

Learning Objectives:

Using interactive discussion and exercises, students will understand the regulations, context, and history of quality system regulations. They will learn concepts and techniques for developing a quality management system that is both effective and efficient. They will come away with key concepts, practice in these concepts, and extensive course notes for future use and reference

- Quality System Expectations
- Characteristics of an effective QMS
- Characteristics of an efficient QMS
- Roles, responsibilities, capabilities
- Quality leadership and a seat at the table
- Vision, Strategy, and Planning
- Case for Quality
- Red Flags and warning signs
- Improvement tools and techniques
- Inspection preparedness and management
- Best Practices

Day Two

- Maturity Modeling
- Value proposition for Quality

Break

- CAPA, investigation, and root cause analysis - essentials for improvement

Lunch Break

- Risk Management for Compliance
- Creating a strategy and quality plan

Break

- Inspection preparedness and management

Why you should attend:

This seminar will help you understand regulatory requirements and how to translate them into a quality system that is both effective and efficient. You'll learn how to plan, structure, and implement a quality system specific for your business needs. We'll explore the capabilities that every medical device company needs to ensure quality products and a compliant quality system. We'll discuss how to define your current situation and create a quality strategy and plans. Will discuss methods to identify, prioritize, and analyze risks. Then will move on to continuous improvement, six sigma, and Corrective and Preventive Action to address issues within your Quality System. You'll learn how to effectively communicate and escalate risk as well as monitor performance and progress.

This seminar can help you get your quality system off to a good start and avoid common problems including MDRs, recalls, 483s, and warning letters!

The expectations for quality and compliance continue to increase. We will discuss changing regulations and expectations and what you can do to prepare for them. This seminar will allow you to interact personally with an industry expert with over 30 years' experience in medical devices. The instructor has worked in manufacturing, design, quality and compliance at industry leaders like GE, Johnson and Johnson, and Medtronic. She has traveled throughout the world developing, auditing, and improving quality 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

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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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