




2-day In-person Seminar:

Audit Like the FDA - What you need to know for a truly effective internal audit program

-  Boston, MA
-  May 4th & 5th, 2017
-  9:00 AM to 6:00 PM



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 industry leaders like 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. 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.

Overview :

This 2 day seminar will explore how to create and implement an efficient and effective internal audit program. Internal Audit is a required part of an effective quality system. More importantly, it is an incredibly powerful tool to identify areas of non-compliance. A well-designed audit program can be an effective tool in understanding, communicating, and reducing quality and compliance risk.

However, estimates indicate that up to 75% of companies conduct audits only because they are required to by regulation.

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.*



Agenda:

Day One

Lecture 1: Overview

Lecture 2: Introductions

Lecture 3: Regulatory expectations

Lecture 4: Quality Systems requirements for medical devices

Lecture 5: Types and goals of audits

Lecture 6: Creating a program

- Goals
 - Risk Analysis
 - Audit schedule
 - Oversight, communication, monitoring, and escalation
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Lecture 7: Linkages in your Quality System

- CAPA
 - Metrics and monitoring
 - Management Review
 - What the FDA can look at
 - Record keeping and documentation
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Lecture 8: Auditor qualifications and skills

Day Two

Lecture 1: The auditing process

- Preparation
 - Planning
 - Conducting
 - Interviewing techniques
 - Good documentation
 - Following-up
 - Monitoring progress
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Lecture 2: Focus on Supplier Auditing

Lecture 3: Red Flags and Warning Signs

Lecture 4: Best Practices

Who will benefit:

- Quality Systems Specialists
- Document Control Specialists
- Quality and Compliance Specialists
- Auditors
- Internal Auditors
- Supplier Auditors
- Auditor Managers
- Supplier Auditors
- CAPA Specialists

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
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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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