

Quality and Compliance for Medical Devices - What Every Executive or General Manager Needs to Know About Quality and Compliance to Protect your Business

November

29

2016

10:00 AM PDT | 01:00 PM EDT

Duration: 90 Minutes

Instructor: Susanne Manz

[Registration](#)

Overview:

The role of Quality leaders, general managers, and executives includes "Management Responsibility". It includes:

- Quality Policy
- Organization
- Management Review
- Quality Planning
- Quality System Procedures

Areas Covered in the Session:

- Basics of the Quality System Regulation (QSR) requirements
- What "Management Responsibility" means to the FDA
- Park Doctrine and FDCA (Food, Drug, and Cosmetic Act) Violations
- The ten commandments for creating a culture of quality in your organization
- How to use management review to ensure you have a suitable quality system
- Case studies and examples
- Risk-based decision making
- Creating quality plans and strategies

Who Will Benefit:

- Quality Leaders
- Quality Managers, Directors, VPs
- Management Representatives
- Compliance Leaders
- Quality Systems Specialists
- Internal Auditors
- CAPA Specialists
- Process Owners wishing to monitor and improve their processes
- IT Personnel supporting Quality, Compliance, Clinical, Regulatory Organizations
- General Managers wanting to reduce Quality and Compliance Risk
- Executives

About Speaker:

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, 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,... [more](#)

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