

Webinar on

# Internal Audit for Medical Device Companies

## **Learning Objectives**

- Failures of internal audit
- Red flags indicating your program is not effective
- \_\_\_\_\_ Identify weaknesses in your internal audit program
- Risk Analysis techniques
- Audit Program Structure
- Improvements for your Audit Program



## **Areas Covered** *Regulatory requirements Using a structured program to identify* areas of risk leading to an effective audit strategy How to develop a meaningful structure of audit, oversight, transparent communication, and escalation to management review How to ensure your audit staff is well trained to proactively identify, communicate, and escalate issues How a culture of quality and compliance can encourage clear and transparent communication of risk How to prioritize, resource, and *implement corrective actions* Tools for monitoring and communicating risk and improvement over time

# **Areas Covered** How to identify residual risk *Monitoring and Controlling progress over* time Signs that your company culture is taking unnecessary compliance or quality risk *How to ensure management gets* valuable information from your audit program How to prioritize, resource, and *implement corrective actions* Tools for monitoring and communicating risk and improvement over time

This webinar will highlight red-flags and ways to reduce compliance and quality risk.

#### **PRESENTED BY:**

Susanne Manz, MBA, MBB, RAC, CQA is an accomplished leader in the medical device industry with an emphasis on quality, compliance, and six sigma. She has worked at industry-leading companies such as GE, J&J, and Medtronic with an extensive background in quality and compliance for medical devices from new product development, to operations, to post-market activities.

**On-Demand Webinar** 

**Duration: 90 Minutes** 

Price: \$200



## **Webinar Description**

Internal Audit should be a key part of self-awareness and understanding strengths and weaknesses within your Quality Management System. It should be an essential guide to corrective and preventive action and drive improvement. But it doesn't always work that way. In this webinar, we'll cover the reasons internal audit doesn't work and how you can correct that. This webinar will explore how to improve your internal audit program, so it is an efficient and effective tool it is meant to be. 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 and quality risks. A well-designed audit program can be an effective tool in understanding, communicating, and reducing quality and compliance risk.

However, many companies conduct audits only because they are required to by regulation. Businesses often see internal audit as a non-value-added activity leading to meaningless findings, bureaucracy, and cumbersome processes. And despite having an internal audit program, management is often surprised when they receive a 483, Warning Letter, or even a Consent Decree.



### Who Should Attend?

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

Quality/Compliance managers or directors for Medical Device companies General Managers wanting to learn how to Management Review and expectations



## Why Should You Attend?

Continuous Improvement starts with an awareness of issues and opportunities. And without an effective internal audit program, management lacks awareness of the issues within their quality system. Management is blind to the gaps in the quality system and the risk that poses for the company. Even worse, management is blind to the impact on product quality and risk to the customer. This webinar will highlight red-flags and ways to reduce compliance and quality risk.







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