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*Webinar on*

# Medical Device Recall Management

# Learning Objectives

- *Regulatory Expectations*
- *Medical device authority and guidance*
- *Recall Types and Classifications*
- *Failure Investigation*
- *Difference between a product enhancement and a recall*
- *Recall strategy and FDA notification*
- *Linkages between Complaint Handling, MDRs, Recalls, and CAPA*
- *Preparing for an FDA Inspection*

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This webinar will help you to understand the regulatory requirements for dealing with a medical device recall.

**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 including roles as Executive Business Consultant, World Wide Director of Product Quality, and Director of Corporate Compliance.*

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

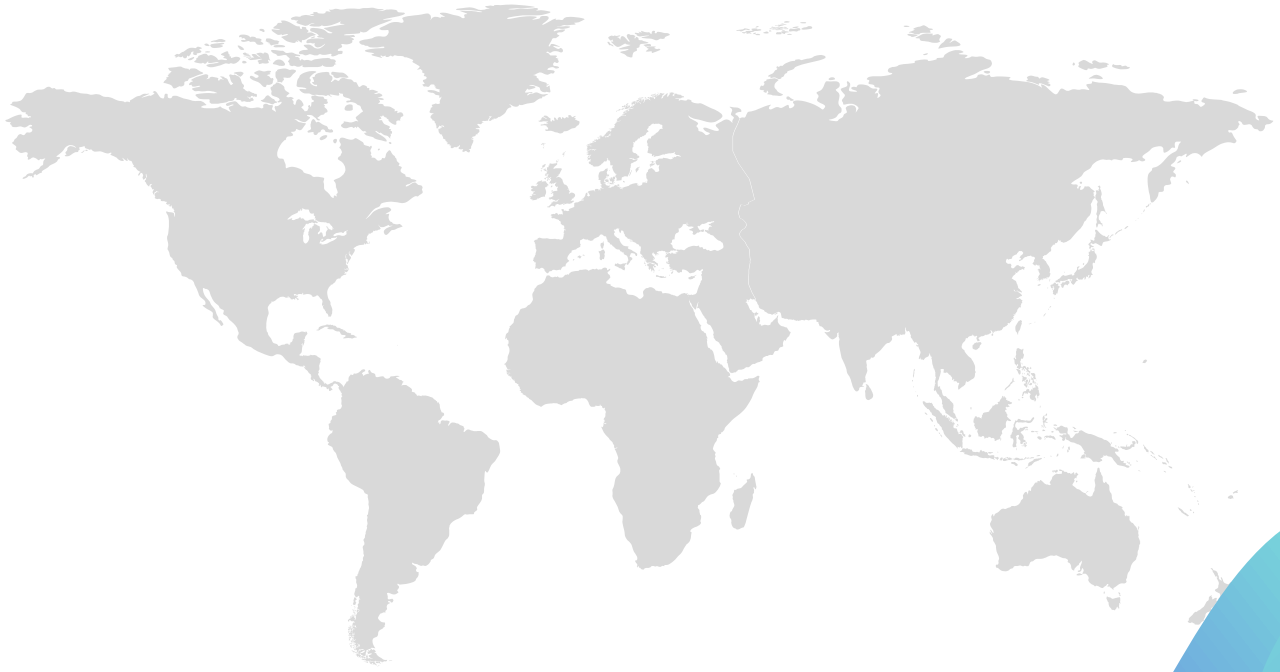
# Webinar Description

Despite best efforts, serious quality issues resulting in the recall can occur. Medical Device companies need to be prepared in advance to handle a difficult situation. This webinar will prepare you to understand the signals that trigger a need to recall, the investigation and other actions required, taking corrective and preventive action, and notifications to customers and regulatory bodies.

This webinar will help you to understand the regulatory requirements for dealing with a medical device recall. You'll learn about FDA expectations and regulations as well as lessons learned from 483s and warning letters. We'll discuss how you can develop your processes to efficiently and effectively manage failure investigations, recalls, and take appropriate corrective and preventive action. In addition, we'll discuss how to link these processes link to other parts of your Quality Management System. We'll cover best practices so you can be prepared for a possible post-recall FDA inspection.

# Who Should Attend ?

*Complaint Specialists*
*Complaint Handling Unit staff*
*Medical Device Reporting staff*
*Individuals participating in Failure Investigations*
*Individuals analyzing returned products / Complaint Analysis*
*Regulatory Affairs*
*Quality Engineers*
*Clinical Affairs*
*Compliance Specialists*
*Quality Managers*
*Management Representatives*



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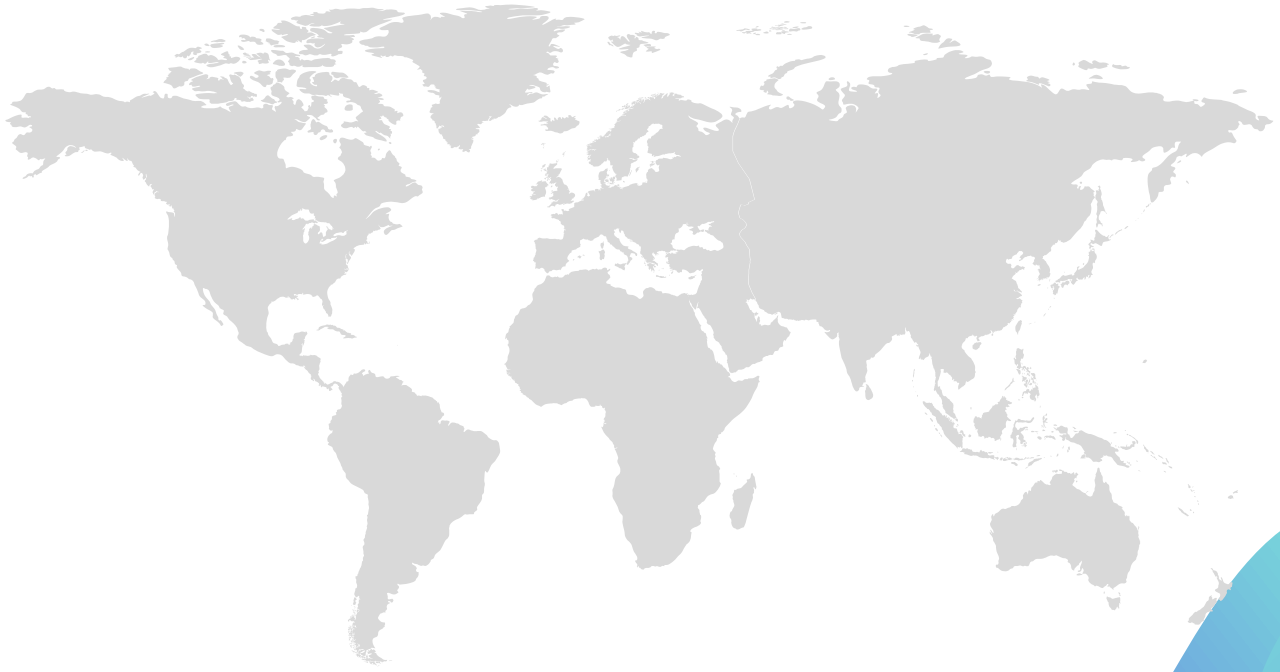
# Why Should You Attend ?

*A quality issue resulting in a recall is a serious issue for a medical device company. A company's actions must be commensurate with the risk of such a serious issue. A recall can be a time of great pressure with a need for urgent investigation and actions. It is best to have procedures ready in advance in order to handle all activities in a diligent and compliant manner. Don't try to figure it out as you go along. Additionally, a recall can trigger regulatory inspection and enforcement actions. This webinar will cover these possibilities and how you can best prepare for them. A recall is always a difficult situation but having good procedures and processes in place can help you do the right thing to protect your customers. This webinar can help you ensure you are ready in the event of a recall-initiated, for-cause inspection.*



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