

Webinar on

Best Practices for Managing an FDA Inspection

Learning Objectives

- FDA Inspection approach*
- Inspection preparedness strategy and planning*
- Inspection readiness checklists*
- How to manage an inspection*
- Key roles during an inspection*
- SME (Subject Matter Expert) training*
- Common mistakes to avoid*
- How to respond to inspection observations*



Although an effective Quality System should always be inspection ready, many medical device companies make basic mistakes during inspections leading to 483s and even warning letters.

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.

On-Demand Webinar

Duration : 90 Minutes

Price: \$200

Webinar Description

Although an effective Quality System should always be inspection ready, many medical device companies make basic mistakes during inspections leading to 483s and even warning letters. This webinar can help you prepare for and manage inspections efficiently and effectively. A professional, polished, responsive approach sets a good tone for an inspection. You will learn how to present information about your quality system in the most competent and professional manner.



Who Should Attend ?

Quality Engineers

Compliance Specialists

Compliance Managers and Directors

CAPA specialists and managers

Complaint Handling Unit specialists and managers

Quality Managers and Directors

Management Representatives

Business Leaders wishing to present a professional and compliant organization

Cross-functional leaders wanting to make sure their organizations are well prepared

Anyone involved with an FDA or NB inspection



Why Should Attend ?

An FDA inspection can be a very stressful and challenging experience. These stresses can lead even experienced people to make very costly mistakes during an inspection. But a good preparation can ease the stresses and lead to much more favorable results. This webinar can help you prepare a strategy and detailed plans to more successfully prepare for, manage, and respond to an FDA or Notified Body Inspection. If you've had a recall, an increase in MDRs, or it's been more than 2 years since your last inspection, you can benefit from this webinar.



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