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Webinar on

Write It Right – Well Written Procedures Are Essential For QMS Effectiveness

Areas Covered

- *FDA expectations for SOPs, Ensuring adequate training to your SOPs*
- *Lessons Learned from 483s and warning letters,Common problems and mistakes*
- *How to structure your QMS and SOPs, How to outline and format your SOPs*
- *Using process maps to make procedures clear, Using diagrams and visuals*
- *Maintaining and controlling SOPs, Best Practices*

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The webinar will help you to write clear, unambiguous, and flexible SOPs. You will learn techniques for creating easy to read and understand SOPs that your employees can consistently follow.

PRESENTED BY:

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 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.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

The webinar will help you to write clear, unambiguous, and flexible SOPs. You will learn techniques for creating easy to read and understand SOPs that your employees can consistently follow.

Well written procedures are a critical ingredient in an effective and efficient quality management system. They are an essential part of meeting the regulatory requirement to “establish and maintain” a suitable and effective quality management system. SOPs are typically one of the first things an investigator asks for during an FDA inspection. Well written procedures send a message to the FDA and Notified Bodies that your QMS is complete, accurate, and establishes regulatory requirements. More importantly, well-written procedures are the very means to ensure that your personnel can accurately and consistently follow your processes resulting in correct outcomes and quality work.

Who Should Attend ?

Quality Systems Specialists, Document Control Specialists

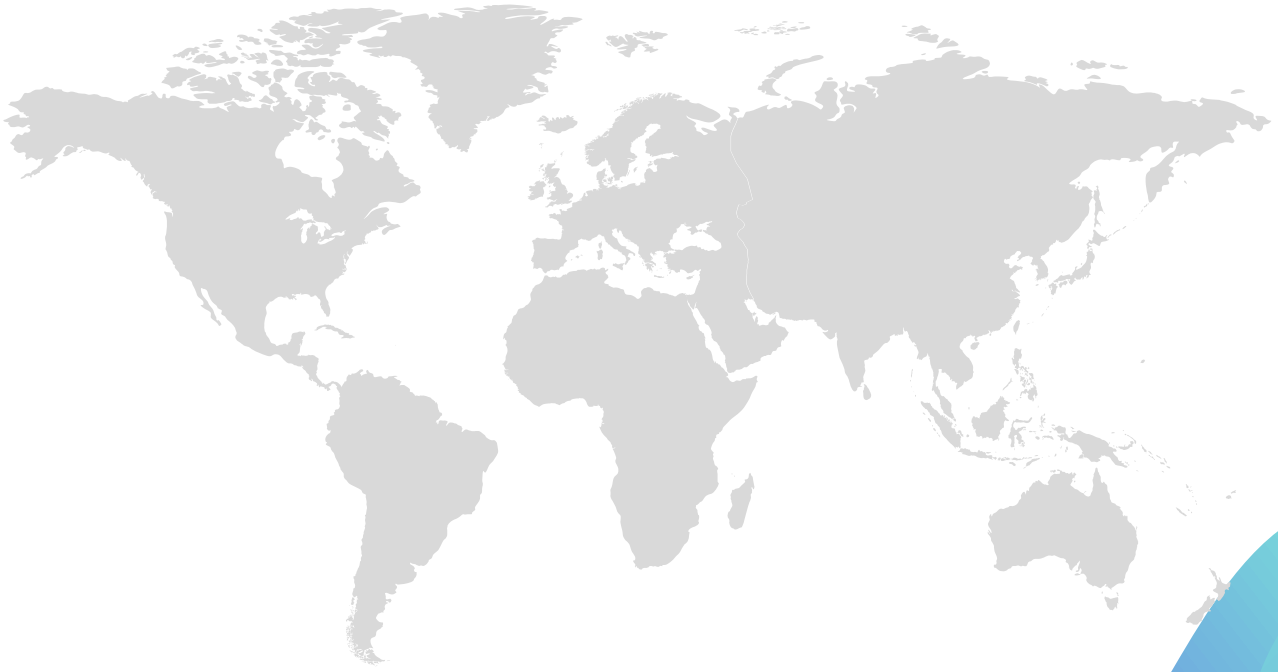
Quality and Compliance Specialists, Internal Auditors and Managers

Training Specialists, CAPA Specialists

Quality/Compliance managers or directors for Medical Device companies

General Managers wanting to learn how to understand Quality System requirements

Subject Matter Experts who write procedures



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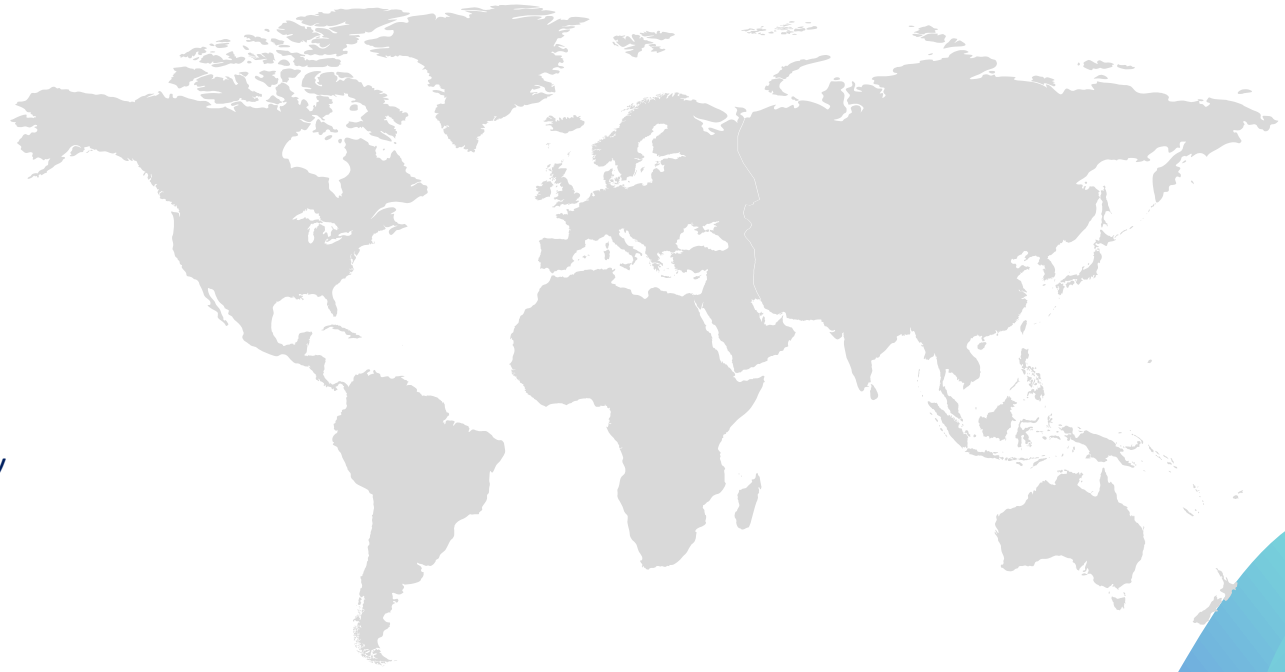
Why Should Attend ?

“Inadequate SOP” observations still rank among the most frequently cited 483 and Warning Letter observations. SOPs are one of the first things an auditor/ investigator will review during an inspection. Most importantly, poorly written procedures make it difficult for your employees to understand and consistently follow procedures. This can lead to disastrous consequences including quality problems and even recalls. Poorly written SOPs can and do impact your business.



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