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Live webinar

How to Manage a Medical Device Recall Efficiently and Effectively

November
21
2016
10:00 AM PDT | 01:00 PM EDT

Duration: **60 Minutes**

Instructor: **David R. Dills**

Registration

Overview:

This webinar will provide valuable assistance and guidance to medical device firms that are either going through or preparing to go through a recall and want to understand the strategy and expectations of a recall and FDA's involvement.
Recall means the correction or removal of a device for human use where FDA finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death. It is an action taken to address a problem with a medical device that violates FDA law.

Areas Covered in the Session:

- Create and use a recall operational procedure and what should it contain
- Understand what are effectiveness checks
- What happens in a medical device recall
- Learn why a recall is either a correction or a removal depending on where the action takes place.
- Understand why is required for the recall strategy as expected by FDA
- Medical device recall authority and guidance
- Depth of recall and using a viable, sustainable and effective strategy
- Understand why the documentation and paper trail are so critical and termination of a recall

Who Will Benefit:

- This webinar will provide valuable assistance and guidance to device companies in involved in vigilance reporting. Employees who will benefit include:
  - All levels of Management for all departments and those who desire a better understanding
  - QA/QC/Compliance/Regulatory Affairs
  - Marketing & Sales
  - Engineering/Technical Services
  - Consultants
  - Operations and Manufacturing

About Speaker:

David R. Dills
Regulatory Affairs and Compliance Consultant,
David R. Dills, Global Regulatory Affairs & Compliance Consultant, has an accomplished record with more than 26 years of experience within regulatory affairs, compliance and quality consultative services for early-stage/established Class I/II/III medical devices, IVDs, and bio/pharmaceutical manufacturers on the global landscape.,.. more

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