Topics in Quality Assurance for Medical Devices

Stay current on the ever-changing medical device regulatory environment with 10 audio recordings of industry experts offering practical guidance on quality assurance issues.

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Topics in this collection have a global appeal and are relevant for multiple departments within your organization—R & D, Market Research, Compliance, and more. Each of the 10 recordings consists of a 45-minute, telephone-based presentation delivered by expert international speakers, followed by a 15-minute question-and-answer session (collection available with and without transcripts).

RECORDINGS:

1. Revisions to EN ISO 14971 and 13485 – What Do They Mean for Device Manufacturers?
   Speaker: Dan O’Leary, President, Ombu Enterprises

2. EU Medical Device Vigilance Reporting Requirements Under MEDDEV 2.12-1 Rev 7
   Speaker: Helen Colquhoun, Senior Vice President, Cromsource

3. How to Document and Implement an FDA-Ready CAPA System
   Speaker: Mark Perkins, Principal Consultant, Medical Device QA/RA Consulting

4. Risk Management Throughout the Medical Device Product Lifecycle
   Speaker: Bill White, Senior Consultant, Quality System Strategies LLC

5. Device Master Records & Device History Records: Are You Compliant?
   Speaker: Dan O’Leary, President, Ombu Enterprises

6. Regulatory Requirements for Medical Device Calibration Programs
   Speaker: Dan O’Leary, President, Ombu Enterprises

7. Global Clinical Trials & ISO 14155: 2011 Compliance - Are Your Quality Systems Up to Date?
   Speaker: Dr. Joy Frestedt, President & CEO, Frestedt Incorporated

8. Avoiding FDA 483s, Warning Letters and Recalls with Harmonized Supplier Qualification
   Speakers: John Avellanet, Managing Director & Principal, Cerulean Associates LLC

9. Sample Size for Design Verification and Validation
   Speaker: Steven Walfish, Statistician, GE Healthcare

10. Medical Device Design Requirements and Considerations for Risk Management
    Speaker: Dan O’Leary, President, Ombu Enterprises
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