Topics in Regulatory Affairs for Medical Devices

Stay current on the ever-changing medical device regulatory environment with 10 audio recordings of industry experts offering practical guidance on navigating federal requirements and approval processes.

Ovid and FX Conferences offer thousands of professional development hours for your teams, conveniently packaged and delivered as a collection of audio recordings to save you time and money.

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. Requests for Off-label Information – The FDA Guidance and Its Implications
   Speakers: Wendy Blackburn, Executive Vice President, Intouch Solutions, & Dr. Darshan Kulkarni, Principal Attorney, The Kulkarni Law Firm

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

4. Centralized vs Onsite Monitoring – Applying FDA’s Risk-based Approach
   Speaker: Sandra Maddock, President & CEO, IMARC Research, Inc.

5. An Overview of Recent Risk-based Monitoring Guidance from the FDA
   Speaker: Dr. Joy Frestedt. President & CEO, Frestedt Incorporated

6. EU Language Requirements for Medical Device Labels: Regulation, Exception, and Risk
   Speaker: Cheryl Hill, Regulatory Manager, CROMSOURCE, Inc.

7. The Revised RoHS Directive and What It Means for Device Manufacturers
   Speaker: Dr. Joachim Wilke, Director, Regulatory Affairs & Policy, Europe, Medtronic

8. Taking the Literature Route for EU Medical Device Clinical Evaluations
   Speaker: Helen Colquhoun, Senior Vice President, Cromsource

9. Following the 510(k) and 505(b)(2) Pathways to Regulatory Approval
   Speaker: Dr. Joy Frestedt. President & CEO, Frestedt Incorporated

10. Technical Documentation Requirements for Device Approval in the EU
    Speaker: Tamas Borsai, Division Manager, MHS - Customer Service and Quality,
Topics in Regulatory Affairs for Medical Devices

TUV SUD America Inc.

Publisher

FX Conferences