Topics in Regulatory Affairs for Medical Devices

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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. 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,
TUV SUD America Inc.

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