Topics in Regulatory Affairs for Pharmaceuticals

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

2. Preparing for Upcoming Changes in EU Pharmacovigilance Requirements
   Speaker: Dr. Jan Petracek, CEO & Chief Consultant, PharmInvent

3. Industry Update – Europe’s New Pharmacovigilance Regulations
   Speaker: Stefan Blesse, Principal Consultant, Granzer Regulatory Consulting & Services

4. Effectively Managing an FDA Inspection – Opening Meeting to Rapid 483 Response
   Speaker: John Avellanet, Managing Director & Principal, Cerulean Associates LLC

5. FDA Update – Responding to Unsolicited Requests for Off-Label Information
   Speaker: Marian J. Lee, Partner and Beverly H. Lorell, Senior Adviser, King & Spalding LLP

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

7. Off-label Promotion – What FDA Looks For & What You Need to Know
   Speaker: Alan Minsk, Partner, Arnall Golden Gregory LLP

8. Expedited and Periodic Safety Reporting for Drug Trials
   Speakers: Helen Colquhoun, Vice President, Cromsource

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

10. Successfully Responding to FDA 483s and Warning Letters
    Speaker: Michael A. Swit, Special Counsel, FDA Practice, Duane Morris LLP
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