Topics in Legal Affairs

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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, Principle Attorney, The Kulkarni Law Firm

2. Managing the Litigation Risks Arising from FDA Actions
   Speakers: Kelly Savage Day and Carol Brophy, Sedgwick LLP

3. Meeting New Transparency Requirements and Implementing a Scalable Aggregate Spend Solution
   Speaker: John P. Oroho, Principal and Kiaema R. Reid, Senior Regulatory Analyst, Porzio Bromberg & Newman, PC

4. Off-label Investigations: Recent Actions, Settlements and Enforcement Trends
   Speakers: John E. Kelly, Partner, and Cori Annapolen Goldberg, Senior Associate, Fulbright & Jaworski LLP

5. Off-Label Marketing Enforcement and Risks for Medical Device Companies and Service Providers
   Speakers: Michael Volkov and Michael Ruggio, Partners, LeClair Ryan

   Speaker: Kattina V. Barsik, Intellectual Property and Registered Patent Attorney

7. FDA Imports: How to Deal with Holds, Detentions and Refusals
   Speaker: Kyle Sampson, Partner, Hunton & Williams LLP

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

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

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

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