Stay current on the ever-changing regulatory environment with 10 audio recordings of industry experts offering practical guidance for executives, directors, managers, and associates concerned with regulations in the pharmaceutical market.

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. 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
   Speakers: 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
Topics in Regulatory Affairs for Pharmaceuticals