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In your highly regulated industry, it can be challenging to keep up-to-date with the most current research and stay compliant with the latest regulatory requirements. At the same time, many companies are struggling to provide employees with adequate training when professional development budgets are shrinking.

Now available from Ovid, FXConferences offers thousands of professional development hours for your teams, conveniently packaged and delivered as a collection of audio recordings to save you time and money. These presentations address relevant topics for your company to stay current with the ever-changing regulatory environment in the field.

- Choose from 10 industry- and topic-specific collections, each featuring 10 audio-recorded events delivered by international expert speakers (collections are available with or without transcripts)
- Each event includes a 45-minute audio presentation and a 15-minute Q&A session
- Topics are relevant to teams across the entire organization and practical content can be applied to their daily work in R&D, product development, clinical trials, quality assurance, and more
- Use the content in multiple ways – during a team meeting, in your office, or on your daily commute
- Share the recordings with anyone in the company to maximize usage and get everyone on the same page



Turn over for additional details

Who Needs FX Conferences?

Titles

C-Level Executives
 Senior Executives
 Vice Presidents
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 Managers
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 Specialists
 Investigators
 Coordinators

Departments and Teams

Business Development
 Clinical Group
 Compliance
 Engineering
 Health & Safety
 HR, Recruitment/Hiring
 Legal
 Marketing, Market Research
 Medical Writing & Editing

Product Management
 Project Management
 Quality
 Regulatory Affairs
 R&D
 Software Development

Topics in Regulatory Affairs for Medical Devices

1. An Overview of Recent Risk-based Monitoring Guidance from the FDA
2. Centralized vs Onsite Monitoring – Applying FDA’s Risk-based Approach
3. EU Language Requirements for Medical Device Labels: Regulation, Exception, and Risk
4. EU Medical Device Vigilance Reporting Requirements Under MEDDEV 2.12-1 Rev 7
5. Following the 510(k) and 505(b)(2) Pathways to Regulatory Approval
6. Requests for Off-label Information – The FDA Guidance and Its Implications
7. Revisions to EN ISO 14971 and 13485 – What Do They Mean for Device Manufacturers?
8. Taking the Literature Route for EU Medical Device Clinical Evaluations
9. Technical Documentation Requirements for Device Approval in the EU
10. The Revised RoHS Directive and What It Means for Device Manufacturers

Topics in Regulatory Affairs for Pharmaceuticals

1. Centralized vs Onsite Monitoring – Applying FDA’s Risk-based Approach
2. Effectively Managing an FDA Inspection – Opening Meeting to Rapid 483 Response
3. Expedited and Periodic Safety Reporting for Drug Trials
4. FDA Update – Responding to Unsolicited Requests for Off-Label Information
5. Following the 510(k) and 505(b)(2) Pathways to Regulatory Approval
6. Industry Update – Europe’s New Pharmacovigilance Regulations
7. Off-label Promotion – What FDA Looks For & What You Need to Know
8. Preparing for Upcoming Changes in EU Pharmacovigilance Requirements
9. Requests for Off-label Information – The FDA Guidance and Its Implications
10. Successfully Responding to FDA 483s and Warning Letters

Topics in Clinical Trials for Pharmaceuticals

1. Best Practices for Source Documentation and Verification
2. Budget Development Considerations for Clinical Research Sites
3. Centralized vs Onsite Monitoring – Applying FDA’s Risk-based Approach
4. Clinical Study Reports 101: Writing the Synopsis

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5. Conducting Clinical Trials in China – What Does SFDA Want?
6. Implementing the FDA Guidance on Investigator Responsibility
7. Improving Study Feasibility- Why Sites Fail and How to Avoid It
8. Patient Recruitment: How It's Broken and Five Ways to Fix It
9. Site Visit Follow-up – Letters, Notes to File and CAPA Plans
10. Writing Clinical Data Queries – Best Practices and Pitfalls

Topics in Regulatory Affairs for Medical Devices

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10. The Revised RoHS Directive and What It Means for Device Manufacturers

Topics in Quality Assurance for Medical Devices

1. Avoiding FDA 483s, Warning Letters and Recalls with Harmonized Supplier Qualification
2. Device Master Records & Device History Records: Are You Compliant?
3. EU Medical Device Vigilance Reporting Requirements Under MEDDEV 2.12-1 Rev 7
4. Global Clinical Trials & ISO 14155: 2011 Compliance - Are Your Quality Systems Up to Date?
5. How to Document and Implement an FDA-Ready CAPA System
6. Medical Device Design Requirements and Considerations for Risk Management
7. Regulatory Requirements for Medical Device Calibration Programs
8. Revisions to EN ISO 14971 and 13485 – What Do They Mean for Device Manufacturers?
9. Risk Management Throughout the Medical Device Product Lifecycle
10. Sample Size for Design Verification and Validation

Topics in Quality Assurance for Pharmaceuticals

1. 7 Critical FDA Expectations of Senior Management
2. Developing Effective Quality Agreements: Legal and Regulatory Issues
3. Driving Your Quality System With Effective Management Controls
4. FDA's Part 11 Inspections: How to Prepare Yourself to Prove Data Integrity
5. How to Document and Implement an FDA-Ready CAPA System
6. Industry Update – Europe's New Pharmacovigilance Regulations
7. Preparing for Upcoming Changes in EU Pharmacovigilance Requirements
8. Process Validation – Implementing the Finalized FDA Guidance
9. Responding to Audit Recommendations and Observations Without Confrontation or Frustration
10. Using Practical Statistics to Interpret Stability Results

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To learn more, contact your Ovid Representative or sales@ovid.com

Topics in Biotechnology

1. Biomedical Applications and Considerations for Hydrogels
2. Centralized vs Onsite Monitoring – Applying FDA’s Risk-based Approach
3. FDA Update – Responding to Unsolicited Requests for Off-Label Information
4. Implementing the FDA Guidance on Investigator Responsibility
5. Industry Update – European Human Tissues Regulation
6. Off-label Promotion – What FDA Looks For & What You Need to Know
7. Optimizing the Bioprocessing of Future Research Samples: Focusing on Integrity, Quality and Control (webinar)
8. Site Visit Follow-up – Letters, Notes to File and CAPA Plans
9. Who Owns What? Patent Ownership Issues with the Exchange of Biotechnology
10. Writing Clinical Data Queries – Best Practices and Pitfalls

Topics in Legal Affairs

1. FDA Imports: How to Deal with Holds, Detentions and Refusals
2. FDA Update – Responding to Unsolicited Requests for Off-Label Information
3. Managing the Litigation Risks Arising from FDA Actions
4. Meeting New Transparency Requirements and Implementing a Scalable Aggregate Spend Solution
5. Off-label Investigations: Recent Actions, Settlements and Enforcement Trends
6. Off-Label Marketing Enforcement and Risks for Medical Device Companies and Service Providers
7. Off-label Promotion – What FDA Looks For & What You Need to Know
8. Requests for Off-label Information – The FDA Guidance and Its Implications
9. Successfully Responding to FDA 483s and Warning Letters
10. Who Owns What? Patent Ownership Issues with the Exchange of Biotechnology

Topics in Food & Beverage Industry

1. Avoiding and Responding to FDA Import Alerts
2. Contaminated Food Product Insurance – Are You Covered?
3. Effective Sanitation Programs for Listeria Control
4. FDA Targeted Inspections – Determining if Your Facility is High-Risk
5. Food Defense – Regulatory Requirements and New Developments
6. Food Industry Update – Responding to an FDA Form 483
7. FSMA and Traceability – Complying With FDA’s New Requirements
8. The Food Safety Modernization Act – What It Really Means (And What It Doesn’t)
9. The Foreign Supplier Verification Program and What It Means for the Food Industry
10. The Secret FSMA Time Bombs Affecting the International Food Supply Chain

Topics in HR, Leadership, Training and Development

1. Complying with Employment Law When Interviewing & Hiring
2. Finding, Recruiting and On-Boarding Top Talent in the Life Sciences
3. Influencing and Changing the Behaviour of Key Stakeholders and Decision Makers
4. Negotiating with Suppliers – Asking The Right Questions
5. Preventing Harassment in the Workplace
6. Selective Retention – How to Keep the People You Need
7. Six Steps to More Successful Negotiation
8. Stopping Workplace Absenteeism and FMLA Abuse
9. Succession Planning: How to Engage, Retain and Develop Your Best Talent
10. Turning Technical Experts into Great Leaders