Topics in Quality Assurance for Pharmaceuticals

Stay current on the ever-changing pharmaceutical regulatory environment with 10 audio recordings of industry experts offering practical guidance on quality assurance issues.

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

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

3. How to Document and Implement an FDA-Ready CAPA System
   Speaker: Mark Perkins, Principal Consultant, Medical Device QA/RA Consulting

4. Process Validation – Implementing the Finalized FDA Guidance
   Speaker: Todd Arney, Principal Consultant, Technical & Quality Services, LLC

5. FDA’s Part 11 Inspections: How to Prepare Yourself to Prove Data Integrity
   Speaker: John Avellanet, Managing Director & Principal, Cerulean Associates LLC

6. Using Practical Statistics to Interpret Stability Results
   Speaker: Steven Walfish, President, Statistical Outsourcing Services

7. Driving Your Quality System With Effective Management Controls
   Speaker: Vinny Sastri, President, Winovia LLC

8. Responding to Audit Recommendations and Observations Without Confrontation or Frustration
   Speaker: Thomas J Purcell, Principal, Urtech Medical Writing & Consultancy, LLC

9. 7 Critical FDA Expectations of Senior Management
   Speaker: John Avellanet, Managing Director & Principal, Cerulean Associates LLC

10. Developing Effective Quality Agreements: Legal and Regulatory Issues
    Speaker: Alan Minsk, Partner, Arnall Golden Gregory LLP
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