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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
   Speakers: 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