



Training Course Agenda

PDA 569 Drug Delivery Device and Combination Product Risk Management and Safety Assurance Cases

DAY 1

8:30 Welcome and Introductions

9:00 Risk Management Fundamentals
ISO 14971:2019 Standard and AAMI TIR Updates
Risk Analysis for Drug Delivery Combination Products

10:30 Coffee/Tea Break

10:45 Risk Analysis Tool

- Boundary Diagrams for a System of Systems
- Preliminary/System Hazard Analysis for Drug Delivery Combination Products
- Sub System/Use Risk Analysis
- Design and Process FMEA

12:00 Lunch

13:00 Risk Analysis Tool

- Fault Tree and Reliability Analysis
- Top-Down/Bottom-Up Consolidation

Risk Assessment Summary Documentation
Introduction of Safety Assurance Cases I

14:30 Coffee/Tea Break

14:45 Introduction of Safety Assurance Cases II
Traceability/Relations Between Assurance Case, Risk Management, EPRs and Reliability

16:00 End of Training Course