



# 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, ICH Q9, AAMI TIR 105, QMSR, and AAMI TIR/Standards Updates  
Complexity and Challenges for Drug Device Combination Product Risk Management

### 10:30 Break

10:45 Regulator's Perspective - Quality Challenges and Considerations in Injectable Drug-Device Combination Products  
Risk Analysis Tools

- Context and Boundary Analysis
- Preliminary/System Hazard Analysis

### 12:00 Lunch

13:00 Risk Analysis Tools (cont.)

- Use Related Risk Analysis and System FMEA
- Design and Process FMEAs
- Fault Tree and Reliability Analysis
- Top-Down/Bottom-Up Consolidation

Risk Communications and Documentation

### 14:30 Break

14:45 Introduction of Safety Assurance Cases  
Relations between Safety and Risk Management, Design Controls/Quality by Design, and Reliability

### 16:00 End of Training Course