



# Training Course Agenda

PDA 190.1 Assessing Packaging and Processing Extractables/Leachables

## DAY 1

### 8:30 Welcome and Introductions

Current Compliance and 21<sup>st</sup> Century Regulatory Expectations

- 9:00
- Evolving Regulatory Landscape Overview of Global Compliance
  - Expectations, Recommendations, Standards and Reporting

### 10:30 Break

Thresholds and Best Practices: Drug Product Packaging and Medical Devices

- 10:45
- Drugs/Biologics Products and Drugs-Device Combination Products
  - Manufacturing Systems

### 12:00 Lunch

Acquiring and Assessing Extractables: Clarifying Supplier-Pharma Responsibly

- 13:00
- Designing and Justifying Studies
  - Identification and Interpretation

### 14:30 Break

Leachables Study Designs and Application Information

- 14:45
- Designing a Leachables Study
  - Correlating Leachables with Extractables
  - Case Examples Clarifying Supplier-Pharma Responsibly

### 16:00 End of Training Course