



Training Course Agenda

PDA 352 Sterile Pharmaceutical Dosage Forms: Basic Principles

DAY 1

8:30 **Welcome and Introductions**

9:00 Introduction to Sterile Dosage forms
Principles of Sterilization

10:30 **Coffee/Tea Break**

10:45 Cleanroom Facilities

12:00 **Lunch**

13:00 Sterilization Case Reviews
Preformulation, Formulation and Stability

14:30 **Coffee/Tea Break**

14:45 Lyophilization
Primary Packaging

16:00 **End of Day 1**

DAY 2

8:30 **Recap Day 1**

9:00 Compounding, Processing and Filtration
Filling, Sealing and Container-closure Integrity

10:30 **Coffee/Tea Break**

10:45 Particulate Matter: Visible and Subvisible
Aseptic Process Simulation (Media Fill)

12:00 **Lunch**

13:00 Product Specific Validation
Formulation Case Studies
Regulatory Trends

14:30 **Coffee/Tea Break**

14:45 Pyrogen, Bacterial Endotoxin and Sterility Testing

16:00 **End of Training Course**