



Training Course Agenda

PDA #

Title: Extractables and Leachables for Parenteral Applications

577

DAY 1

8:30 **Welcome and Introductions**

9:00 Introduction into E/L: A Helicopter View (Definitions, History, and Regulatory Landscape)

10:00 **Coffee/Tea Break**

10:15 Introduction into Polymers and Glass: Classification, Properties and Composition (Intentionally/Non-Intentionally Added Substances)

Mechanism of Polymer Migration

12:00 **Lunch**

13:00 Recent Developments in Regulatory Landscape (PQRI, USP)

14:30 **Coffee/Tea Break**

14:45 E/L for Single Use Systems

16:00 **End of Day 1**

DAY 2

8:30 Setting Up E/L Studies

Putting Regulatory Requirements into Executables Concepts and Study Designs

10:00 **Coffee/Tea Break**

10:15 Analytical Instrumentation and Methodologies Used in E/L Research

Errors in Chromatographic Screening Methodologies to Discover, Identify and Quantify E/L and How to Avoid these Issues

12:00 **Lunch**

13:00 E/L for Small Volume Parenterals

E/L for Large Volume Parenterals and Simulation Studies

14:30 **Coffee/Tea Break**

14:45 Case Study Presentation: Often Occurring Flaws in the Set-up and Evaluation of E/L Studies for Pharmaceutical Packaging

16:00 **End of Training Course**