Event Agenda

Extractables/Leachables for Parenteral Applications Training Course (PDA 577)

DAY 1	
8:30	Welcome and Introductions
9:00	Introduction into E/L: A Helicopter View (Definitions, History, and Regulatory Landscape)
10:00	**Break**
10:15	Introduction into Polymers and Glass: Classification, Properties and Composition (Intentionally/Non-Intentionally Added Substances) The Mechanisms of Polymer Migration and Material-Drug Product Interaction
12:00	**Lunch**
13:00	Recent Developments in Regulatory Landscape (PQRI, USP, ICH Q3E)
14:30	**Break**
14:45	E/L for (Bio)Manufacturing Equipment: Implementing USP<665> and USP<1665>
16:00	**End of Day 1**
DAY 2	
8:30	Setting Up Extractable and Leachable Studies and the Crucial Role of the Analytical Evaluation Threshold (AET)
9:00	Putting Regulatory Requirements into Executables Concepts and Study Designs
10:00	**Break**
10:15	Analytical Instrumentation and Methodologies Used in E/L Research Errors in Chromatographic Screening (NTA) 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 and Lyophilized Drug Products E/L for Large Volume Parenterals and Simulation Studies
14:30	**Break**
14:45	Combination Products and Their Specific Considerations
16:00	**End of Event**