

PDA Extractables and Leachables Training Course Fall Edition

DAY 1 – Thursday, 23 October 2025	
8:45	Welcome and Setting the Stage Learning objectives
9:15	Introduction & Regulatory Aspects
10:15	Polymers 101
10:30	Networking Coffee Break
10:45	Polymers 101
12:00	Networking Lunch Break
13:00	How to Set-Up & Do's/Don'ts in Extractables Studies
14:45	The AET: Cornerstone of the Qualification
15:00	Networking Coffee Break
15:15	How to Set-Up & Do's/Don'ts in Leachables Studies
16:00	New & Upcoming Regulatory Documents & Impact
16:30	Toxicology 101
17:00	End of Training Course Day 1

DAY 2 – Friday, 24 October 2025	
08:45	Analytical Approaches in E/L
09:15	E/L and SVP Applications
10:15	Networking Coffee Break
10:30	Disposable and SUS
11:45	LVP & Simulation Studies
12:30	Networking Lunch Break
13:30	Special Case: Biologics
14:00	USP Update
14:45	Networking Coffee Break
15:00	Combination Devices
16:00	End of Course