Training Course Agenda

Exploring Container Closure Integrity (CCI) Testing Methods Training Course (PDA 109.1)

DAY 1	
8:30	**Welcome and Introductions**
8:45	Regulatory Requirements CCI introduction, regulatory requirements, and industry trends
9:15	Introduction • CCI assurance throughout product lifecycle • Testing requirement definition – risk based approach • CCI profile & testing strategy development
10:15	**Break**
10:30	CCI Method Fundamentals • CCI defects and commonly used positive controls • "Sizing" and characterization of CCI defects • Evolution of CCI testing technology: liquid flow, gas flow, electron flow (electric current) • Deterministic vs probabilistic definitions
11:15	CCI Test Methods: Overview • Physicochemical methods vs microbiological methods: differences and correlations • Microbial and dye ingress testing • Seal quality testing
12:00	**Lunch**
13:00	Special Topic
13:30	Helium Leak Detection of Syringes
14:00	CCI Testing Technologies • Tracer gas (helium leak detection) • Vacuum and pressure decay • Mass extraction • Headspace analysis • HVLD • OES
14:30	**Break**
14:50	CCI Testing Technologies (cont.)
15:20	Special Topic
15:50	Application Case Studies • Vacuum & pressure decay • Mass extraction
16:20	Day 1 Wrap-Up
16:30	**End of Day 1**

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DAY 2	
9:00	Application Case Studies • Helium leak detection • Optical emission spectroscopy

9:40	Hands-On Training: Rotation 1 & 2
	• All instrument stations
	  ○ HVLD station (PTI)
	  ○ Vacuum decay (Wilco)
	  ○ Headspace (Lighthouse)
	  ○ Helium leak detection (LDA by PTI)
	  ○ Mass extraction (Pfeiffer)
	  ○ OES (Pfeiffer)

10:30	**Break**
10:50	Application Case Studies • Headspace • HVLD
11:30	Hands-On Training: Rotations 3
12:00	**Lunch**
13:00	Application Case Studies • Residual seal force
13:30	Residual Seal Force Machine Demo
13:50	Hands-On Training: Rotations 4&5
14:40	**Break**
15:00	Hands-On Training: Rotation 6
15:25	Approaches to CCI Testing Method Selection • Method selection considerations
16:00	Group Exercise #1 • Method selection review, discussion, Q&A
17:00	**End of Day 2**

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DAY 3	
9:00	**Current Topics** "Case Study: Systemic Evaluation of Vial Container Closure System Suitability at Frozen Conditions" Peter Sargent, Eli Lilly and Company
9:30	Development and Validation of Integrity Test Methods • Method development best practices • Method validation strategy • Pitfalls and solutions • Case study
10:15	Method Development Introduction
10:30	**Break**
11:00	Method Development in Groups (one instrumentation station per group) • Based on a set of samples, work to develop best/sensitive CCI method for routine analysis
12:00	**Lunch**
13:00	Method Development in Groups (one instrumentation station per group) • Based on a set of samples, work to develop best/sensitive CCI method for routine analysis
14:15	Class Discussion
14:30	Recognition and Certification
14:30	**End of Event**