Training Course Agenda

PDA 109.1 Container Closure Systems and Integrity Testing

DAY 1	
8:30	Welcome and Introduction • Learning objectives and benchmarking questionnaire
8:45	Regulatory Requirements • CCI introduction • Regulatory requirements • 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	Helium Leak Detection of Syringes
13:30	CCI Testing Technologies • Tracer gas (helium leak detection) • Vacuum and pressure decay • Mass extraction • Headspace analysis • HVLD • OES
14:30	**Break**
14:45	Airborne Ultrasound – Presentation and Demo
15:30	Application Case Studies • Vacuum & pressure decay • Mass extraction
16:10	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 • HVLD station (PTI) • Vacuum decay (Wilco) • Headspace (Lighthouse) • Helium leak detection (LDA by PTI) • Mass extraction (Pfeiffer) • OES (Pfeiffer)
10:30	**Break**
10:45	Application Case Studies • Headspace • HVLD
11:25	Hands-On Training: Rotation 3 & 4 & 5 (Total 6 rotations, 25min/rotation)
12:40	**Lunch**
13:40	Application Case Studies / Video Residual Seal Force
14:10	Residual Seal Force Machine Demo
14:30	Hands-On Training: Rotation 6 (Total 6 rotations, 25min/rotation)
15:00	**Break**
15:15	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" Coralie Richard, 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 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) (cont.) Based on set of samples, work to develop best/sensitive CCI method for routine analysis
14:15	Class Discussion, Recognition, Certification
14:30	**End of Training Course**