Training Course Agenda

PDA EU00107 Container Closure Integrity Testing – Basic Course

DAY 1 – 25 April 2024	
9:00	**Welcome and Introduction** Learning objectives and benchmarking questionnaire
9:15	**Regulatory Requirements**: CCI introduction, regulatory requirements, and industry trends
9:45	**Introduction** • CCI Assurance throughout Product Lifecycle • Testing requirement definition – risk-based approach • CCI Profile & Testing strategy development
10:30	***Coffee Break (30 min)***
11:00	**CCI test methods: Fundamentals** • CCI defects and commonly used positive controls • Evolution of CCI testing technology: liquid flow, gas flow, electron flow (electric current)
11:30	**CCI test methods: Overview** • Deterministic vs probabilistic definitions • Physicochemical methods vs microbiological methods: differences and correlations Microbial and Dye ingress Testing basics
12:00	***Lunch Break (60 min)***
13:00	**CCI testing technologies** (Approximately 15 min each) • Vacuum and pressure decay • Mass Extraction • Headspace gas ingress • HVLD - PTI • Tracer gas (helium leak detection)
14:00	**Special Topic: API Container Testing using Helium leak detection – Sartorius-Stedim**
14:30	***Coffee break (30 min)***
15:00	**Application Case Studies (Part 1)** • Tracer gas (Helium leak detection) – **LDA a PTI company** • AMI Optical emission spectroscopy for CCI testing – **Pfeiffer**
15:40	**Airborne Ultrasound - PTI**

16:10	**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/ATC)
	  ○ AMI Optical Emission Spectroscopy (Pfeiffer)

16:50	**Day 1 Wrap Up and End of Training Course Day 1**

DAY 2 – 26 April 2024	
08:30	**Welcome**
08:40	**Application Case Studies (Part 2)** • Vacuum and pressure decay - **Wilco** • Mass Extraction – **Pfeiffer**
09:20	**Hands-on training**: Rotation 3,4 • All instrument stations
10:10	***Coffee Break (30 min)***
10:40	**Application Case Studies (Part 3)** • Headspace gas ingress – **Lighthouse** • HVLD - **PTI**
11:20	**Hands-on training**: Rotation 5,6 • All instrument stations
12:00	***Lunch Break (60 min)***
13:00	**Special Topic – Residual Seal Force: A Powerful Vial Seal Quality Test**
13:30	**Special Topic: Systemic Evaluation of Vial Container Closure System Suitability at Frozen Conditions**
14:00	**Approaches to CCI testing method selection** – 20 min
14:30	***Coffee Break (30 min)***
15:00	**Development and Validation of integrity test methods** – 40 min • Method development best practices • Method validation strategy • Pitfalls and solutions
15:40	**Group exercise**: Product life cycle testing and method selection (Class divided into sub-groups)
16:10	**Group Exercise - presentations & discussion**
16:30	***End of Course***