

Training Course Agenda

PDA EU00107 Container Closure Integrity Testing – Basic Course

DAY 1 – April 20 th , 2022	
9:00	Welcome and Introduction Learning objectives and benchmarking questionnaire
9:15	Regulatory Requirements: CCI introduction, regulatory requirements, and industry trends
9:45	Introduction <ul style="list-style-type: none"> CCI Assurance throughout Product Lifecycle Testing requirement definition – risk-based approach CCI Profile & Testing strategy development
10:30	<i>Coffee Break (30 min)</i>
11:00	CCI test methods: Fundamentals <ul style="list-style-type: none"> CCI defects and commonly used positive controls Evolution of CCI testing technology: liquid flow, gas flow, electron flow (electric current)
11:30	Lenox Laser: Laser Drilled Defects
12:00	<i>Lunch Break (60 min)</i>
13:00	CCI test methods: Overview <ul style="list-style-type: none"> Deterministic vs probabilistic definitions Physicochemical methods vs microbiological methods: differences and correlations Microbial and Dye ingress Testing basics
13:30	CCI testing technologies (Approximately 15 min each) <ul style="list-style-type: none"> Vacuum and pressure decay Mass Extraction Headspace gas ingress HVLD - PTI Tracer gas (helium leak detection)
14:30	<i>Coffee break (30 min)</i>
15:00	Special Topic: Case Study: Systemic Evaluation of Vial Container Closure System Suitability at Frozen Condition
15:30	Application Case Studies (Part 1) <ul style="list-style-type: none"> Tracer gas (Helium leak detection) – LDA a PTI company AMI Optical emission spectroscopy for CCI testing – Pfeiffer
16:10	Hands-on training: Rotation 1, 2 <ul style="list-style-type: none"> All instrument stations <ul style="list-style-type: none"> 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 – April 21st, 2022

08:30	Welcome
08:40	Application Case Studies (Part 2) <ul style="list-style-type: none"> • Vacuum and pressure decay - Wilco • Mass Extraction – Pfeiffer
09:20	Hands-on training: Rotation 3,4 <ul style="list-style-type: none"> • All instrument stations
10:10	<i>Coffee Break (30 min)</i>
10:40	Application Case Studies (Part 3) <ul style="list-style-type: none"> • Headspace gas ingress – Lighthouse • HVLDT - PTI
11:20	Hands-on training: Rotation 5,6 <ul style="list-style-type: none"> • All instrument stations
12:00	<i>Lunch Break (60 min)</i>
13:00	Special Topic – Residual Seal Force: A Powerful Vial Seal Quality Test
13:30	Airborne Ultrasound
14:00	Approaches to CCI testing method selection – 20 min
14:30	<i>Coffee Break (30 min)</i>
15:00	Development and Validation of integrity test methods – 40 min <ul style="list-style-type: none"> • 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	<i>End of Course</i>