

Training Course Agenda

PDA EU00107 Container Closure Integrity Testing – Basic Course

DAY 1, 19 October 2023		09:00 – 17:00
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	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 	
12:00	<i>Lunch Break (60 min)</i>	
13:00	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) 	
14:00	Special Topic: Case Study: Systemic Evaluation of Vial Container Closure System Suitability at Frozen Condition	
14:30	<i>Coffee break (30 min)</i>	
15:00	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 	
15:40	Airborne Ultrasound	
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	
17:00	<i>End of Training Course Day 1</i>	

DAY 2, 20 October 2023		08:30-16:30
08:30	Welcome	
08:40	Special Topic: Single Use Systems - Sartorius	
09:10	Application Case Studies (Part 2) <ul style="list-style-type: none"> • Vacuum and pressure decay - Wilco • Mass Extraction – Pfeiffer 	
09:50	Hands-on training: Rotation 3,4 <ul style="list-style-type: none"> • All instrument stations 	
10:30	<i>Coffee Break (30 min)</i>	
11:00	Application Case Studies (Part 3) <ul style="list-style-type: none"> • Headspace gas ingress – Lighthouse • HVLD - PTI 	
11:40	Hands-on training: Rotation 5 <ul style="list-style-type: none"> • All instrument stations 	
12:00	<i>Lunch Break (60 min)</i>	
13:00	Hands-on training: Rotation 5 All instrument stations	
13:20	Special Topic – Residual Seal Force: A Powerful Vial Seal Quality Test	
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 Training Course</i>	