

Training Course Agenda

PDA EU00107 Container Closure Integrity Testing – Basic Course

DAY 1 – 31 May 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	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)
13:30	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	Special Topic: API Container Testing using Helium leak detection – Sartorius-Stedim
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
17:00	<i>End of Day 1</i>

DAY 2 – 1 June 2022

DAY 2 – 1 June 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/ ATC
09:20	Hands-on training: Rotation 3,4 <ul style="list-style-type: none"> • All instrument stations
10:10	Coffee Break (30 min)
10:40	Application Case Studies (Part 3) <ul style="list-style-type: none"> • Headspace gas ingress – Lighthouse • HVLD - PTI
11:20	Hands-on training: Rotation 5,6 <ul style="list-style-type: none"> • All instrument stations
12:00	Lunch Break (60 min)
13:00	Special Topic – Residual Seal Force: A Powerful Vial Seal Quality Test
13:30	Approaches to CCI testing method selection – 20 min
13:50	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
14:30	Coffee Break (30 min)
15:00	Group exercise: Product life cycle testing and method selection (Class divided into sub-groups)
15:30	Group Exercise - presentations & discussion
16:00	End of Course