

PDA Container Closure Integrity Testing - Basic Training Course Fall Edition

DAY 1 – Thursday, 23 October 2025	
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	Networking Coffee Break
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	Special Topic: Lenox Laser
12:00	Networking Lunch Break
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 • Tracer gas (helium leak detection)
14:30	Networking Coffee Break
15:00	Special Topic: Using Helium Leak Detection CCI Testing to Inform Container Closure System Design

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15:30	Application Case Studies (Part 1) <ul style="list-style-type: none"> • Tracer gas (Helium leak detection) • AMI Optical emission spectroscopy for CCI testing
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 ○ Vacuum decay ○ Headspace ○ Helium leak detection ○ Mass extraction ○ AMI Optical Emission Spectroscopy
16:50	Day 1 Wrap Up and End of Training Course Day 1

DAY 2 – Friday, 24 October 2025	
08:30	Welcome
08:40	Application Case Studies (Part 2) <ul style="list-style-type: none"> • Vacuum and pressure decay • Mass Extraction
09:20	Hands-on training: Rotation 3,4 <ul style="list-style-type: none"> • All instrument stations
10:10	Networking Coffee Break
10:40	Application Case Studies (Part 3) <ul style="list-style-type: none"> • Headspace gas ingress • HVLD
11:20	Hands-on training: Rotation 5,6 <ul style="list-style-type: none"> • All instrument stations
12:00	Networking Lunch Break
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

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14:00	Approaches to CCI Testing Method Selection
14:30	<i>Networking Coffee Break</i>
15:00	Development and Validation of Integrity Test Methods <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>