



Training Course Agenda

PDA 109.1 Container Closure Systems and Integrity Testing

DAY 1

8:30 Welcome and Introductions

- Learning objectives and benchmarking questionnaire

8:45 **Regulatory Requirements:** CCI introduction, regulatory requirements, and industry trends

Introduction

- 9:15
- CCI Assurance throughout Product Lifecycle
 - Testing requirement definition – risk-based approach
 - CCI Profile & Testing strategy development

10:00 **Break**

CCI Method Fundamentals

- 10:15
- CCI defects and commonly used positive controls
 - “Sizing” and characterization of CCI defects
 - Evolution of CCI testing technology: liquid flow, gas flow, electron flow (electric current)
 - Deterministic vs probabilistic definitions

CCI test methods: Overview

- 11:00
- Physicochemical methods vs microbiological methods: differences and correlations
 - Microbial and Dye ingress Testing
 - Seal Quality Testing

12:00 **Lunch**

13:00 **CCI test methods: Overview (continued)**

13:15 **Lenox Laser**

14:15 **Break**

CCI testing technologies

- 14:30
- Tracer gas (helium leak detection)
 - Vacuum and pressure decay
 - Mass extraction
 - Headspace analysis
 - HVLD – PTI
 - OES

15:30 **Airborne Ultrasound – Presentation and Demo**

Application Case Studies

- 15:45
- Vacuum & pressure decay
 - Mass Extraction

16:00 **End of Day 1**



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DAY 2

Hands-on training: Rotation 1 & 2

All instrument stations:

8:30

- HVLD station (PTI)
- Vacuum decay (Wilco)
- Headspace (Lighthouse)
- Helium leak detection (LDA by PTI)
- Mass extraction (Pfeiffer/ATC)

Application Case Studies

9:30

- Helium Leak Detection
- Headspace

10:10

Break

Application Case Studies (continued)

10:30

- HVLD

10:50

Hands-On Training: Rotation 3 (Total 5 rotations, 30min/rotation)

12:45

Lunch

13:30

Hands-On Training: Rotation 4 & 5 (Total 5 rotations, 30min/rotation)

Application Case Studies

13:30

- Residual Seal Force

14:30

Break

Current Topics

14:45

- Optical Emission Spectroscopy

Approaches to CCI testing method selection

15:15

- Method selection considerations

15:35

Group Exercise #1 Method Selection review, discussion, Q&A

16:00

End of Day 2



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DAY 3

Current Topics

8:30 "Case Study: Systemic Evaluation of Vial Container Closure System Suitability at Frozen Conditions"
Coralie Richard, Eli Lilly and Company

Development and Validation of integrity test methods

- 9:00**
- Method development best practices
 - Method validation strategy
 - Pitfalls and solutions
 - Case Study

9:45 **Method Development Introduction**

10:15 **Break**

10:30 **Method Development in Groups** (one instrumentation station per group)

- Based on set of samples, work to develop best/sensitive CCI method for routine analysis

12:00 **Lunch**

13:00 **Method Development in Groups** (one instrumentation station per group)

- Based on set of samples, work to develop best/sensitive CCI method for routine analysis

14:00 **Class Discussion**

14:45 **Recognition**

15:00 **End of Course**