

# Container Closure Integrity Testing

## - Basic Course -

### Overview

This training course focuses on theoretical and practical fundamentals of various CCI testing technologies and provides a systematic approach to apply these testing methods for CCI verification throughout drug product lifecycle. The training course will enable the participants to implement CCI testing strategies to ensure adequate drug product protection and be compliant with relevant regulatory and compendia requirements. In this training course, participants gain critical problem solving skills through:

- interactive discussions with a panel of cross-functional technical experts consisting of CCI testing laboratory experts, testing instrument suppliers/manufacturers, and pharmaceutical packaging development engineers
- hands-on testing training on the newest innovations and state-of-the-art instruments
- real-world case studies

### Who Should Attend

- Parenteral drug packaging engineers and formulation scientists
- Laboratory scientific staff and managers
- Parenteral manufacturing staff
- Sterility Quality Assurance
- Regulatory affair scientists
- Pharmaceutical packaging component manufacturing staff

Presentation of Technology, Instruments Demo and Hands-on Training kindly supported by

**several suppliers of Container Closure Integrity testing systems and services**

### Learning Objectives

This training course utilizes lectures, case studies, and interactive hands-on training on testing instruments to provide insight into the latest developments of Container Closure Integrity (CCI) Testing, with focus on achieving the following key objectives:

- Understanding up-to-date regulatory and pharmacopeia requirements on CCI.
- Defining CCI requirements for various container and drug product types using a risk-based approach.
- Explaining working principles of various CCI testing techniques and their practical applications, with focus on deterministic methods such as tracer gas detection (e.g. helium leak detection), electrical conductivity and capacitance (HVLD), vacuum decay leak detection, laser-based gas headspace analysis, mass extraction leak test.
- Selecting and applying appropriate testing methods for both laboratory and in-process testing to formulate comprehensive package integrity verification profiles.
- Defining CCI testing method development and validation approach and best practices.
- Avoiding common issues and pitfalls in CCI testing applications.



**Allison L. Dill, PhD, Eli Lilly and Company**

Allison Dill, Ph.D. is a Senior Research Scientist in Delivery and Device Connected Solutions at Eli Lilly and Company, Indianapolis, IN. She received a BS in Chemistry and Biology from Indiana University, and worked for 4 years as an analytical chemist in Product Research and Development before attending graduate school. She received her Ph.D. in Analytical Chemistry from Purdue University, studying imaging mass spectrometry for disease state characterization. While at Lilly, she has been responsible for the analytical control strategy of many solid oral and parenteral dosage forms and has contributed to several regulatory submissions. Her recent contributions have focused on enabling the delivery of the early phase portfolio within a complex global network with responsibility for the analytical control strategy of both the active pharmaceutical ingredient and the drug product. She is now focusing on the CCI strategy for multiple molecules with a concentration in on-line high voltage leak detection for 100% inspection.

**Thursday, 27 February 2020 9:00 – 17:30**

- 9:00 Welcome and Introduction**
- 9:15 Regulatory Requirements:**  
CCI introduction, regulatory requirements, and industry trends
- 10:00 Introduction**
- CCI assurance throughout product lifecycle
  - Testing requirement definition – risk based approach
  - CCI profile & testing strategy development
- 10:30 Coffee Break**
- 11:00 CCI Test Methods: Fundamentals**
- CCI defects and commonly used positive controls
  - Evolution of CCI testing technology: liquid flow, gas flow, electron flow (electric current)
- 11:40 Methodologies for Sizing CCI Defects Using Gas Flow Dynamics**
- 12:00 Lunch Break**
- 13:00 CCI Test Methods: Overview**
- Deterministic vs probabilistic definitions
  - Physicochemical methods vs microbiological methods: differences and correlations
  - Microbial and dye ingress testing basics
- 14:00 CCI Testing Technologies**
- Vacuum and pressure decay
  - Mass Extraction
  - Headspace analysis
  - HVLD
  - Tracer gas (helium leak detection)
  - Seal quality testing (residual seal force)
- 15:00 Coffee Break**
- 15:30 Current Topics: Industry Best-Practices and Novel Technologies**
- AMI optical emission spectroscopy for CCI testing & demo
- 16:00 Application Case Studies – Part 1**
- Tracer gas (helium leak detection)
  - API container testing using helium leak detection & video
- 17:30 End of Day 1**

**Friday, 28 February 2020 8:30 – 16:30**

- 8:30 Application Case Studies – Part 2**
- Vacuum and pressure decay
  - Mass extraction
- 9:10 Hands-on Training**
- 10:10 Coffee Break**
- 10:40 Application Case Studies – Part 3**
- Headspace analysis
  - HVLD
- 11:20 Hands-on Training**
- 12:00 Lunch Break**
- 13:00 Development and Validation of Integrity Test Methods**
- Method development best practices
  - Method validation strategy
  - Pitfalls and solutions
  - A Case study
- 14:10 Approaches to CCI Testing Method Selection Introduce group exercise:**  
Product life cycle testing and method selection
- 14:30 Coffee Break**
- 15:00 Group Exercise - Breakout**
- 16:00 Group Exercise - Presentations & Discussion**
- 16:30 End of Workshop**



**Brandon Zurawlow**, *Principal Consultant, Containsure*

Brandon is a Principal Consultant working with life-science clients to develop and implement comprehensive container testing strategies through Containsure, his consulting firm founded in 2018. Brandon leverages 8 years of cGMP experience at Whitehouse Laboratories applying compendial chapters such as USP <381>, <660>, <661> and their EP counterparts; as well as the choice, development, and validation of CCI methods now found in USP <1207>. Brandon is a contributor to industry documents and textbook chapters, and a speaker on the topic of compendial container testing and CCI at client sites, training seminars, and conferences in the US, Europe, and Asia. Brandon holds a B.S. in Biology from The College of New Jersey in the US.