Container Closure Integrity Testing

Overview

This workshop focuses on theoretical and practical fundamentals of various CCI testing technologies and provides a systematic approach to applying these testing methods for CCI verification throughout drug product lifecycle. The Workshop 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 Workshop, 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

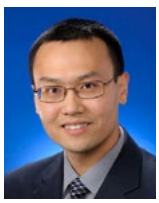
Presentation of Technology, Instruments Demo and Hands-on Training kindly supported by

ATC, Genesis Packaging Technology, Lighthouse, Pfeiffer Vacuum, pti, Wilco

Learning Objectives

This workshop 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



Lei Li, *Ph.D, Associate Engineer Advisor Delivery and Device R&D, Eli Lilly*

Lei Li currently serves as an engineer advisor at Delivery and Device R&D, Eli Lilly and Company. Lei has 9 years of experience in pharmaceutical and medical device industry, with focus on developing API and drug product packaging in support of clinical development and product commercialization, and establishing cold-chain distribution for biologic products. His current responsibilities include developing package integrity verification profiles for Lilly's diverse pipeline portfolio, developing and validating CCI testing methods, and supporting commercial control strategy development for CCI verification throughout drug product and device life cycle. He is a frequent speaker at PDA conferences and author of peer-reviewed articles and book chapters on CCI test methods. Lei Li received his Ph. D. in Analytical Chemistry from West Virginia University; prior to joining Eli Lilly, he worked at GE Plastics as an analytical and material scientist.

Thursday, 9 November 2017 9:00 – 17:30

9:00 **Welcome and Introduction**

9:30 **Opening Remarks:**
CCI Introduction, Regulatory Requirements, and Industry Trends

10:00 **Introduction:**
Packaging Integrity Profile and CCI Testing
- Introduction to container closure integrity
- Testing requirement definition – risk based approach
- CCI Profile & Testing strategy development

10:20 **Introduction to Group Exercise #1:**
Product life cycle testing and method selection

10:30 **Coffee Break**

11:00 **CCI test methods: Fundamentals**

11:30 **CCI test methods: Overview**

12:00 **Lunch Break**

13:00 **Introduction to Group Exercise #2:**
Method Characteristics

13:30 **Advanced CCI Testing Technologies and Seal Quality Testing Technologies**
1. Vacuum and pressure decay
2. Mass Extraction
3. Headspace analysis

15:00 **Coffee Break**

15:30 **Advanced CCI Testing Technologies and Seal Quality Testing Technologies**
4. HVLD
5. Tracer gas (helium leak detection)
7. Seal Integrity method example – residual seal force

17:00 **Group Exercise #1 & #2: Break Out**
Discussion/review of survey results
Day-1 Summary Q&A

17:30 **End of Day 1**

Friday, 10 November 2017 9:00 – 16:30

9:00 **Day-1 Review**

9:10 **Method Application Case Studies – Helium Leak Detection**
1. HeLD for syringe testing (Eli Lilly)
2. API Container Testing using HeLD (Satorius Stedim)

10:00 **Instrument Demo and Hands-on Training**
1. HVLD station
2. Vacuum decay
3. Headspace
4. Helium leak detection
5. Mass extraction & Residual Seal Force

10:30 **Coffee Break**

11:00 **Instrument Demo and Hands-on Training (cont.)**

12:30 **Lunch Break**

13:30 **Group Exercise #2 Method Characteristics Review, Discussion, and Q&A**

13:50 **Development and Validation of Integrity Test Methods**
- Method development best practices
- Method validation strategy
- Pitfalls and solutions

14:30 **Coffee Break**

15:00 **Approaches to CCI Testing Method Selection**
- Method selection considerations
- Class discussion - examples

15:30 **Group Exercise #1 Method Selection Review, Discussion, Q&A**

16:00 **Course Summary**

16:30 **End of Workshop**

Jennifer Roark, *B.S., Manager Chemistry & Container Testing, Eurofins Medical Device Testing*

As Manager of Chemistry and Container Testing, Jennifer Roark oversees testing to support the container and package testing needs of both pharmaceutical and medical device clients. Her group specializes in various CCI testing technologies such as vacuum decay, high-voltage leak detection, FMS oxygen headspace, pressure decay, and dye immersion. She also supervises the physiochemical testing associated with the USP, EP, and JP General Chapters on plastics, elastomeric closures, glass, and container performance testing. Jennifer has more than 22 years of analytical testing experience and serves as one of Eurofins' leading subject matter experts for Extractables and Leachables Testing. She currently serves on ASTM Committee E55 on the Manufacture of Pharmaceutical and Biopharmaceutical Products, Subcommittee E55.04 General Biopharmaceutical Standards, leading the efforts to draft standard WK43945. Jennifer Roark has been involved with small molecule methods development and validation for over 12 years, and has co-published a series of articles on method validation.