Container Closure Integrity Testing

Overview

This workshop 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 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

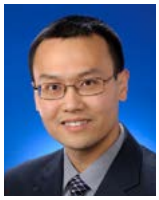
Presentation of Technology, Instruments Demo and Hands-on Training kindly supported by

Genesis Packaging Technology, Lighthouse, Pfeiffer Vacuum, pti, Sartorius Stedim, 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, 1 March 2018 9:00 – 17:30

9:00 **Welcome and Introduction**

9:15 **Regulatory Requirements:**
CCI Introduction, Regulatory Requirements, and Industry Trends

9:45 **CCI Assurance throughout Product Lifecycle**
- Testing requirement definition – risk based approach
- CCI Profile & Testing strategy development

10:30 **Coffee Break**

11:00 **Introduction to Group Exercise #1:**
Product life cycle testing and method selection

11:15 **CCI Test Methods: Fundamentals and Overview**
- CCI defects and commonly used positive controls
- "Sizing" CCI defects using gas flow dynamics
- Evolution of CCI testing technology: liquid flow, gas flow, electron flow (electric current)

12:00 **Lunch Break**

13:00 **CCI Test Methods: Fundamentals and Overview** (continued)
- Deterministic vs probabilistic definitions
- Physicochemical methods vs microbiological methods: differences and correlations
- Microbial and Dye Ingress Testing Basics
- Seal Quality Testing
- Introduction **group exercise #2: Method Characteristics**

14:00 **Advanced CCI Testing Technologies**
- Vacuum and pressure decay
- Mass Extraction
- Headspace analysis
- HVLD

15:00 **Coffee Break**

15:30 **CCI Testing Technologies** (continued)
- Tracer gas (helium leak detection)
- Seal Integrity method example (residual seal force)

16:00 **Current Topics: Industry Best-Practices and Novel Technologies**
1. AMI Optical emission spectroscopy for CCI testing
2. API Container Testing using HeLD; Review Helium leak detection video

17:00 **Group Exercise #2: Method Characteristics**
- review, discussion

Day 1 Review, Q&A

17:30 **End of Day 1**

Friday, 2 March 2018 8:30 – 16:30

8:30 **Application Case Studies – Section 1**
- Vacuum and pressure decay
- Mass Extraction

9:10 **Hands-on Training**

9:50 **Application Case Studies – Section 2**
- Headspace analysis
- HVLD

10:30 **Coffee Break**

11:00 **Application Case Studies – Section 3**
- Tracer gas (helium leak detection)
- SQT (Residual Seal Force)

11:40 **Instrument Demo and Hands-on Training**

12:40 **Lunch Break**

13:40 **Development and Validation of Integrity Test Methods**
- Method development best practices
- Method validation strategy
- Pitfalls and solutions

14:30 **Approaches to CCI Testing Method Selection**
- Method selection considerations
- Class discussion - examples

15:00 **Coffee Break**

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

16:00 **Class Discussion, Recognition, Certification**

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.