TWO-DAY TRAINING COURSE

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

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 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 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.
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.

### Thursday, 16 March 2017 9:00 – 18:00

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<tr>
<td>9:00</td>
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| 9:30 | CCI Introduction, Regulatory Requirements, and Industry Trends  
- Introduction to container closure integrity  
- Regulatory requirements |
| 10:30 | Coffee Break |
| 11:00 | CCI Introduction, Regulatory Requirements, and Industry Trends (Continued)  
- Compendia updates: USP 1207 revision updates, EP  
- PDA TR 27 revision updates |
| 11:30 | Introduction to CCI Test Methodologies  
- Classification: deterministic vs probabilistic; microbiological vs physicochemical methods; by limit of detection  
- Key method performance characteristics  
- Laboratory bench-top testing v.s. online 100% inspection  
- CCI v.s. Seal Integrity Testing |
| 12:00 | Lunch Break |
| 13:00 | Advanced CCI Testing Technologies and Seal Quality Testing Technologies  
1. Vacuum decay  
2. Mass Extraction  
3. Headspace analysis  
4. Headspace moisture |
| 15:00 | Coffee Break |
| 15:30 | Advanced CCI Testing Technologies and Seal Quality Testing Technologies (Continued)  
5. HVLD  
6. Helium leak detection  
7. Seal quality test |
| 17:30 | Day-1 Summary; Case Study Assignment |
| 18:00 | End of Day 1 |

### Friday, 17 March 2017 9:00 – 16:30

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<th>Time</th>
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<tr>
<td>9:00</td>
<td>Day-1 Review</td>
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| 9:30 | Development of CCI Testing Strategy  
- Testing requirement definition  
- Testing strategy development  
- Examples and case study exercise |
| 10:00 | Approaches to CCI Testing Method Selection  
- Method selection considerations  
- Testing method selection guidance  
- Examples and case study exercise |
| 10:30 | Coffee Break |
| 11:00 | Instrument Demo and Hands-on Training:  
1. HVLD station  
2. Vacuum decay  
3. Mass Extraction |
| 12:30 | Lunch Break |
| 13:30 | Instrument Demo and Hands-on Training:  
4. Headspace  
5. Helium leak detection  
6. Seal quality tests |
| 14:30 | Coffee Break |
| 15:00 | Development and Validation of Integrity Test Methods  
- Method development best practices  
- Method validation strategy  
- Pitfalls and solutions |
| 16:00 | Course Summary |
| 16:30 | End of Workshop |

pda.org/eu/CCI2017