

WORKSHOP

Container Closure Integrity Testing ●

OVERVIEW

This workshop will describe the current status of Container Closure Integrity Testing (CCIT) in the industry. Starting with explanations of industry trends and new regulatory requirements, industry case studies involving implementations of modern testing techniques will be described along with approaches for method development and validation. In addition, in-depth laboratory demonstrations will give participants further insight and hands-on experience. The workshop will enable the participant to implement CCI testing strategies to ensure adequate drug product protection and to be compliant with relevant regulatory requirements.

TOPICS & DISCUSSIONS WILL INCLUDE

- The changing regulatory landscape and the use of modern CCI techniques: Industry trends and new regulatory requirements, including updates to the EU Annex 1 and USP <1207>, will be covered and an overview of CCI testing methods will be given.
- Industry case studies: Real world CCI testing case studies will be presented, covering CCI testing practices throughout the product life cycle, from Development to Manufacturing and Quality Control.
- Strategies for statistical sampling in sterile manufacturing: Regulators are paying closer attention to the generation of statistical data. This presentation will provide a framework for developing a statistical sampling strategy.
- Approaches for CCI test method development and validation: Covered topics include the use of positive controls, demonstrating detection of a critical leak, and leak rate modeling.

WHO SHOULD ATTEND

- Packaging engineers and formulation scientists
- Laboratory science staff and managers
- Staff from parenteral development, manufacturing and quality control departments
- Sterility Quality assurance

HOW TO SIGN UP

To register for the workshop and get your ticket, please go to:

www2.lighthouseinstruments.com/EU2019/CCITWorkshop

PRACTICAL INFORMATION

When: Thursday, May 9th 2019

Where: Lighthouse Instruments European Support Center, Science Park, Amsterdam

Time: 9.30 AM - 5.00 PM (Amsterdam time).

Accommodation: Lighthouse has arranged a special rate for all workshop attendees.

For bookings at Hotel V in Amsterdam, you can receive a 10% discount by using the following promotional code when booking online - WBACKV.

Attendees will be invited for a social activity and dinner on May 8th, prior to the Workshop.

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WORKSHOP AGENDA

09:30 - 10:00 Registration and Coffee/Tea

10:00 - 10:05 Welcome and Introduction

10:05 - 10:45 Keynote Address 'Changing Regulatory Environment and the Use of Modern CCIT Techniques':
Brandon Zurawlow, Industry CCI Expert at Containsure.

10:45 - 11:15 Industry case studies: 'Implementing Robust CCIT Practices Throughout the Product Life Cycle':
Dr. Derek Duncan, Director Product Line at Lighthouse Instruments

11:15 - 11:30 Coffee/Tea

11:30 - 12:15 Strategies for statistical sampling in sterile manufacturing:
Dr. James Veale, Founder and President of Lighthouse Instruments

12:15 - 13:15 Lunch

13:15 - 14:00 CCI method development & validation strategies:
Josine Wilmer, Senior Study Manager at Lighthouse Instruments

14:00 - 14:15 Refreshments

14:15 - 16:00 Laboratory demonstrations. Topics will include: CCI during deep cold storage, gas ingress determination, raised stopper sensor qualification, data integrity compliance.

16:00 - 17:00 Q&A Session with CCI Experts. There will also be opportunity for private discussions with a CCI expert. Specific questions can be emailed in advance to CCITexperts@lighthouseinstruments.com.

SPEAKER BIOGRAPHIES



Brandon Zurawlow: Brandon Zurawlow founded Containsure Solutions, a consulting firm, after spending 8 years at AMRI's Whitehouse Laboratories. In his tenure there, Brandon most recently served as Associate Director of Container

Testing, gaining hands-on industry experience and then leading container testing applications such as USP / EP compendia and choice, development, validation, and implementation of deterministic container closure integrity test instruments and methods.



Dr. Derek Duncan: Dr. Duncan began his career at the Dutch Institute for Atomic & Molecular Physics in Amsterdam. He moved into industry holding product and application development positions.

At Lighthouse Instruments since 2003, Dr. Duncan is responsible for developing applications for process monitoring and finished product inspection.



Dr. Jim Veale: Dr. James Veale is the founder and President of Lighthouse Instruments. He received his PhD in Physics from the University of Virginia. His research and business interests are in developing laser spectroscopic methods for

unmet needs in the pharmaceutical industry. His current focus at Lighthouse is on developing laser headspace analysis systems for various applications in the sterile pharmaceutical industry.



Josine Wilmer, MSc: With a degree in Chemistry, from the Radboud University of Nijmegen, Josine Wilmer began her career at Lighthouse Instruments in 2014. In the position Application

Scientist, Josine gained experience in various applications of headspace analysis. Currently, as a Senior Study Manager, Josine is responsible for customer projects, offering a variety of Headspace Analysis solutions. Since Container Closure Integrity Testing is a leading application of headspace analysis, CCI method development has become an area of expertise for Josine.