



Event Agenda

Exploring Container Closure Integrity (CCI) Testing Methods Training Course (PDA 109)

DAY 1

8:30 Welcome and Introductions

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| | Regulatory Requirements |
| 8:45 | <ul style="list-style-type: none">• CCI Introduction• Regulatory Requirements• Industry Trends |
| 9:15 | <ul style="list-style-type: none">• CCI Assurance Through Product Lifecycle• Testing Requirement Definition – Risk-Based Approach• CCI Profile & Testing Strategy Development |

10:00 Break

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| | CCI Test Methods: Fundamentals |
| 10:15 | <ul style="list-style-type: none">• CCI Defects and Commonly Used Positive Controls• Evolution of CCI Testing Technology: Liquid Flow, Gas Flow, Electron Flow (Electric Current) |

11:00 Special Topic: Lenox Laser

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| | CCI Test Methods: Overview |
| 11:30 | <ul style="list-style-type: none">• Deterministic vs Probabilistic Definitions• Physicochemical Methods vs Microbiological Methods: Differences and Correlations• Microbial and Dye Ingress Testing Basics |

12:15 Lunch

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| | CCI Testing Technologies |
| 13:15 | <ul style="list-style-type: none">• Vacuum and Pressure Decay• Mass Extraction• Headspace Gas Ingress• HVLD - PTI• Tracer Gas (Helium Leak Detection)• OES |

14:30 Helium Leak Detection of Syringes

15:00 Break

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| | Application Case Studies (Part 1) |
| 15:20 | <ul style="list-style-type: none">• Tracer gas (Helium leak detection)• Optical Emission Spectroscopy for CCI Testing |

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| | Hands-On Training: Rotation 1, 2 |
| 16:00 | <ul style="list-style-type: none">• All Instrument Stations<ul style="list-style-type: none">○ HVLD Station (PTI)○ Vacuum Decay (Wilco)○ Headspace (Lighthouse)○ Helium Leak Detection (LDA by PTI)○ Mass Extraction (Pfeiffer/ATC)○ Optical Emission Spectroscopy (Pfeiffer) |

17:00 End of Day 1



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DAY 2

8:30 Recap Day 1

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| 8:40 | Application Case Studies (Part 2) <ul style="list-style-type: none">• Vacuum and Pressure Decay• Mass Extraction |
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| 9:20 | Hands-On Training: Rotation 3,4 <ul style="list-style-type: none">• All Instrument Stations |
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10:10 Break

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| 10:30 | Application Case Studies (Part 3) <ul style="list-style-type: none">• Headspace Gas Ingress – Lighthouse• HVLD - PTI |
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| 11:10 | Hands-On Training: Rotation 5,6 <ul style="list-style-type: none">• All Instrument Stations |
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| 11:50 | Special Topic <ul style="list-style-type: none">• Residual Seal Force: A Powerful Vial Seal Quality Test & Demo |
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12:30 Lunch

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| 13:30 | Special Topic <ul style="list-style-type: none">• Systemic Evaluation of Vial Container Closure System Suitability at Frozen Conditions & Using Helium Leak Detection CCI Testing to Inform Container Closure System Design |
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| 14:00 | Approaches to CCI Testing Method Selection |
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14:30 Break

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| 15:00 | Development and Validation of Integrity Test Methods <ul style="list-style-type: none">• Method Development Best Practices• Method Validation Strategy• Pitfalls and Solutions |
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| 15:40 | Group exercise <ul style="list-style-type: none">• Product Life Cycle Testing and Method Selection |
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| 16:10 | Group Exercise <ul style="list-style-type: none">• Presentations & Discussion |
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16:30 End of Event