

Thursday, 27 February 2020

9:00 – 17:00

09:00	<b>Welcome and Introduction</b>
09:15	<b>Regulatory Requirements</b> CCI introduction, regulatory requirements, and industry trends
9:45	<b>Introduction</b> <ul style="list-style-type: none"><li>• CCI Assurance throughout Product Lifecycle</li><li>• Testing requirement definition – risk-based approach</li><li>• CCI Profile &amp; Testing strategy development</li></ul>
10:30	<i>Coffee Break</i>
11:00	<b>CCI Test Methods: Fundamentals</b> <ul style="list-style-type: none"><li>• CCI defects and commonly used positive controls</li><li>• Evolution of CCI testing technology: liquid flow, gas flow, electron flow (electric current)</li></ul>
11:30	<b>Methodologies for Sizing CCI Defects Using Gas Flow Dynamics</b>
12:00	<i>Lunch Break</i>
13:00	<b>CCI Test Methods: Overview</b> <ul style="list-style-type: none"><li>• Deterministic vs probabilistic definitions</li><li>• Physicochemical methods vs microbiological methods: differences and correlations</li><li>• Microbial and Dye ingress Testing basics</li></ul>
13:30	<b>CCI Testing Technologies</b> <ul style="list-style-type: none"><li>• Vacuum and pressure decay</li><li>• Mass Extraction</li><li>• Headspace gas ingress</li><li>• HVLD</li><li>• Tracer gas (helium leak detection)</li></ul>
14:30	<i>Coffee Break</i>
15:00	<b>Special Topic: Preventative Studies Critical Dimensions and Capping</b>
15:30	<b>Application Case – Part 1</b> <ul style="list-style-type: none"><li>• Tracer gas (Helium leak detection)</li><li>• Vacuum and pressure decay</li></ul>
16:10	<b>Hands-on Training</b> <ul style="list-style-type: none"><li>• All instrument stations<ul style="list-style-type: none"><li>○ HVLD station</li><li>○ Vacuum decay</li><li>○ Headspace</li><li>○ Helium leak detection</li><li>○ Mass extraction</li><li>○ AMI Optical Emission Spectroscopy</li></ul></li></ul>

16:50	<b>Day 1 Review, Q&amp;A</b>
17:00	<i>End of Day 1</i>

Friday, 28 February 2020		8:30 – 16:00
08:30	<b>Welcome</b>	
08:40	<b>Application Case Studies - Part 2</b> <ul style="list-style-type: none"> <li>• Mass Extraction</li> <li>• AMI Optical emission spectroscopy for CCI testing</li> </ul>	
09:20	<b>Hands-on Training</b> <ul style="list-style-type: none"> <li>• All instrument stations</li> </ul>	
10:10	<i>Coffee Break</i>	
10:40	<b>Application Case Studies – Part 3</b> <ul style="list-style-type: none"> <li>• Headspace gas ingress</li> <li>• HVLD</li> </ul>	
11:20	<b>Hands-on training</b> <ul style="list-style-type: none"> <li>• All instrument stations</li> </ul>	
12:00	<i>Lunch Break</i>	
13:40	<b>Approaches to CCI Testing Method Selection</b> <b>Method Selection Case Studies</b>	
13:00	<b>Development and Validation of Integrity Test Methods</b> <ul style="list-style-type: none"> <li>• Method development best practices</li> <li>• Method validation strategy</li> <li>• Pitfalls and solutions</li> </ul>	
14:20	<b>Introduce Group Exercise</b> Product life cycle testing and method selection	
14:30	<i>Coffee Break</i>	
15:00	<b>Group Exercise - Breakout</b>	
15:30	<b>Group Exercise - Presentations &amp; Discussion</b>	
16:00	<i>End of Course</i>	