

## Thursday, 27 February 2020

**Training Location:**  
Mercure Lenzburg Krone  
Kronenplatz 20  
5600 Lenzburg  
Switzerland

09:00	<b>Welcome and Introduction</b>
09:15	<b>Holistic CCI Approach</b>
10:00	<b>Regulatory Requirements:</b> <ul style="list-style-type: none"><li>- USP&lt;1207&gt;</li><li>- EU Annex 1</li><li>- ICH Q9</li></ul>
10:45	<b>Coffee Break</b>
11:00	<b>Technology Overview</b> <ul style="list-style-type: none"><li>- Differential pressure</li><li>- High voltage</li><li>- Headspace analysis</li><li>- Tracer Gas / Mass Spectroscopy</li></ul>
12:00	<b>Test Method Selection</b> <ul style="list-style-type: none"><li>- Understanding and application of relevant criteria</li><li>- Adapted feasibility approach</li></ul>
12:30	<b>Lunch Break</b>
13:45	<b>Positive Controls</b> <ul style="list-style-type: none"><li>- Fundamentals</li><li>- Types</li></ul>
14:45	<b>Method Development and Validation</b> <ul style="list-style-type: none"><li>- Process analysis</li><li>- FMEA</li><li>- Fixture qualification</li><li>- Method qualification</li><li>- Test method validation</li></ul>
15:30	<b>Coffee Break</b>
15:45	<b>Manufacturing Control Strategy</b> <ul style="list-style-type: none"><li>- QC lab or 100% inspection</li><li>- Risk Assessment</li><li>- Sealing and Capping Forces</li><li>- Supply CCI in lieu of sterility on stability</li><li>- Chain and end-users exposures</li><li>- Visual Inspection</li><li>- Leak Testing</li></ul>
16:30	<b>Wrap-up Day 1</b>
17:00	<b>End of Day 1</b>
19:00	<b>Networking Event</b>

## Friday, 28 February 2020

**Training Location:**  
Wilco AG  
Rigackerstrasse 11  
5610 Wohlen  
Switzerland

08:30	<b>Recap Day 1 &amp; Open Questions</b>
09:00	<b>Lab Session 1 (Hands-on)</b> <b>Positive Controls</b> <ul style="list-style-type: none"><li>- Preparation</li><li>- Pros and Cons</li><li>- Verification with He Mass spec.</li></ul> <b>Lab Equipment (DP/HSA)</b> <ul style="list-style-type: none"><li>- Operation of lab equipment</li><li>- Considerations on installation sites</li><li>- Daily business considerations</li><li>- Method development</li><li>- Use of positive controls</li></ul>
10:45	<b>Coffee Break</b>
11:00	<b>Hands-on Inline System</b> <ul style="list-style-type: none"><li>- System presentation and training</li><li>- Calibration procedures</li><li>- Validation runs</li><li>- Considerations on installation site</li><li>- Daily business considerations</li></ul>
12:15	<b>Lunch Break</b>
13:45	<b>Lab Session 2 (Hands-on) (cont.)</b> <ul style="list-style-type: none"><li>- Operation of inline equipment</li><li>- Daily business considerations</li><li>- Considerations on installation site</li><li>- Method development</li></ul>
14:30	<b>Coffee Break</b>
14:45	<b>Product Life Cycle</b> <ul style="list-style-type: none"><li>- Feasibility trials Implementation</li><li>- Day to day use</li><li>- Maintenance</li><li>- Change control</li><li>- New technologies</li><li>- Retrofits</li><li>- Line modifications</li></ul>
15:30	<b>Wrap-up</b>
16:00	<b>End of Course</b>