

## Training Course Agenda

# PDA EU00163 All about Pre-Filled Syringe Systems

DAY 1 – 20 April 2023	
9:00	<b>Welcome and Introduction</b>
9:15	<b>Overview and Introduction into Pre-Filled Syringe Market</b> <ul style="list-style-type: none"> <li>• Overview &amp; Trends</li> <li>• Stakeholders</li> <li>• User's perspective</li> </ul>
10:15	<b>Technical Aspects</b> <ul style="list-style-type: none"> <li>• Syringe</li> <li>• Stopper</li> <li>• Plunger</li> <li>• Needle</li> <li>• Needle shield</li> <li>• Safety Devices</li> <li>• Autoinjector</li> <li>• Regulatory guidelines and technical standards: EU / US / ISO / ...</li> </ul>
10:45	<i>Coffee Break</i>
11:15	<b>Technical Aspects (cont.)</b>
11:45	<b>Overview and Introduction into Drug-Syringe Interactions</b> <ul style="list-style-type: none"> <li>• Aggregation</li> <li>• Degeneration</li> <li>• Oxidation</li> <li>• Viscosity</li> <li>• Bubbles</li> </ul>
12:15	<b>Overview and Introduction to Manufacturing Process of Pre-Filled Syringes</b> <ul style="list-style-type: none"> <li>• Barrel forming</li> <li>• Washing</li> <li>• Siliconization</li> <li>• Sterilization</li> <li>• Regulatory guidelines and technical standards: EU / US / ISO / ...</li> </ul>
13:00	<i>Lunch Break</i>
14:00	<b>Fill and Finish</b> <ul style="list-style-type: none"> <li>• Bag opening</li> <li>• Tub opening</li> <li>• Filling</li> <li>• Stoppering</li> </ul>
14:45	<b>Hands-on Session 1</b>
15:30	<i>Coffee break</i>
16:00	<b>Hands-on Session 1 (cont.)</b>
16:45	<b>Q&amp;A</b>
17:00	<i>End of Day 1</i>

DAY 2 – 21 April 2023	
09:00	<b>Recap Day 1</b>
09:15	<b>The Syringe (Body) - Example Specification</b> <ul style="list-style-type: none"> <li>• Materials (glass, polymer)</li> <li>• Shape</li> <li>• Cone</li> <li>• Diameter</li> <li>• Mechanical properties</li> <li>• Chemical Properties</li> <li>• Siliconization</li> <li>• Impact of different drug properties</li> <li>• Needle shield, tip cap</li> <li>• Nest, tub</li> <li>• Integrated needles, luer lock adapter, cone types</li> <li>• Back stops, rods</li> <li>• Regulatory guidelines and technical standards: EU / US / ISO / ...</li> </ul>
10:15	<i>Coffee Break</i>
10:45	<b>Plunger Stopper, Needle Shields, Tip Caps</b> <ul style="list-style-type: none"> <li>• Materials</li> <li>• Physical properties</li> <li>• Chemical properties</li> <li>• Washing</li> <li>• Siliconization</li> <li>• Impact of different drug properties</li> <li>• Syringe system functionality</li> <li>• Regulatory guidelines and technical standards: EU / US / ISO / ...</li> </ul>
11:45	<b>Manufacturing Aspects Regarding Filling, Finishing and Assembly</b> <ul style="list-style-type: none"> <li>• Rod insertion and labeling</li> <li>• Combi filling</li> <li>• Robot filling</li> <li>• New trends</li> </ul>
12:30	<i>Lunch Break</i>
13:30	<b>Hands-on Session 2</b>
14:30	<b>Q&amp;A</b>
15:00	<i>End of Course</i>