

Training Course Agenda

PDA EU00163 All about Pre-Filled Syringe Systems

DAY 1, 19 October 2023	
9:00	Welcome and Introduction
9:15	Overview and Introduction into Pre-Filled Syringe Market <ul style="list-style-type: none"> • Overview & Trends • Stakeholders • User's perspective
10:15	Technical Aspects <ul style="list-style-type: none"> • Syringe • Stopper • Plunger • Needle • Needle shield • Safety Devices • Autoinjector • Regulatory guidelines and technical standards: EU / US / ISO / ...
10:45	<i>Coffee Break</i>
11:15	Technical Aspects (cont.)
11:45	Overview and Introduction into Drug-Syringe Interactions <ul style="list-style-type: none"> • Aggregation • Degeneration • Oxidation • Viscosity • Bubbles
12:15	Overview and Introduction to Manufacturing Process of Pre-Filled Syringes <ul style="list-style-type: none"> • Barrel forming • Washing • Siliconization • Sterilization • Regulatory guidelines and technical standards: EU / US / ISO / ...
13:00	<i>Lunch Break</i>
14:00	Fill and Finish <ul style="list-style-type: none"> • Bag opening • Tub opening • Filling • Stoppering
14:45	Hands-on Session 1
15:30	<i>Coffee break</i>
16:00	Hands-on Session 1 (cont.)
16:45	Q&A
17:00	<i>End of Day 1</i>

DAY 2, 20 October 2023	
09:00	Recap Day 1
09:15	The Syringe (Body) - Example Specification <ul style="list-style-type: none"> • Materials (glass, polymer) • Shape • Cone • Diameter • Mechanical properties • Chemical Properties • Siliconization • Impact of different drug properties • Needle shield, tip cap • Nest, tub • Integrated needles, luer lock adapter, cone types • Back stops, rods • Regulatory guidelines and technical standards: EU / US / ISO / ...
10:15	Coffee Break
10:45	Plunger Stopper, Needle Shields, Tip Caps <ul style="list-style-type: none"> • Materials • Physical properties • Chemical properties • Washing • Siliconization • Impact of different drug properties • Syringe system functionality • Regulatory guidelines and technical standards: EU / US / ISO / ...
11:45	Manufacturing Aspects Regarding Filling, Finishing and Assembly <ul style="list-style-type: none"> • Rod insertion and labeling • Combi filling • Robot filling • New trends
12:30	Lunch Break
13:30	Hands-on Session 2
14:30	Q&A
15:00	End of Course