

Training Course Agenda

PDA EU00135 Best Practices for Glass Primary Containers

W. Europe Summer Time (UTC +2)

Day 1, 12 April 2023		
9:00	Welcome and Introduction Participants' Expectations	
	Manufacture and Characteristics of Glass as Primary Packaging Material	
9:15	Glass Science <ul style="list-style-type: none"> • Chemical structure • Physical properties • Different glass types in the pharmaceutical industry 	Folker Steden, SCHOTT
10:30	<i>Coffee Break</i>	
11:00	Glass Making <ul style="list-style-type: none"> • Glass Melting • Tubing Production • Container conversion • Molded containers 	Folker Steden, SCHOTT
12:00	<i>Lunch Break</i>	
13:00	Glass Strength and Fracture Mechanics <ul style="list-style-type: none"> • Glass Breakage – Fundamentals • Assessment of Flaws • Fractography - Fundamentals 	Florian Maurer, SCHOTT
14:30	Visit SCHOTT Tubular Glass Manufacturing	
16:00	<i>Coffee Break</i>	
	Receiving Inspection of Glass Primary Packaging Material	
16:15	Requirements from Pharmacopoeias (EP, JP, USP) and Incoming Inspection <ul style="list-style-type: none"> • Overview Pharmacopoeia • Testing Parameters • Testing Methods, Equipment, Tools • Defects and PDA Technical Report #43 	Karl Siemoneit, Sanofi-Aventis
17:00	How to Do in Practice <ul style="list-style-type: none"> • Sampling (AQL) • Sample size • Testing 	Karl Siemoneit, Sanofi-Aventis

	<ul style="list-style-type: none"> • Documentation • Supplier certification & test reduction 	
17:30	End of Day 1	
Day 2, 13 April 2023		
9:00	Recap of Learning Objectives Day 1	
	Receiving Inspection of Glass Primary Packaging Material (cont.)	
09:30	Inspection of Glass: What to Consider, Common Problems <ul style="list-style-type: none"> • Practical examples, case study 	Karl Siemoneit, Sanofi-Aventis
10:15	Coffee Break	
10:45	Coordination Process Packaging Manufacturer and Customer <ul style="list-style-type: none"> • Important parameters Measured variables Regulating variables Control loop Interaction with manufacturer Effort reduction 	Karl Siemoneit, Sanofi-Aventis
	Machine Use of Glass Primary Packaging Material	
11:15	Machine Runability of Glass Primary Packaging <ul style="list-style-type: none"> • Roughness of glass primary packaging material Geometrics, tolerances Quality of glass Impact of machine speed 	Markus Heinz, Syntegon Technology
11:45	Lunch Break	
12:45	Use of Glass Primary Packaging Material Along the Process Chain <ul style="list-style-type: none"> • Considering different kind of containers, bulk and nested: Washing machine Depyrogenation tunnel Filling machines Stoppering Rod insertion and labelling for syringes Conveyor belts Automated inspection Packaging line 	Markus Heinz, Syntegon Technology
13:30	Case Study: What to Consider, What are Common Problems, How to Avoid Them <ul style="list-style-type: none"> • Collision analysis • Basics of good glass handling • Technologies to avoid glass to glass contact 	Markus Heinz, Syntegon Technology
14:15	Coffee Break	
14:45	Coordination Process Primary Packaging Material and Machine <ul style="list-style-type: none"> • Important parameters Control loop Synchronization 	Markus Heinz, Syntegon Technology
15:30	Q&A	
16:00	Summary & End of Training Course	