



Training Course Agenda

PDA EU00189 Best Practices for Glass Primary Containers

W. Europe Summer Time (UTC +2)

11-12 June 2024

| 08:45 | Welcome and Introduction Participants' Expectations | | |
|-------------|--|------------------------------------|--|
| lanufacture | and Characteristics of Glass as Primary Packaging Material | | |
| | Glass Science | | |
| | Chemical structure | | |
| 9:00 | Physical properties | Folker Steden, SCHOTT | |
| | Different glass types in the pharmaceutical industry | | |
| 9:45 | Glass Making | | |
| | Glass Melting | | |
| | Tubing Production | Folker Steden, SCHOTT | |
| | Learning from Mistakes: Glass Defects | | |
| 10:40 | Coffee Break | 1 | |
| | Glass Converting Process | | |
| | Glass containers for pharmaceutical application | | |
| | Container production from glass tubing | | |
| | Factors that affect surface chemistry in glass | | |
| 10:55 | conversion to vials | Serena Panighello, Stevanato Group | |
| | Molded container production | | |
| | Additional proprieties with internal and/or external | | |
| | treatment/coating | | |
| 12:20 | Lunch Break | | |
| | Glass Strength and Fracture Mechanics | | |
| | Glass Breakage – Fundamentals | | |
| 13:20 | Assessment of Flaws | Florian Maurer, SCHOTT | |
| | Fractography - Fundamentals | | |
| 14:50 | Practice and Hands-on Demonstration: Fractography | Florian Maurer, SCHOTT | |
| 15:20/15:35 | Visit SCHOTT Tubular Glass Manufacturing | | |
| 17:05 | Coffee Break | | |



| 17:20 18:00 Day 2, 12 | Requirements from Pharmacopoeias (EP, JP, USP) and Incoming Inspection • Overview Pharmacopoeia • Testing Parameters • Testing Methods, Equipment, Tools • Defects and PDA Technical Report #43 June 2024 | Sonja Wicks, Vetter Pharma |
|-----------------------------|--|-----------------------------------|
| 08:45 | How to Do in Practice Sampling (AQL) Sample size Testing Documentation Supplier certification & test reduction | Sonja Wicks, <i>Vetter Pharma</i> |
| Receiving Ins | pection of Glass Primary Packaging Material (cont.) | |
| 09:15 | Inspection of Glass: What to Consider, Common Problems Practical examples, case study | Sonja Wicks, <i>Vetter Pharma</i> |
| 10:00 | Coffee Break | |
| 10:30 | Coordination Process Packaging Manufacturer and Customer Important parameters Measured variables Regulating variables Control loop Interaction with manufacturer Effort reduction | Sonja Wicks, <i>Vetter Pharma</i> |
| Machine Use | of Glass Primary Packaging Material | |
| 11:00 | Machine Runability of Glass Primary Packaging 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 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 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 Important parameters Control loop Synchronization | Markus Heinz, Syntegon Technology |
| 15:15 | Questionnaire Elaboration by participants Presentation of the correct solution and discussion of the results | |
| 16:00 | Final Q&A & Check if all expectations are fulfilled | |
| 16:15 | End of Training Course | |