

2020 PDA EUROPE

# Best Practices for Glass Primary Containers

**SCHOTT**

glass made of ideas

WITH SITE VISIT  
AT SCHOTT  
TUBULAR GLASS  
MANUFACTURING



**6-7 OCTOBER 2020**  
NOVOTEL MAINZ  
MAINZ, GERMANY

WELCOME TO  
MAINZ



# Best Practices for Glass Primary Containers

Glass vials, ampoules, syringes and cartridges are commonly used in packaging of parenteral pharmaceuticals. Good glass handling practices are essential to assuring glass-based container performance as intended in maintaining the safety and efficacy of the drug product. The two-day course will offer **insights into the science of glass and its inherent properties**. It will review container design and dimensioning, cover glass strength and fracture mechanics as well as review the fundamental principles of good glass handling and inspection. The course will follow step-by-step the processes for packaging of parenterals in vials, ampoules, cartridges and syringes. Further insights into glass breakage including an overview of fracture analysis using fractography will be presented.

## Who Should Attend

- Packaging engineers
- Quality personnel
- Filling line technicians
- Supervisors and engineering support
- Those responding to failure complaints
- Root cause investigators

## Prerequisites

- Technical aptitude
- Some familiarity with pharmaceutical fill/finish processes

## Learning Objectives

### Upon completion of the course the participant

- Understands the nature of glass
- Knows what glass breakage causes
- Is aware of regulatory requirements and how to perform QC incoming inspection
- Knows how to inspect glass containers for breakage-relevant defects
- Is able to apply the knowledge to avoid glass breakage in the filling line
- Is able to apply a structured way of evaluating in case of glass breakage
- Is able to 'read' from the splinters and broken glass



**Felix Brosi**, PhD, Product Manager Pharmaceutical Tubing, SCHOTT

Felix Brosi studied chemistry before he obtained his PhD in inorganic chemistry from the Freie Universität Berlin, Germany. In May 2017, he joined the Scientific Services and Product Management team of SCHOTT AG Tubing being responsible for providing global scientific support. This primarily includes glass trainings for converters and pharmaceutical companies, fault analyses of defect samples as well as advice on specific regulations.



**Florian Maurer**, PhD, Senior Scientist for Strength, Reliability & Lifetime and Fractography, SCHOTT

Florian Maurer earned his doctorate in Materials Science and Engineering in 2007 at Darmstadt University of Technology, Germany. Since then, he has been with SCHOTT with focus on strength, reliability & lifetime and fracture analysis of glass primary packaging containers used in the pharmaceutical industry. Florian and his team provide a powerful toolbox for the identification, characterization and the assessment of flaw-creating mechanisms, which can occur during manufacturing, processing and transportation of glassware.




**Karl Siemoneit**, PhD, Head Quality Supplier Management, Sanofi-Aventis

Karl Siemoneit is Head of Quality Supplier Management for the Sanofi Insulin manufacturing operations in Frankfurt-Hoechst. This role includes incoming testing and release of primary packaging components such as vials, cartridges and closure components. Karl has over 20 years industrial experience in the IVD / medical device and pharmaceutical industry. He has held various management positions in technical and quality areas. Karl Siemoneit obtained his degree in Biology from the University of Ulm, Germany.



**Klaus Ullherr**, Senior Product Manager, Syntegon Technology (former Bosch Packaging Technology)

Klaus Ullherr has a degree in electrical engineering. After university, he worked for several years as a project manager in the electrical industry. In March 2000, he joined Robert Bosch GmbH, Packaging Technology, Product Division Pharma Liquid (now Syntegon Technology). During the first two years, he was responsible for handling complex customer orders. Since 2002, he is product manager for the business fields syringes and filling systems with global product responsibility. His main responsibilities are Market Analysis, Initiating New Product Developments, and Business development. He is an expert for syringe processing. He is member of the "PDA Interest Group Pre-filled Syringes" and works as an expert in the DIN/ISO group for primary packaging. He is a popular speaker at conferences covering trends and solutions for fill/finish equipment especially for pre-filled syringes and single-use-filling-systems.

<b>Tuesday, 6 October 2020</b>		<b>9:00 – 17:45</b>
<b>9:00</b>	<b>Welcome and Introduction Participants' Expectations</b>	All
<b>Manufacture and Characteristics of Glass as Primary Packaging Material</b>		
<b>9:15</b>	<b>Glass Science</b> <ul style="list-style-type: none"> <li>• Chemical structure</li> <li>• Physical properties</li> <li>• Different glass types in the pharmaceutical industry</li> </ul>	Felix Brosi
<b>10:30</b>	<b>Coffee Break</b>	
<b>11:00</b>	<b>Glass Making</b> <ul style="list-style-type: none"> <li>• Glass Melting</li> <li>• Tubing Production</li> <li>• Container conversion</li> <li>• Molded containers</li> </ul>	Felix Brosi
<b>12:00</b>	<b>Lunch Break</b>	
<b>13:00</b>	<b>Glass Strength and Fracture Mechanics</b> <ul style="list-style-type: none"> <li>• Glass Breakage - Fundamentals</li> <li>• Assessment of Flaws</li> <li>• Fractography - Fundamentals</li> </ul>	Florian Maurer
<b>14:30</b>	<b>Visit SCHOTT Tubular Glass Manufacturing</b>	
<b>16:00</b>	<b>Coffee Break</b>	
<b>Receiving Inspection of Glass Primary Packaging Material</b>		
<b>16:15</b>	<b>Requirements from Pharmacopoeias (EP, JP, USP) and Incoming Inspection</b> <ul style="list-style-type: none"> <li>• Overview Pharmacopoeia</li> <li>• Testing Parameters</li> <li>• Testing Methods, Equipment, Tools</li> <li>• Defects and PDA Technical Report #43</li> </ul>	Karl Siemoneit
<b>17:00</b>	<b>How to Do in Practice</b> <ul style="list-style-type: none"> <li>• Sampling (AQL)</li> <li>• Sample size</li> <li>• Testing</li> <li>• Documentation</li> <li>• Supplier certification &amp; test reduction</li> </ul>	Karl Siemoneit
<b>17:45</b>	<b>End of Day 1</b>	

<b>Wednesday, 7 October 2020</b>		<b>9:00 – 16:00</b>
<b>9:00</b>	<b>Recap of Learning Objectives Day 1</b>	All
<b>Receiving Inspection of Glass Primary Packaging Material (cont.)</b>		
<b>9:30</b>	<b>Inspection of Glass: What to Consider, Common Problems</b> • Practical examples, case study	Karl Siemoneit
<b>10:15</b>	<b>Coffee Break</b>	
<b>10:45</b>	<b>Coordination Process Packaging Manufacturer and Customer</b> • Important parameters   Measured variables   Regulating variables   Control loop   Interaction with manufacturer   Effort reduction	Karl Siemoneit
<b>Machine Use of Glass Primary Packaging Material</b>		
<b>11:15</b>	<b>Machine Runability of Glass Primary Packaging Material</b> • Roughness of glass primary packaging material   Geometrics, tolerances   Quality of glass   Impact of machine speed	Klaus Ullherr
<b>11:45</b>	<b>Lunch Break</b>	
<b>12:45</b>	<b>Use of Glass Primary Packaging Material Along the Process Chain</b> Considering different kind of containers, bulk and nested: • Washing machine   Depyrogeneration tunnel   Filling machines   Stoppering   Rod insertion and labelling for syringes   Conveyor belts   Automated inspection   Packaging line	Klaus Ullherr
<b>13:30</b>	<b>Case Study</b> <b>What to Consider, What are Common Problems, How to Avoid Them</b> • Collision analysis • Basics of good glass handling • Technologies to avoid glass to glass contact	Klaus Ullherr
<b>14:15</b>	<b>Coffee Break</b>	
<b>14:45</b>	<b>Coordination Process Primary Packaging Material and Machine</b> • Important parameters   Control loop   Synchronization	Klaus Ullherr
<b>15:30</b>	<b>Q &amp; A</b>	All
<b>16:00</b>	<b>Summary &amp; End of Training Course</b>	

## VENUE

### Novotel Mainz

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## DIRECTIONS

© Google For directions click on the picture, scan the QR-code or go to <http://bit.ly/2PscW2n>

## CONTACT INFORMATION

### Registration Customer Care

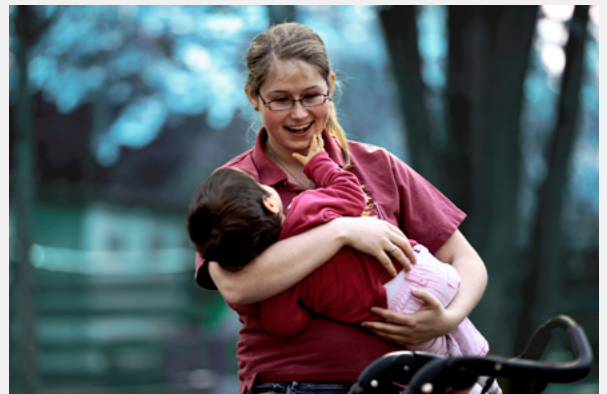
Tel: + 49 30 436 55 08-10  
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## PDA Europe supports the children's hospice „Sonnenhof“

The Sonnenhof Hospice, located near PDA's office in Berlin, offers support and assistance to families with children suffering from incurable and/or debilitating diseases. At Sonnenhof, children, together with their families, can spend the time they have left as they wish and find some relief from their suffering. Instead of purchasing expensive gifts for the conference speakers, PDA has decided to donate this amount to the Sonnenhof Hospice. You can also contribute and help us increase the amount, it is easy:

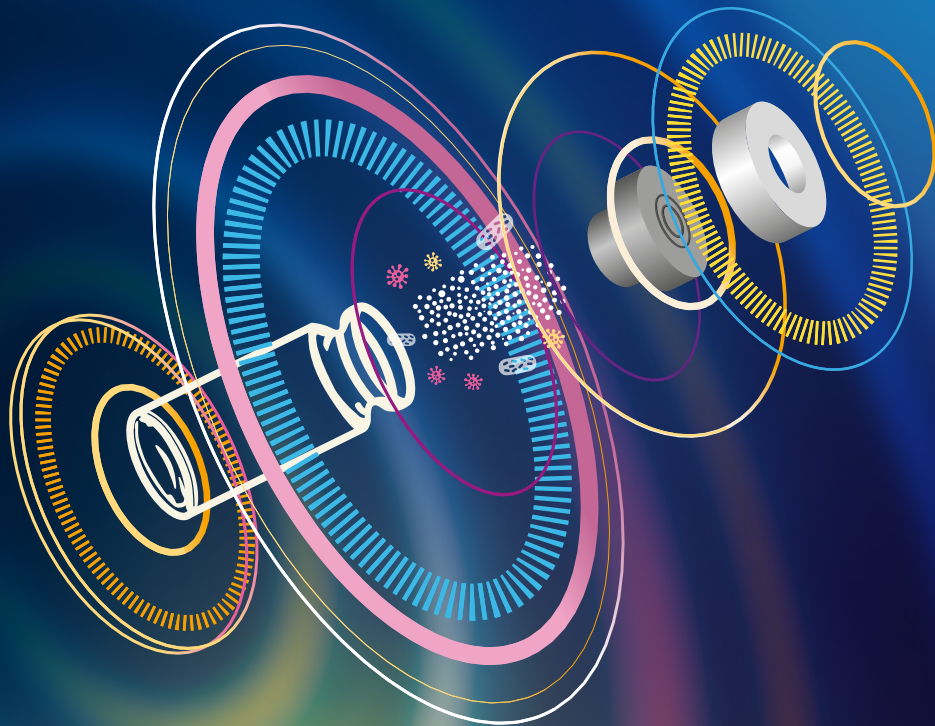
**buy a package of chewing gums at the registration desk. THANK YOU!**

To know more about the Sonnenhof Hospice, please visit [www.bjoern-schulz-stiftung.de](http://www.bjoern-schulz-stiftung.de)

Björn Schulz   
**STIFTUNG**  
Für eine Zeit voller Leben

2021 PDA EUROPE

# Parenteral Packaging



**23-24 MARCH 2021**  
BASEL, SWITZERLAND  
EXHIBITION: 23-24 MARCH  
TRAINING: 25-26 MARCH

# PDA EUROPE EVENTS



## 2020

8-9 September Medical Devices and Connected Health ★ Virtual Conference

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22-23 September BioManufacturing ★ Virtual Conference

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24-25 September Pharmaceutical Freeze Drying Technology ★ Virtual Conference

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19-20 October Visual Inspection Forum ★ Berlin, Germany

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20-21 October Aseptic Animal Health ★ Virtual Conference

## 2021

23-24 March Parenteral Packaging ★ Basel, Switzerland

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5-6 October Universe of Pre-Filled Syringes and Injection Devices ★ Gothenburg, Sweden

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Subject to change

For latest info: [pda.org](https://pda.org)

Shortlist 9 Jul 2020