

The Parenteral Drug Association presents:

PDA Europe Education Program

Glass Handling

Best Practices for Glass Primary Containers

18-19 October 2017 | Training Course

18-19 October 2017
Mainz | Germany

GENERAL INFORMATION

SCHEDULE AT A GLANCE

| | | | |
|---------------|---------------------|--|---|
| 18 Oct | 9:00 – 17:30 | Best Practices for Glass Primary Containers | Training Location: SCHOTT AG Hattenbergstrasse 10 55122 Mainz Germany |
| 19 Oct | 9:00 – 16:00 | Best Practices for Glass Primary Containers | Training Location: InterCityHotel Mainz Mainz Germany |

For latest information, please visit: pda.org/eu/GPC2017

VENUE

Day 1: Wednesday, 18 October 2017

SCHOTT AG

Hattenbergstrasse 10
55122 Mainz | Germany

Day 2: Thursday, 19 October 2017

InterCityHotel Mainz

Binger Strasse 21
55131 Mainz | Germany
Tel: +49 696 65 64-460

Special Rates

PDA Europe has reserved a limited number of bedrooms until the **25 August 2017**. Book your group rate for PDA by phone. **Room 135€ per room and night**. Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.

DIRECTIONS



© Google
For directions click on the picture, scan the QR-code or go to

<https://goo.gl/maps/QSVuG3xC4xT2>

CONTACT INFORMATION

Registration & Customer Care

Tel: +49 30 436 55 08-10
info-europe@pda.org

Education Program Inquiries

Elke von Laufenberg
Manager Training & Education
laufenberg@pda.org

ORGANIZER

PDA Europe gGmbH
Am Borsigturm 60
13507 Berlin, Germany
Tel: +49 30 436 55 08-0
Fax: +49 30 436 55 08-66

Training & Education Program

europa.pda.org



PDA Education offers courses that are developed and taught by experts. They are uniquely targeted to professionals involved in the development and manufacturing of quality pharmaceutical and biopharmaceutical products.

Facts that Make a Difference

-  **Up-to date training courses and workshops taught by internationally renowned instructors**
-  **Wide range of training courses with hands-on experience to drive expertise, awareness, and innovation**
-  **Customized in-house training courses and workshops available**



Best Practices for Glass Primary Containers

Overview

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



Claudia Heinel, PhD, Product Manager Pharmaceutical Tubing, SCHOTT AG

Claudia Heinel studied Chemistry and Biology for teaching profession before she obtained her PhD in Inorganic/Organometallic Chemistry at the University of Regensburg, Germany. In December 2015, she 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.



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 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, Robert Bosch GmbH

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. 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.

Training Location:

SCHOTT AG
Hattenbergstrasse 10
55122 Mainz | Germany

Competition Clause:

We ask you for your understanding that participants of competing companies cannot take part in the site visit on 18 October 2017.

Wednesday, 18 October 2017

9:00 – 17:30

9:00 **Welcome and Introduction** All
Participants' Expectations

Manufacture and Characteristics of Glass as Primary Packaging Material

9:15 **Glass Science** Claudia Heintl

- Chemical structure
- Physical properties
- Different glass types in the pharmaceutical industry

10:30 **Coffee Break**

11:00 **Glass Making** Claudia Heintl

- Melting
- Molded containers
- Tube drawing and container conversion

12:15 **Lunch Break**

13:15 **Preparation for Site Visit** Claudia Heintl

13:30 **Visit SCHOTT Tubular Glass Manufacturing**

14:15 **Glass Strength and Fracture Mechanics** Claudia Heintl

- Trigger for glass breakage
- Crack formation and propagation
- Theory of Fractography

15:15 **Q & A** All

15:30 **Coffee Break**

Receiving Inspection of Glass Primary Packaging Material

16:00 **Requirements from Pharmacopoeias (EP, JP, USP) and Incoming Inspection** Karl Siemoneit

- Overview Pharmacopoeia
- Testing Parameters
- Testing Methods, Equipment, Tools
- Defects and PDA Technical Report #43

16:45 **How to Do in Practice** Karl Siemoneit

- Sampling (AQL)
- Sample size
- Testing
- Documentation
- Supplier certification & test reduction

17:30 **End of Day 1**

| Thursday, 19 October 2017 | | 9:00 – 16:00 |
|---|--|---------------------|
| 9:00 | Recap of Learning Objectives Day 1 | All |
| Receiving Inspection of Glass Primary Packaging Material (cont.) | | |
| 9:30 | What to Consider, What are the Common Problems, How to Avoid Them <ul style="list-style-type: none"> • Indications for (later) glass breakage Practical examples | Karl Siemoneit |
| 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 |
| Machine Use of Glass Primary Packaging Material | | |
| 11:15 | Machine Runability of Glass Primary Packaging Material <ul style="list-style-type: none"> • Roughness of glass primary packaging material Geometrics, tolerances Quality of glass Impact of machine speed | Klaus Ullherr |
| 11:45 | Lunch Break | |
| 12:45 | Use of Glass Primary Packaging Material Along the Process Chain Considering different kind of containers, bulk and nested: <ul style="list-style-type: none"> • Washing machine Depyrogenation tunnel Filling machines Stoppering Rod insertion and labelling for syringes Conveyor belts Automated inspection Packaging line | Klaus Ullherr |
| 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 | Klaus Ullherr |
| 14:15 | Coffee Break | |
| 14:45 | Coordination Process Primary Packaging Material and Machine <ul style="list-style-type: none"> • Important parameters Control loop Synchronization | Klaus Ullherr |
| 15:30 | Q & A | All |
| 16:00 | Summary & End of Training Course | |

3 WAYS TO REGISTER

- 1 **ONLINE:** pda.org/eu/GPC2017
- 2 **FAX:** +49 30 436 55 08-66
- 3 **EMAIL:** registration-europe@pda.org

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

1 Your Contact Information

If this form is an update to a previously submitted form, please check here.

Mr. Ms. Dr. Nonmember **I want to become a PDA Member.**
Please send me a subscription form
 PDA Member ID Number

Name (Last, First, MI) *

Job Title *

Company* Department

Mailing Address

City Postal Code

Country Email *

Business Phone Fax

Substituting for

(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

* This information will be published in the conference attendee list. Should you not wish us to publish these details, please contact us.

Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to PDA EU four weeks prior to the start of the event at the latest. For later registrations, PDA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

2 Registration

No PDA membership included

All fees given in Euro and excluding VAT (7 %)

Training Course (18 – 19 October)
 Best Practices for Glass Primary Containers
 All Participants **1495**

The fee includes course documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be given. The fee does not include the hotel accommodation.

Statement by SCHOTT / Competition Clause:

Day 1 of the PDA Europe Glass Handling course is to be held at the SCHOTT facility in Mainz, Germany. As part of the course agenda, SCHOTT will allow access to their manufacturing area as well as share information related to their activities and processes. Due to the nature of what will be shared, SCHOTT will be unable to permit entry to registrants who work for competing organizations.

3 Payment Options

By Credit Card (one week prior to event)

American Express MasterCard VISA

For your credit card information safety:
 Please send your details by fax only (+49 30 436 55 08-66) or register online.

By Bank Transfer

Beneficiary: PDA Europe gGmbH
IBAN: DE73 1007 0024 0922 8735 00
BIC (SWIFT-Code): DEUTDE33HAN
Bank Address: Deutsche Bank, Welfenallee 3-7, D-13465 Berlin, Germany

By Purchase Order Purchase Order Number

PDA Europe VAT I.D.: DE254459362

Billing Same as contact information address above.
Address: If not, please send your billing address to: registration-europe@pda.org

Your Company VAT I.D.:

This number starts by your country code with two characters
 (example: PDA Europe's country code starts with: DE | followed by the number)

Date Mandatory Signature

CONFIRMATION: Transmitting your filled-in registration form constitutes a binding application for the specific event. PDA Europe will send you a confirmation including payment details. **A legally binding contract is concluded once PDA Europe has sent a written invoice by mail to you.** A letter of confirmation will be sent to you within one week once payment has been received. You must have this written confirmation to be considered enrolled for this PDA event. PDA Europe reserves the right to deny access to anyone unable to provide written confirmation that all dues have been fully settled. **SUBSTITUTIONS:** If you are unable to attend, substitutions are welcome and can be made at any time, including on site at the prevailing rate. If you are registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until 2 weeks prior to the start of the event. After this two-weeks period, there will be a charge of € 100 excl. VAT per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **17 September 2017** you will receive a full refund minus a 150 € excl. VAT handling fee. After that time, no refund or credit requests will be approved. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA Europe works PCI-Compliant. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at registration-europe@pda.org or fax to +49 30 4365508-66. **DOCUMENTATION:** With your signature you give complete picture usage right to PDA and allow to film your exhibition space and intervention in the event, including the recording of your presentation for video purposes (with your slides, voice and image). This right extends also to the use of the resulting images in film documentation for webinars and similar items produced by PDA.

2017 PDA EUROPE CONFERENCES

- | | | |
|--------------------------|--|---------------------------------|
| 19 – 20 September | Pharmaceutical Freeze Drying Technology | ★ Cologne, Germany |
| 26 – 27 September | Particles in Injectables | ★ Berlin, Germany |
| 26 – 27 September | 10th Workshop on Monoclonal Antibodies | ★ Berlin, Germany |
| 10 – 11 October | Pharmaceutical Cold & Supply Chain Logistics | ★ Prague, Czech Republic |
| 7– 8 November | The Universe of Pre-filled Syringes and Injection Devices | ★ Vienna, Austria |
| 21 – 22 November | Outsourcing & Contract Manufacturing | ★ Munich, Germany |

Subject to change

For latest info: pda.org/pda-europe

Shortlist
5. July 2017, 11:59 AM

★ Events with additional Education Program. More information – pda.org/pda-europe

General Information

PDA Europe gGmbH
Am Borsigturm 60
13507 Berlin, Germany
Tel: +49 30 4365508-0
Fax: +49 30 4365508-66
info-europe@pda.org



Connecting People, Science and Regulation®



www.pda.org/pda-europe