All about Pre-filled Syringe Systems

From Initial Development to Final Fill and Finish

Overview

Join us on our journey from the components of a syringe to a customer needs oriented pre-filled syringe system. This two-day interactive course will provide an overview of relevant practical aspects and trends of developing and processing of pre-filled syringes. It will also address relevant regulatory requirements related to materials, components and processes of pre-filled syringes. Special focus is given to the perspectives of health care practitioners and patients covering the relationships of syringe properties with aspects of drug administration. In hands-on sessions participants will have the opportunity to study pieces of equipment such as syringes, stoppers, needle shields and tip caps in more detail. Processing steps, inspection and quality aspects will be demonstrated using state-of-the-art technology. Discussions of real case examples and Q&A sessions will complement the course.

Who Should Attend

- Packaging engineers with little or no experience in Pre-filled syringes
- Pharmacists and formulation developers who want to learn about prefilled syringes as a device
- Quality, Purchasing, Business Development, Sales

Learning Objectives

Upon completion of the course participants

- Know the stakeholders in Pre-fillable and Pre-filled syringes
- Understand what the packaging supplier can support with and what can only be done at the pharma company
- Understand Pre-filled syringe technologies, materials, applications and requirements
- Are able to develop a syringe system that fits the needs of a dedicated application
- Are able to compare different syringe types with regard to their advantages and disadvantages

Christa Jansen-Otten, *Director Global Product Management Prefilled Systems and Delivery, West*

Since 2016 Christa holds her position as Director of Global Product Management, Prefilled Systems and Delivery, at West Pharmaceutical Services, Inc. She has worked within the pharmaceutical industry for more than 20 years. Christa gained experience as Quality Assurance Manager in one of the world's leading pharmaceutical companies for sterile filling and packaging. In addition, she spent several years with the leading pre-fillable syringe manufacturer in the Customer Quality Assurance department. She joined West in 2005 and developed an expertise in pre-filable systems and delivery technology in the Technical Customer Service and Marketing departments. Christa holds a diploma in Biomedical Engineering from the University of Aachen.

Klaus Ullherr, *Senior Product Manager, Robert Bosch Packaging*

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.

Bernd Zeiss, *Head of Global Technical Support Gx® Solutions & Syringe Systems, Gerresheimer*

Bernd Zeiss is biologist by education and graduated from the University of Göttingen, Germany. After several years working as a biostatistician, in lab automation and in pharma sales, he today is a member of the Gerresheimer business development team since 2011. Currently he works in the Gerresheimer Centre of Excellence for pre-fillable syringes as Head of Technical Support Medical Systems. His main areas of work are technical customer support with regard to syringe systems as well as investigating possible interactions between syringe components and drug substance.

13 Juni 2019

Thursday, 24 October 2019 9:00 – 17:30

9:00 **Welcome**

9:15 **Overview and Introduction into Pre-filled Syringe Market**
- Overview & Trends
- Stakeholders
- User's perspective

10:15 **Technical Aspects**
- Syringe
- Stopper
- Plunger
- Needle
- Needle shield
- Autoinjector
- Regulatory guidelines and technical standards: EU / US / ISO / …

11:15 **Coffee Break**

11:45 **Overview and Introduction into Drug-syringe Interactions**
- Aggregation
- Degeneration
- Oxidation
- Viscosity
- Bubbles

12:15 **Lunch Break**

13:15 **Overview and Introduction to Manufacturing Process of Pre-filled Syringes**
- Barrel forming
- Washing
- Siliconization
- Sterilization
- Regulatory guidelines and technical standards: EU / US / ISO / …

14:00 **Fill and Finish**
- Filling
- Stoppering
- Assembly
- Technical Standards: ISO

14:45 **Hands-on Session 1**

15:45 **Coffee Break**

16:15 **Hands-on Session 1 (cont.)**

17:15 **Q & A**

17:30 **End of Day 1**

Friday, 25 October 2019 9:00 – 15:45

9:00 **Recap Day 1**

9:30 **The Syringe (Body) - Example Specification**
- Materials (glass, polymer)
- Shape
- Cone
- Diameter
- Mechanical properties
- Chemical Properties
- Siliconization
- Impact of different drug properties
- Dual-chamber syringe
- 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**
- 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**
- Bulk versus nested
- Nest sizes
- Standard processing for Rod Insertion and Labelling
- Handling of syringes considering glass to glass vs. no glass to glass contact

12:30 **Lunch Break**

13:30 **Assembly of Syringes and Administration Devices**
- Pen Injectors
- Safety Systems
- Autoinjectors
- Manual versus automated

Design Independent Assembly

14:30 **Hands-on Session 2**

15:30 **Q & A**

15:45 **End of Course**