

Test-Methods for Pre-filled Syringe Systems

Overview

The course will be an interactive lecture around Pre-filled Syringe Systems including ISO compliance testing. The participants will benefit from first hand information of both lecture leaders based on practical experience. The lecture includes the life cycle of a PFS from the idea to finished marketed product.

Who Should Attend

- The course is designed specifically for those who are involved or interested in the development, manufacturing and QC-testing of a Pre-filled Syringe System
- Engineers and Managers in Device Development and all other technical functions surrounding syringe systems
- Quality Personal / Regulatory Personal
- Clinical and commercial Drug Product Manufacturing

Learning Objectives

- Materials used for PFS Systems
- Luer Cone and Luer Lock Compliance Testing
- Requirements for the empty sterile sub-assembled syringe ready for filling
- Test Methods for Drug Product Filled Syringes
- PFS used in Delivery Systems

Faculty



Horst Koller, CEO, HK Packaging Consulting

Prior to becoming a consultant, Horst worked for Abbott Diagnostic and SCHOTT Pharmaceutical Packaging with a total of more than 20 years industry experience. His consulting company is focusing on Technical, Regulatory and QM-Support around Primary and Secondary Packaging Systems including Medical Devices. He is an active member within the technical ISO Committees TC76 and TC84 as well as an active speaker on international conferences. He holds an Engineering degree in Biotechnology from the University of Applied Sciences in Mannheim / Germany.

Thursday, 21 March 2019 9:00 – 17:45

- 9:00 **Welcome**

- 9:15 **Introduction to Syringe Systems and Components**

- 10:30 **Coffee Break**

- 11:00 **Regulatory Requirements of Finished Pre-filled Syringes – Part 1**
 - System Characterization / Physical Characterization

- 12:30 **Lunch Break**

- 13:30 **Regulatory Requirements of Finished Pre-filled Syringes – Part 2**
 - Pharmaceutical Characterization

- 15:30 **Coffee Break**

- 16:00 **Luer cone and Luer lock Compliance Testing for Glass and Polymer Syringes**

- 17:30 **Wrap-up of Day 1**

- 17:45 **End of Day 1**

Friday, 22 March 2019 9:00 – 15:30

- 9:00 **Requirements for the Empty Sterile Sub-assembled Syringes Ready for Filling- Part 1**
 - Cone Breakage / Flange Breakage / Leakage

- 10:15 **Coffee Break**

- 10:45 **Requirements for the Empty Sterile Sub-assembled Syringes Ready for Filling- Part 1 (cont.)**
 - Cone Breakage / Flange Breakage / Closure Testing

- 11:45 **Requirements for the Empty Sterile Sub-assembled Syringes Ready for Filling- Part 2**
 - Break Loose and Gliding Force / Needle Testing / Particulate Matter

- 13:15 **Lunch Break**

- 14:15 **Additional Testing for Use in Delivery Devices**

- 15:15 **Wrap-up of Day 2**

- 15:30 **End of Training Course**