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

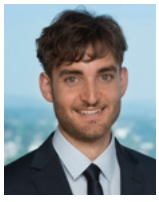
Upon completion of the course the participants will have solid knowledge of

- 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.



Roman Mathaes, *PhD, Senior Group Leader, Lonza Drug Product Services*

Roman is leading the Lonza particle lab and the container closure integrity testing. In this role, he is responsible for container closure integrity testing of vials and Pre-filled syringes and process development of capping / crimping. Prior to this assignment, Roman was working within Roche / Genentech network supporting process development of the commercial manufacturing vial capping process. Roman is a pharmacist by training and conducted his studies at the University of Marburg and King's College London. He holds a PhD in Pharmaceutical Technology from the University of Munich for work on subvisible particle characterization.

Thursday, 28 June 2018 — 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, 29 June 2018 — 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**