

Development and Manufacturing of Pre-filled Syringes

A Hands-on Training Course

Overview

This two-day interactive course will provide an overview of relevant practical aspects and trends of developing and processing of bulk and pre-sterilized primary packaging systems, especially pre-filled syringes. It will also address relevant regulatory aspects and topics such as container handling in the filling process, glass defects, particulates and visual inspection and the relevant test methods. In addition to theoretical insights, participants will have the opportunity to use equipment and perform testing by themselves in hands-on sessions. Processing steps, inspection and quality aspects will be demonstrated using state-of-the-art technology. There are discussion and Q&A sessions with real case examples.

Who Should Attend

This course offers valuable insights and updates for anyone involved in development, production, quality, auditing, project management and purchasing

Learning Objectives

Upon end of this course you know about and have an overview of:

- Processes involved in primary packaging manufacturing, filling and processing
- Test methods for development, IPCs and quality testing
- Relevant machines and test equipments

Learn about the complexity and interdependencies of the development and manufacturing of Pre-filled Syringes and get an understanding what to consider for a successful project.

Faculty

Moderator:

Egmont Semmler, *PhD, Director Research & Development, Groninger*

Speaker:

Erik Berndt, *Industry Manager Medical/Pharmaceutical, Zwick*

Alessandro Morandotti, *Product Manager Syringes, Nuova Ompi*

Christa Jansen-Otten, *Director Marketing PFS Europa, West*

Horst Koller, *CEO, HK-Packaging Consulting*

Oliver Valet, *PhD, Managing Director, rap.ID*

Bernd Zeiss, *Manager Technical Support Medical Systems, Gerresheimer*

Thursday, 9 November 2017		9:00 – 18:00
9:00	Welcome	Egmont Semmler, <i>Groninger</i>
9:05	Advantages of Pre-filled Syringes and Market Trends in Primary Packaging <ul style="list-style-type: none"> • Properties and advantages of Pre-filled Syringes • Market overview of the injectables markets • Trends in parenteral applications 	Christa Jansen-Otten, <i>West</i>
9:30	Development and Regulatory Aspects of Primary Packaging <ul style="list-style-type: none"> • The relevant guidelines • Vial- syringe life cycle management considerations 	Horst Koller, <i>HK Packaging</i>
10:00	The Complete Manufacturing Process of Pre-filled Syringes <ul style="list-style-type: none"> • Washing, endotoxin testing • Siliconization, types of silicon oils and application • Sterilization and silicon oil fixing • Ready to fill glass syringe handling 	Egmont Semmler, <i>Groninger</i>
10:30	Coffee Break	
11:00	The Complete Manufacturing Process of Pre-filled Syringes (cont.) <ul style="list-style-type: none"> • Filling methods, pumps • Stoppering methods • Selection criteria for filling and stoppering 	Egmont Semmler, <i>Groninger</i>
11:30	Q&A on Manufacturing	
12:00	Lunch Break	
13:00	Testing of Pre-filled Syringes (Siliconization, Visual Inspection) <ul style="list-style-type: none"> • Silicon oil layer measurements • Visual inspection, criteria 	Oliver Valet, <i>rap.ID</i>
13:30	Testing of Pre-filled Syringes (ISO 11040-4 and more) <ul style="list-style-type: none"> • The ISO standards • Flange and Luer cone breakage resistance • Glide force tests • Needle penetration test • Pull-off forces on tip caps • Test equipments • Luer-lock tests 	Erik Berndt, <i>Zwick</i>
14:00	Q&A on Testing	
14:30	Coffee Break	
15:00	Interactive Hands-on Session <ul style="list-style-type: none"> • Manufacturing machines: Siliconization, filling procedures, stoppering methods • Testing equipment: Silicon layer, particle identification, glide force and methods acc. to ISO 11040-4 • Container closure integrity testing 	
17:00	Q&A, Discussion and Real Case Examples <ul style="list-style-type: none"> • What can go wrong and how to avoid or fix it 	
18:00	End of Day 1	

Friday, 10 November 2017		9:00 – 17:00
9:00	Glass Syringes <ul style="list-style-type: none"> • Manufacturing of glass • Glass forming • Physical and chemical properties • Bulk and Ready to fill concepts • Quality aspects 	Alessandro Morandotti, <i>Nuova Ompi</i>
9:45	Polymer Syringes <ul style="list-style-type: none"> • Materials • Physical and chemical properties • Processing and quality 	Bernd Zeiss, <i>Gerresheimer</i>
10:15	Q&A	
10:30	Coffee Break	
11:00	Elastomeric Closures for Pre-filled Syringes and Cartridges <ul style="list-style-type: none"> • Manufacturing of elastomers • Physical and chemical properties • Processing: washing / siliconization • Quality aspects / coated and uncoated /bulk and ready to use 	Christa Jansen-Otten, <i>West</i>
12:00	Q&A	
12:30	Lunch Break	
13:30	Assembly of Syringes into Devices <ul style="list-style-type: none"> • ISO Standards 11608 • Tests of the primary containers • Tests on the assembled primary container-device • Equipment and test procedures 	Erik Berndt, <i>Zwick</i>
14:15	Q&A	
14:30	Coffee Break – Parallel to next Agenda Topic	
14:30	Interactive Hands-on Session, small groups: <ul style="list-style-type: none"> • Polymer and glass syringes • Elastomer types and selection criteria • Devices • Test Methods 	
16:00	Q & A, Discussion with Real Life Examples	
17:00	End of Course	