Container Closure Development

Overview

The course will give an overview on how to develop a container closure system for parenteral products. Starting with setting up a product profile of the final product container, all aspects will be covered, like selection of materials, assessment of container closure systems, specification and documentation of components and entire systems. In addition, current hot topics such as glass delamination and container closure integrity testing will be discussed.

For all topics of the agenda presentations will be given. The participants are invited to add own experience, ask questions and offer issues to be discussed within the group and/or with the trainer. The intention is to work in an open workshop-like atmosphere.

Who Should Attend

- Scientists in Drug Product Development
- Scientists/ Engineers in Packaging Development
- Regulatory Affairs Experts

Learning Objectives

- Set-up of a target product profile of a container closure system
- Select appropriate container closure materials, components, and systems
- Apply the appropriate regulations and standards to container closure systems for parenteral formulations
- Prepare a development plan of a container closure systems from the early development until market phase
- Specify container closure systems regarding technical aspects and regulatory requirements
- Understand compendial requirements and quality as well as technical standards regarding
- container closure components and systems

Jörg Zürcher, *Senior Scientist, Bayer*

Jörg Zürcher is a pharmacist by education. After his studies and PhD thesis at the Free University in Berlin, he started his career in the pharmaceutical industry 1990 with the former Schering AG. He is responsible for the development of container closure systems and application devices at Bayer HealthCare and has more than 25 years' experience in that field. His current focus is the development of systems/devices for liquid and parenteral as well as ophthalmic dosage forms.

Thursday, 21 March 2019	9:00 – 17:00
09:00	**Welcome and Introduction**
09:30	**Definitions** • Compendial definition • Functional definition • Components vs CCS • Description of options • Materials
09:45	• **Regulatory Background** • Ph.Eur. • USP • JP • FDA Guideline • EU Directive • Relevant eCTD sections
10:45	**Coffee Break**
11:15	• **Development of Container Closure Systems** • Set-up of target profile • Packaging materials • Modification of materials • Extractables & Leachables (E&L) testing • Permeability • Light transmission • Processability • Functional testing • Container closure integrity (CCI) • Shipping assessment • Combination products
12:30	**Lunch Break**
13:30	**Workshop: Develop Your CCS**
15:00	**Coffee Break**
15:30	**Presentation of Workshop Results**
16:00	• **Setting of Specifications / Submission Documentation** • Technical/ Quality specification • Regulatory specification • Technical drawing • Regulatory drawing • DMF for US submission
16:30	**Wrap-up and Final Q&A**
17:00	**End of Course**