# 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 of 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 system 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.

23 May 2017

## Thursday, 9 November 2017 — 9:00 - 17:00

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| **9:00** | **Welcome & Introduction** |
| **9:10** | **Setting up a Target Profile**<br>• Influence of formulation (small molecule, biological)<br>• Use of product (patient, nurse, physician....)<br>• Regulatory requirement |
| **9:30** | **Material Selection**<br>• Ph.Eur. / USP / JP<br>• Plastic vs. glass<br>• Coating of material<br>• Stopper material |
| **10:30** | **Coffee Break** |
| **11:00** | **Selection of Packaging Solution** |
| **11:30** | **Assessment of Packaging Solutions – Development Data**<br>• Testing of injection vials/bottles and their respective components<br>• Testing of pre-filled syringes (PFS) and their respective components<br>• Extractables & Leachables (E&L) testing<br>• Mechanical and functional testing |
| **12:30** | **Lunch Break** |
| **13:30** | **Manufacturing of Packaging Solutions**<br>• Test runs<br>• Process validation (risk assessment, critical parameters)<br>• Container closure integrity (physical vs. microbiological testing – USP 1207)<br>• Shipping test for PFS |
| **14:00** | **Setting of Specifications**<br>• Technical drawings<br>• Technical / quality specification<br>• Testing standard, defect evaluation list<br>• Examples |
| **15:00** | **Coffee Break** |
| **15:30** | **Preparing the Submission**<br>• Relevant eCTD sections (drug substance and drug product)<br>• Regulatory drawings<br>• DMF for US |
| **16:00** | **Routine and Release Testing**<br>• Certificates<br>• Routine E&L testing<br>• Reduced testing |
| **16:15** | **Change Management**<br>• EU requirements |
| **16:30** | **Wrap-up, Discussion, Q & A** |
| **17:00** | **End of Training Course** |