

Innovative Drug Delivery Systems/ Combination Products

From Project Initiation to Life Cycle Management

Workshop Description

Increasingly, parenteral products are injected using devices like pen-injectors, auto injectors and wearable pumps. Typically, the primary containers are pre-filled syringes and cartridges. The materials are glass or polymer. Special applications have treated surfaces or coated materials.

Starting with a key note presentation describing the needs of the pharmaceutical and biopharmaceutical industry, this workshop will give an overview of currently used devices. Technical aspects, handling and training, as well as regulations will be highlighted. Device companies will present their products and focus on the most current drug delivery requirements such as:

- Mixing technology for liquid/liquid or lyo/liquid formulation combinations
- Large Volume
- High Viscosity
- High Precision Dosing

Challenges in development impeding a life cycle approach will be one of the themes of the workshop.

Learn from suppliers' solutions, and hear guest speakers and facilitators share approval and life-cycle management experiences from developing their drug delivery combination products.

Listen to the latest trends in final assembly during drug product manufacturing and what the benefits of target-focused training for users and health care professionals can be. Learn which activities succeeded and hear about the lessons learned. Interact with other participants and speakers during panel discussions and exchange on all issues vital for ensuring success of your product.

Who Should Attend:

The target audience for this workshop is from departments like Device Development, Compliance, Operations, Regulatory Affairs, Manufacturing, Pharmaceutical Formulation and Process Development, Business Development, Marketing, Procurement, CMC, Distribution, Packaging, Quality Assurance/Control, Clinical Affairs.

Learning Objectives:

Upon participation of this workshop you will be able to:

- Use combination products to gain market differentiation
- Identify to best possible and innovative drug delivery solution for your drug product
- Understand the latest trends in drug delivery technology
- Implement world class training solutions to prepare for a smooth market entrance
- Understand best in class assembly concepts

Monday, 6 November 2017**10:00 – 18:00**

10:00	Welcome and Introduction	Thomas Schoenknecht, SHL
10:15	Data-driven Discovery: Knowledge Management for Drug Delivery Technologies	Jeffrey Schacherl, <i>Amgen</i> Christian Marc Schmidt, <i>Schema Design</i>
10:45	Life Cycle Approach for Devices	Christian Herget, <i>BD</i>
11:15	Q&A, Discussion	
11:30	Device Companies Presentation Overview of Devices by • Becton Dickinson • Bepak • BIOCORP • Ypsomed	
12:30	Lunch Break	
13:30	Device Companies Presentation (cont.) Overview of Devices by • Dali Medical Devices • Haselmeier • Oval Medical • • Sensile • SHL West	
15:30	Coffee Break	
16:00	A Novel Autoinjector for High Volume, High Viscosity, and Outstanding Usability	Avi Eliahu, <i>Genentech</i>
16:30	Training for Patients and Medical Professionals	Joe Reynolds, <i>Noble</i>
17:00	Considerations on Lifecycle Management in Scope of the Changing Regulatory Landscape • Recent changes on standards and regulatory expectations/requirements • Considerations on legacy products in light of changing standards	Rosemary Gonzalez, <i>SHL</i>
17:30	Q&A on Real Cases, Discussion	
18:00	End of Pre-Conference Workshop	

Workshop Chair



Thomas Schoenknecht, PhD, PDA IG Leader Combination Products, SHL

Thomas Schönknecht is currently Executive Director, Business Development at SHL Group, with responsibility for global Business Development, Key Account Management and new Technology Evaluation within SHL's Medical division. Thomas has over 20 years of experience in pharmaceutical industry in various leading roles in project management, research & development and business development. He received his Ph.D. in Biophysical Chemistry from the Max-Planck-Society and the University Goettingen, Germany and a Master's degree in Chemistry from the University Goettingen. He is currently active as PDA interest group leader combination products in Europe. In addition he had been active as member in various DIN ISO committees regarding primary packaging materials and drug delivery devices.