

**Event:** ISPE Frankfurt Conference 2012  
**Track:** Technology Innovations in Aseptic Processing  
**Leader:** Jörg Zimmermann  
**Dates:** 26./27.03.2012  
**Location:** Radisson Blu, Frankfurt, Germany  
**Web Link:** <http://www.ispe.org/2012asepticconference>

### Monday 26 March

Start Time	End Time	Presentation Title	Speaker (Full Name)	Company	Total min.
9:00	10:30	Keynote Address(es)			90
10:30	11:15	Networking Break			45
11:15	12:30	Keynote Address(es)			75
12:30	13:30	Lunch			60
13:30	13:40	Introduction	Jörg Zimmermann	Vetter	10
13:40	14:20	<b>Closed Systems Strategy in biopharmaceutical manufacturing – Implementation for a new facility</b> This case study on the approaches how to minimize impacts on the production process from operators and the environment demonstrates the possibilities available by modern process technology, plant design and operational concepts. The efficient use of the tools available enables to reduce costs, to minimize deviations and to ensure better process robustness. Take home benefits: <ul style="list-style-type: none"> <li>• Example from concept to "real life" operations holistic design</li> <li>• Learn about an approach to maximize benefit between quality demands and manufacturing needs</li> <li>• Examples of modern concepts in biopharmaceutical manufacturing</li> <li>• Lessons learned out of the qualification, start-up and the first GMP campaign</li> </ul>	Dirk Böhm	Merck-Serono	40
14:20	15:00	<b>How to Run A RABS Cleanroom Successfully</b>	Jörg Zimmermann	Vetter	40
15:00	15:30	Networking Break			30
15:30	16:00	<b>Challenges of Biopharmaceutical Product Development...- not only a matter of formulation:</b> Challenges of biopharmaceutical product development are multi-fold due to the numerous ways the stability of a biopharmaceutical drug may be compromised. Instability can be manifested in aggregation and particle formation, chemical instability and structural changes. The first step into such a development work is to comprehensively understand "stability" of the API. Stability has to be understood not as an absolute term, but as a condition that is much dependent on the "eye of the spectator". During this presentation, some facets of the comprehensive term stability will be highlighted and appropriate, innovative techniques for characterization of those particular "views on stability" discussed. Attention will be given to the characterization of structural changes in the samples (intrinsic/extrinsic fluorescence, CD spectroscopy) and the formation of aggregates / particles using innovative techniques, such as Micro-Flow Imaging and Nanoparticle-Tracking Analysis).	Alexandra Kafka	Coriolis Pharma	30
16:00	16:30	<b>Fill-finish processes for MABs: Challenges and Solutions</b> The fill-finish process provides the final dosage form in the desired concentrations and containers or delivery devices. The fill-finish operation consists of various process steps that may impact product quality and process performances when changing excipient matrix, concentration and delivery systems in the scope of life cycle management. Exemplary challenges are the limited volume to administer subcutaneously, the intrinsic stability of the MAB in a highly concentrated aqueous solution along with its compatibility to product contacting processing material, primary closure container and medical devices (e.g autoinjector). Besides the aspect of compatibility the processability and process performance of MABs will be addressed in more detail.	Bärbel Hinneburg	Vetter	30
16:30	17:00	TBD	Rob Roy	IPS	30
17:00		Session Adjourns			
17:00	18:30	<b>Welcome Reception in Exhibit Hall</b>			

### Tuesday 27 March

Start Time	End Time	Presentation Title	Speaker (Full Name)	Company	Total min.
8:30	8:40	Introduction and Recap of Day 1	Jörg Zimmermann	Vetter	10
8:40	9:20	<b>Outsourcing and Technology Transfer of Aseptic Fill-Finish Processes: Challenges, pitfalls, and tools for success</b>	Paul Gauthier	Shire	40
9:20	10:00	<b>New Methods in Controlling Silicone Levels</b> Two trends changed the world of siliconization. The new biotech drugs and the use of significantly more automatic injection devices asked for minimizing the amount of silicone in the barrel and an optimized distribution inside the barrel. Beside of the improvement of the silicone injection technology these goals could only be achieved by a better understanding and control of the process in the machine.	Klaus Ullherr	Bosch	40
10:00	10:30	Networking Break			30
10:30	11:15	<b>Update on the new ISPE sterile facilities guide</b>	Bruce Davis	Consultant	45
11:15	12:00	<b>Highly Flexible Tox. / Aseptic filling of clinical trial material in pre-filled syringes</b> The presentation gives insight into the start-up and qualification phase of a new pre-filled syringe line, designed to support development, scale up and clinical supply activities in pharmaceutical Research and Development.	Joerg Luemkemann	Roche	45
12:00	13:00	Lunch			60
13:00	14:20	<b>Break-out session for discussions</b>			80
14:20	15:00	Networking Break			40
15:00	15:45	<b>Innovations in Closed System Sterile Powder Transfer</b> Maintaining a high level of sterility assurance is imperative while moving drug product and materials through different room classifications into the filling environment. To eliminate the need for repeated sanitization / sterilization treatments, the product and materials can be kept within a closed system. This case study describes a process in which active drug product in powder form is transferred to an aseptic filling line in a completely enclosed system. Take Home Benefits: <ul style="list-style-type: none"> <li>• Introduction to closed system powder transfer</li> <li>• Practical knowledge of rapid transfer port (alpha / beta) connections</li> <li>• Introduction as to how these concepts can be used for transfer of other materials (stoppers, aluminium caps) to the filling line</li> </ul>	Andreas Linz	ATEC	45
15:45	16:30	<b>Design requirements and solutions for a high potent SVP facility</b> The number of pharmaceutical APIs which are considered to be high potent has been rising constantly within the last decades. As a result of this development and due to stricter laws regarding the operator and environmental protection pharmaceutical companies are forced to upgrade their existing facilities or to build new facilities which can fulfill these requirements. Within this presentation terms and definitions as well as their interrelationship are explained. In some small case studies in the second part of the presentation the requirements for the design of the process equipment, from weighing the API up to secondary packaging, are described. In the third part the main fundamental design requirements regarding HVAC design are shown as well as technical possibilities as to how the effluent can be treated. Finally, some recommendations are given regarding specific topics to be considered when designing such a facility in order to make the project a success.	Hartmut Schaz	NNE Pharmaplan	45
16:30	17:00	<b>Closing remarks, seminar adjourns</b>	Jörg Zimmermann	Vetter	30