Drug Delivery Systems: Global Technical, Regulatory and Quality Challenges

Overview

The FDA started to address Drug Delivery Systems as combination products almost 20 years ago and have more recently instituted a growing number of unique ways to regulate the development, registration and control of these products. To make issues more complicated, there are an increasing number of regions that are also starting to treat these products differently. One of these examples is the upcoming Medical Device Regulation (MDR) to be considered also for Drug Device Combinations in Europe. Independent of the regulations, the number, scope and complexity of these products is expanding exponentially. This workshop will provide attendees with insight into the challenges, and potential solutions to dealing with the requirements and regulations related to the development, registration and control of Drug Delivery Systems. The workshop will include speakers from regulators and industry and allow interactive audience participation with panels of experts on each issue to provide a forum for information and discussion on navigating the challenges presented by these products.

Who Should Attend:

This course will be geared towards individuals who are responsible for, have input into, oversight for or actively participate on, drug delivery product development teams. This includes the following practitioners, managers and directors in Medical Device, Pharmaceutical or consulting companies:

- Project Management
- Marketing
- Regulatory Affairs
- Quality Assurance
- Clinical Affairs
- Product Safety
- Human Factors Engineering
- Device Development Engineering
- Quality Engineering
- Formulation
- Testing laboratories
- Design Verification Department

Workshop Leader

Lee Leichter, *P/L Biomedical*
Manfred Maeder, *Novartis*

30 Oct 2017

Thursday, 9 November 2017		9:00 – 17:00
9:00	**Welcome and Introduction**	Manfred Maeder, *Novartis* Lee Leichter, *P/L Biomedical*
	Current Challenges and Changes Due to New Regulatory Expectations	
9:15	**Recent and Upcoming Changes and Challenges in the EU**	Manfred Maeder, *Novartis*
10:00	**Recent and Upcoming Changes and Challenges in the USA**	Lee Leichter, *P/L Biomedical*
10:45	**Coffee Break**	
	Regulatory Considerations – How to Submit a Drug Device Combination Worldwide?	
11:15	**Global Perspective on Drug Delivery Submissions - Regulatory**	Chin-Wei Soo, *Genentech*
12:00	**Regulatory Considerations for Drug Device Combinations**	Nick Lee, *HPRA - Irish Agency*
12:45	**Lunch Break**	
13:45	**Notified Body Position – How Will this be Implemented?**	Bassil Akra, *TUEV Sued*
14:30	**Panel Discussion**	
15:00	**Coffee Break**	
	When There are Two Separate Products, How Do the Companies Coordinate? *Labeling/Promotion/Distribution/Complaints/PMS/Changes*	
15:30	**Successful Drug Delivery Requires an Integrated Approach**	Tibor Hlobik, *West*
16:15	**Panel Discussion**	
16:30	**Q&A**	
17:00	**End of Day 1**	

Lee H. Leichter, *RAC, MBA, President P/L Biomedical*

Lee Leichter has over 40 years' experience in the health care industry, providing direct, hands-on assistance to domestic and international Pharmaceutical, Biotechnology and Medical Device companies for the last 20. Projects have encompassed a multitude of business, technical, regulatory and quality issues, primarily related to drug delivery and combination products for marketing in the USA, Europe and Canada. He has worked with large multi-national companies, as well as start-ups, successfully navigating the challenges posed during the development, testing and marketing approval of products that merge pharmaceutical substances with high-tech device systems. Serving as an independent expert on ISO technical committees for Injection and respiratory products, infusion pumps, needles and catheters, and AAMI Injection and Infusion Devices and Human Factors committees, he assists in establishing international standards for safety and performance of these products. He initiated, and leads the ISO Workgroup developing a standard for On Body Delivery Systems (OBDS). His education includes a Bachelor's degree from the State University of New York at Stony Brook and an MBA with Honors from Florida Gulf Coast University. Lee is currently certified in USA and EU Regulatory Affairs from RAPS and was certified as a Quality Engineer from ASQ.

Friday, 10 November 2017		9:00 - 16:00
	Technical Considerations During Drug Device Combination Products Development	
9:00	**How Can Pharma Benefit from a Well-defined and Robust Delivery Device Platform**	Thomas Schoenknecht, *SHL*
9:30	**Platform Technology**	Stephan Affolter, *Ypsomed*
10:00	**Coffee Break**	
	Human Factors Considerations	
10:30	**US FDA Position/Expectations**	Irene Chan, *FDA*
11:00	**Industry Perspective**	Muriel Didier, *Novartis*
11:30	**Panel Discussion**	
12:00	**Lunch Break**	
	Life Cycle Management Activities of Drug Device Combinations [eg. Changes, PMS, ...]	
13:00	**Company Position – ISO Standard – Risk Based Approach to Combination Product Change Management**	Suzette Roan, *Biogen*
13:30	**Risk Management – Activities During Development and Life Cycle Management**	Alice Maden, *BD*
14:00	**Discussion**	
14:15	**Coffee Break**	
14:45	**Using Risk Management to Establish Product Risk Benefit as Part of the Development Process per ISO 14971 , ICHQ9 and Future GMP Annex 1**	Horst Koller, *HK Packaging*
15:15	**Processes/systems for Risk Based Decisions for Specification etc.**	Lee Leichter, *P/L Biomedical*
15:45	**Discussion**	
16:00	**End of Workshop**	

Manfred Maeder, *PhD, Head Device Development & Commercialization of BTDM, Novartis*

Since 2015 Manfred Maeder is Head Device Development & Commercialization of BTDM (Biologics Technical Development and Manufacturing) at Novartis. Before that he held the position Head of Global Compliance & Audit for Devices & Combination Products overseeing all Alcon, Pharma, and Sandoz sites producing this type of products and Global QA Head of Technical Research and Development starting in 2011. Prior to this position, he was Senior VP of Quality Management & Regulatory Affairs at Ypsomed. Previously, he was responsible for Quality Assurance Management at Sanofi-Aventis for the Frankfurt Injectables site. Before then, being based in Kansas City/ US, he had a global responsibility for Quality and Regulatory for one of the Aventis Blockbuster products. Prior to that, he held several positions in QA and QC. By training he is pharmacist and holds a doctorate in pharmaceutical analytics and statistics by the University of Wuerzburg/ Germany.