Impact of Pre-filled Syringe Packaging Components on Biopharmaceuticals

Workshop Description

Parenteral drug delivery using pre-filled syringes and cartridges in combination with devices is of great importance, especially for the application of biopharmaceutical products.

The development of such delivery systems is complex and therefore it is important to consider critical aspects early on in development. This workshop considers the potential influences of primary packaging components on the quality, in particular for biopharmaceuticals. The most relevant aspects are the quality and the chemical and physical interactions of the packaging material with the product. Special considerations are given to the influence of particles, extractables and leachables, silicon oil and handling on the product quality, e.g. aggregation, degradation routes and stability. Experts from academia, the pharmaceutical industry and suppliers of packaging components will share their experiences. There will be plenty of time for discussion, interaction and questions you may have.

Who Should Attend:

- Professionals in pharma dealing with development and manufacturing of biopharmaceuticals, container and device development, quality and regulatory functions

Workshop Co-Chairs

William Dierick, *Terumo*

William Dierick is Fellow - Science & Technology of TERUMO, a global research & development company, offering a wide range of innovative products related to drug delivery devices and injection technology, cardiology and cardiovascular systems, transfusion, patient monitoring and clinical systems. With extensive experience in the Medical and Pharma sector for more than 40 years, William has held various positions in Terumo, covering quality assurance, manufacturing, product development & engineering, project management, marketing, corporate planning and business development. He serves as expert of ISO/TC76 and ISO/TC84 and is an active member of Eucomed (MedTech Europe) and volunteer of PDA.

John Carpenter, *University of Colorado*

John F. Carpenter is Professor of Pharmaceutical Sciences at the University of Colorado (CU) and Co-Director of the CU Center for Pharmaceutical Biotechnology. His research focuses on mechanisms for protein degradation and stabilization. John has published >270 peer-reviewed papers and holds more than 30 patents. He is an Editor for Journal of Pharmaceutical Sciences and serves on several Editorial Advisory Boards. He has received The Ebert Prize and the American Association of Pharmaceutical Scientists (AAPS) Research Achievement Award in Biotechnology. He is a Fellow of the American Association for Advancement of Science, the AAPS and the National Academy of Inventors.

30 Oct 2017

Monday, 6 November 2017		10:00 – 18:00
10:00	**Welcome**	William Dierick, *TERUMO* John Carpenter, *University of Colorado*
	KEYNOTE PRESENTATIONS	
10:10	**Aggregates, Particles and Patient Immunogenicity with Biopharmaceuticals**	John Carpenter, *University of Colorado*
10:40	**Factors Affecting Stabilities of Biopharmaceuticals in Pre-filled Syringes**	Susumu Uchiyama, *Osaka University*
11:10	**Packaging Components and Biopharmaceuticals: Quality Aspects from Industry Perspective**	Hanns-Christian Mahler, *Lonza*
11:40	**Q&A - Discussion**	
12:00	**Lunch Break**	
Session 1	**Aggregation Phenomena**	
13:00	**Protein – Device Compatibility**	Flora Felsovalyi, *Roche*
13:30	**Characterization of Particles and Practical Implications**	Linda O. Narhi, *Amgen*
14:00	**Ex-Vivo Risk Assessment of Immunogenicity**	Mark Fogg, *Abzena*
14:30	**Q&A – Discussion**	
15:00	**Coffee Break**	
Session 2	**Particles**	
15:30	**Particulates in Sterile Drug Products: Testing, Contributions and Mitigation from Packaging Components**	Fran DeGrazio, *West*
16:00	**Particles in Packaging Components: Numbers and Chemical Composition**	Markus Lankers, *Rap.ID*
16:30	**Q&A - Discussion**	
Session 3	**Extractables & Leachables**	
16:45	**Extractables and Leachables: Impact of Packaging Components on Biopharmaceuticals**	Piet Christiaens, *Toxikon*
Session 4	**Functionality**	
17:15	**Needle Clogging of Staked-In-Needle PFS with High Concentration Protein Therapeutics**	Monica De Bardi, *Roche*
17:45	**Q&A - Discussion**	
17:55	**Closing Remarks by Co-Chairs**	
18:00	**End of Workshop**	