EBF - Focus Workshop

15-16 May 2018, Lisbon

New Modalities and Novel Concepts in Bioanalysis

15 May 2018

08.45 – 09.00	**Welcome and aim of the meeting**
09:00 – 10.00	**Challenges of and advancements in Bioanalysis of (oligo)nucleotides and related molecules**
09:00 – 09:20	Introduction to the session *Cecilia Arfvidsson, on behalf of the EBF*
09:20 – 09:40	LC-MS/MS Quantification of Oligonucleotides using SPE and hybridization extraction *Lieve Dillen, Janssen R&D*
09:40 – 10:00	Validation of qPCR assay for the quantification of gene therapy therapeutics in preclinical and clinical studies *Lydia Michaut, Novartis PK Sciences*
10:00 – 10:50	**Coffee break & networking**
10:50 – 11:10	Utility of Branched DNA Methodology for the Quantitation of Oligonucleotides *Amy Smith, MPI Research*
11:10 – 11:30	Novel Analytical Approaches for the Quantitation of Oligonucleotides - Combining LC-HRMS and LC-FL, ELISA, and RT-PCR based techniques *Alex Behling, PPDi*
11:30 – 12:30	Panel discussion: how to optimally use bioanalytical data from new modalities? A new role for the bioanalytical lab?
12:00 – 13:40	**Lunch**
13:40 – 17:30	**New analytical challenges for Immunogenicity testing**
13:40 – 14:00	Considerations for the Development of ADA Assays for the Analysis of Novel Modalities *Amy Lavelle, PPDi*
14:00 – 14:20	When 2-become- 1; Don't be a Stranger to the Challenges of Immunogenicity Testing in Dual Peptide Therapies *Nick White, MedImmune Ltd*
14:20 – 14:40	A company strategy for immunogenicity testing of peptide drugs *Birgitte Buur Rasmussen, Ferring*
14:40 – 15:00	Immunogenicity Testing Strategies for a Novel Modality: Lipid Nanoparticles Containing Small Interfering RNA Payloads *Renuka C. Pillutla, BMS*
15:00 – 15:40	**Tea break & Networking**
15:40 – 16:00	It's alive! Current and future challenges for bioanalysis of CAR-T cell therapies *Grzegorz Terszowski, Novartis Pharma AG*
16:00 – 16:20	Challenges in ADA/NAb Assay Design to Support Gene Therapy Programs

	Amy Smith, MPI Research
16:20 – 16:40	Immunogenicity assessment of COVA322: beyond classical screening and titer analysis *Wibke Lembke Covagen*
16:40 – 17:30	Panel discussion: challenges for immunogenicity testing for new modalities
17:30	**End of Day 1**

16 May 2018

08:45 – 09:00	**Introduction to day 2**
09:00 – 12:30	**Session theme: Impact of novel formulations for bioanalysis**
09:00 – 09:20	Types of complex formulations. *Joe Stanta, on behalf of the EBF*
09:20 – 09:40	PK/PD modelling perspective – why we need multicomponent assays *Mingguang Li, Covance*
09:40 – 10:00	Characterisation of formulations. Continuation of the introduction. Issues that you can get. *Fred van Heuveln, QPS the Netherlands*
10:00 – 10:20	Pro-drugs: what are the challenges? *Susanne Pihl, Ascendis Pharma*
10:20 – 11:00	**Coffee Break & networking**
11:00 – 11:20	Challenges and strategies for bioanalysis following nanoparticle drug delivery *Amanda Wilson, AstraZeneca*
11:20 – 11:40	Quantification of an excipient in microsamples: the challenges of hydroxypropyl-ß-cyclodextrin determination in a 15-µL drop of blood *Tom Verhaeghe, Janssen R&D*
11:40 – 12:30	Panel discussion on the theme of the session
12:30 – 13:45	**Lunch**
13:45 – 15:00	**Panel discussion – How do we integrate New Modalities and Novel Concepts in Bioanalysis in regulations.**
13:45 – 14:00	Introduction to the closing panel discussion *Philip Timmerman, EBF*
14:00 – 15:00	Closing panel discussion
15:00 – 15:30	**Summary, conclusion and next steps**
15:30 – 16:00	**Closing Tea break and adjourn**

MEETING ORGANISATION

Cecelia Arfvidsson (AstraZeneca), Joe Stanta (Covance), Michaela Golob (Nuvisan), Fred van Heuveln (QPS the Netherlands), Amanda Wilson (AstraZeneca), Magnus Knutsson (Ferring), Jo Goodman (MedImmune), Marianne Scheel Fjording (Novo Nordisk) Wibke Lembke (Janssen Biologics) and Philip Timmerman (EBF)

The Workshop is organized as a non-sponsored non-profit event by European Bioanalysis Forum vwz the day after the Critical Reagent training day