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 Arvidsson (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