Final Agenda

EBF - Focus Workshop

21-22 June 2017, Lisbon

Bioanalytical Strategies for Large Molecules in Modern Drug Development:

LBA and LC-MS United

21-Jun-2017

07:30	Registration desk opens
08.45 – 09.00	**Welcome and aim of the meeting**
09:00 – 10.00	**What is the question asked? What do we need to measure?** ***Session chair: Joe Stanta, Covance***
09:00 – 09:20	Bioanalysis of large molecules in a regulated bioanalytical environment – which is industry's challenge today *Presenter: Philip Timmerman, on behalf of the EBF*
09:20 – 09:40	Setting up a Bioanalytical Strategy - the Role of the Bioanalyst in Interdisciplinary Drug Development Teams *Presenter: Michaela Golob, on behalf of the EBF*
09:40 – 10:00	The importance of clearly defined bioanalytical data *Presenter: Roland Staack, Roche*
10:00 – 10:40	**Coffee break & networking**
10:40 – 12:00	**The toolbox: What are we measuring? How does the technology impact the results?)** ***Session chair: Roland Staack, Roche***
10:40 – 11:00	An industry perspective on the tools used today *Presenter: Pascal Delrat, on behalf of the EBF*
11:00 – 11:20	Why do results for proteins differ? A literature evaluation of different bioanalytical platforms *Presenter: Nico van de Merbel, PRA HS*
11:20 – 11:40	LBA and LC-MS: Why incorporate both for large molecule drug bioanalysis? *Presenter: Surinder Kaur, Genentech, on behalf of the IQ Consortium*
11:40 – 12:00	Panel discussion
12:00 – 13:30	**Lunch**

13:30 –15:00	**The toolbox: What are we measuring? How does the technology impact the results?** ***Session Chair: Nico van de Merbel, PRA HS***
13:30 – 13:40	Introduction into the toolbox discussion *Presenter: Magnus Knutsson, on behalf of the EBF*
13:40 – 14:00	Improvement of specificity for multiplex mAbs DMPK triage studies using LC-MRM3 *Presenter: Quentin Enjalbert, ANAQUANT*
14:00 – 14:20	Cell-based PK assays a useful additional "tool" for large molecule bioanalysis *Presenter: Martin Schäfer, Roche*
14:20 – 14:40	What can LC-MS offer beyond LBA approaches in the field of large molecules bioanalytics? *Presenter: Benno Ingelse, Q^2Solutions*
14:40 – 15:00	A multidisciplinary approach for regulated bioanalysis of ADCs *Presenter: Fabrizia Fusetti, QPS*
15:00 – 15:40	**Tea break & Networking**
15:40 – 17:30	**The regulatory space** ***Session Chair: Michaela Golob, Nuvisan***
15:40 – 15:50	Introduction to the session *Presenter: Magnus Knutsson, on behalf of the EBF*
15:50 – 16:10	Limitations of current PK assay guidelines for the validation of active drug assays *Presenter: Eginhard Schick, Roche*
16:10 – 16:30	Comparison of LBA and LC-MS Using a Well-Defined Set of GLP Study Samples *Presenter: Kevin Bateman, MSD*
16:30 – 17:30	Workshop discussion - what is missing in the regulatory space? *Recommendations to the regulators*
17:30	**End of Day 1**

22-JUN-2017

08:30 –08:40 **Introduction to day 2**

08:40 – 10:00 **Strategizing the bioanalysis for large molecules in early development – learning your molecule**
Session Chair: Matthew Barfield, Glaxo Smith Kline

08:40 – 09:00 LBA versus LC-MS/MS for quantitative analysis of large molecules. Are results comparable?
Presenter: Lieve Dillen, Janssen R&D

09:00 – 09:20 LBA strategies to support Early Drug Development
Presenter: Sarah Childs, GlaxoSmithKline

09:20 – 09:40 Biotherapeutics Quantification in Discovery and Early Development: Comparison of LC-MS Techniques for both Digested and Intact Quantification
John C Gebler, Waters

09:40 – 10:00 Quantification of free and total desmosine and isodesmosine in human plasma & urine by a high-throughput assay
Presenters: Sina Pleiner, Boehringer-Ingelheim

10:00 - 10:40 **Coffee Break & networking**

10:40 – 11:40 **Strategizing the bioanalysis for large molecules in late development – developing your molecule**
Session Chair: Pascal Delrat, Servier

10:40 – 11:00 LC–MS/MS strategies for therapeutic antibodies
Presenter: Joe Stanta, Covance

11:00 – 11:20 Hybrid LC-MS becomes routine: A fully validated assay for measuring clinically relevant concentrations of therapeutic peptides
Presenter: Michael Blackburn, ARCinova

11:20 – 11:40 Elucidation of atypical PK in a clinical trial using a CDR specific anti-peptide antibody and 2D-LC-MS/MS
Presenter: Carsten Krantz, Novartis

11:40 – 12:30 **Workshop - prepare for closing panel discussion - continue over lunch**

12:30 – 13:45 **Lunch**

13:45 - 15:00 **Closing Focus workshop panel discussion**

15:00 – 15:30 **Summary, conclusion and next steps**

15:30 – 16:00 **Closing Tea break, networking and adjourn**