



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

- 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 – 13:40** **Lunch**
- 13:40 – 15:00** **The toolbox: What are we measuring? How does the technology impact the results?**
Session Chair: Nico van de Merbel, PRA HS
- 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, Q²Solutions
- 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**

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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, ARCAInova

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**