



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

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|----------------------|---|
| 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? |
| 09:00 – 09:20 | Bioanalysis of large molecules in a regulated bioanalytical environment – which is industry's challenge today
<i>Presenter: Philip Timmerman, on behalf of the EBF</i> |
| 09:20 – 09:40 | Setting up a Bioanalytical Strategy - the Role of the Bioanalyst in Interdisciplinary Drug Development Teams
<i>Presenter: Michaela Golob, on behalf of the EBF</i> |
| 09:40 – 10:00 | The importance of clearly defined bioanalytical data
<i>Presenter: Roland Staack, Roche</i> |
| 10:00 – 10:40 | Coffee break & networking |
| 10:40 – 12:00 | The toolbox: What are we measuring? How does the technology impact the results?) |
| 10:40 – 11:00 | An industry perspective on the tools used today
<i>Presenter: Pascal Delrat, on behalf of the EBF</i> |
| 11:00 – 11:20 | Why do results for proteins differ? A literature evaluation of different bioanalytical platforms
<i>Presenter: Nico van de Merbel, PRA HS</i> |
| 11:20 – 11:40 | LBA and LC-MS: Why incorporate both for large molecule drug bioanalysis?
<i>Presenter: Surinder Kaur, Genentech, on behalf of the IQ Consortium</i> |
| 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?

13:30 – 13:40 Introduction into the toolbox discussion

Presenter: Olivier Heudi, 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, Q²Solutions

14:40 – 15:00 A multidisciplinary approach for regulated bioanalysis of ADCs

Presenter: Fabrizia Fusetti, QPS

15:00 – 15:30 Tea break & Networking

15:30 – 17:30 The regulatory space

15:30 – 15:40 Introduction to the session

Presenter: Magnus Knutsson, on behalf of the EBF

15:40 – 16:00 Limitations of current PK assay guidelines for the validation of active drug assays

Presenter: Eginhard Schick, Roche

16:00 – 16:20 Comparison of LBA and LC-MS Using a Well-Defined Set of GLP Study Samples

Presenter: Kevin Bateman, MSD

16:20 – 16:40 Regulatory input

Presenter: tbd, from HA

16:40 – 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

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

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, ARCI nova

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