

Open Symposium Program

Day 1 - Wednesday 19 NOV 2014

PLENARY SESSIONS

08:30	08:40	Welcome
08:40	10:20	Large molecules - LBA or LC-MS? Why and when
08:40	09:00	Roland Staack (Hoffmann-La Roche) <i>Protein Quantification by LBA or LC-MS: Key Criteria for the Definition of the Bioanalytical Strategy</i>
09:00	09:20	Barry van der Strate & Nico van de Merbel (PRA Health Sciences) <i>Can 1+1 be 3? The combination of LBA and LC-MS to look beyond the horizon of large molecule quantification</i>
09:20	09:40	Rand Jenkins (PPD, Inc.) <i>Immunogenicity assessments, an important aspect of biotherapeutic drug development: Can LC-MS technology be applied to complement traditional LBA-based approaches?</i>
09:40	10:00	Ronald de Vries (Janssen R&D) <i>Combined use LBA + LC-MS/MS in drug development of a 4kDa peptide: 1+1=3 or where complementary data made a difference</i>
10:00	10:20	Panel Discussion
10:20	11:00	Coffee break
11:00	12:40	Large molecules - LBA and LC-MS! How
11:00	11:20	Matt Barfield (GlaxoSmithKline, on behalf of EBF TT-43) <i>How to develop Antibody Drug Conjugates – Recommendations from TT43 and survey results</i>
11:20	11:40	Charlotte Hagman (Novartis) <i>Characterization of Antibody-Drug Conjugates using Affinity Enrichment and High-Resolution Mass Spectrometry</i>
11:40	12:00	Fabio Garofolo (Algorithme Pharma Inc) <i>Recent Trends in Antibody-Drug Conjugate (ADC) Bioanalysis: Total Antibody Quantification by HRMS</i>

- 12:00 12:20 **Ravindra Chaudhari (Thermo Fisher Scientific)**
Highly Sensitive and Robust Workflow for Therapeutic Monoclonal Antibody Analysis from Complex Matrices
- 12:20 12:40 **Panel Discussion**
- 12:40 14:00 Lunch break**
- 14:00 15:20 Looking Beyond the Horizon**
- 14:00 14:20 **Philip Timmerman (Janssen R&D)**
Making the impossible possible
- 14:20 14:40 **John Varaklis (Abbott)**
Beyond the Horizon: Convergence of Data-enabled Health Solutions and Clinical Development Models
- 14:40 15:00 **Zsofia Berke (AstraZeneca)**
Analytical Comparison Between Point-of-Care Uric Acid Testing Meters
- 15:00 15:20 **Daniela Stoellner (Novartis, on behalf of EBF TT-20)**
How the bioanalytical scientist plays a key role in interdisciplinary project teams in the development of biotherapeutics – a reflection of the European Bioanalysis Forum
- 15:20 16:00 Tea break**
- 16:00 17:45 Scientific or Regulated Validation? AKA Tiered Approach**
- 16:00 16:20 **Philip Timmerman (Janssen R&D, on behalf of EBF)**
EBF proposals on balancing Scientific vs. Regulated Validation
- 16:20 16:40 **David Jones (MHRA)**
An EU Regulator's viewpoint as why Regulatory Guidelines should not be followed
- 16:40 17:00 **Hans Stieltjes (Janssen R&D)**
Tiered Approach for Bioanalysis of Drugs and their Metabolites: Examples of the Use of Qualified Assays at Janssen R&D during the past decade
- 17:00 17:20 **Graeme Smith (Harlan / Huntington Life Sciences)**
A Tiered Approach to Bioanalysis: From Concept to Practice
- 17:20 17:45 **Panel discussion**

18:00 19:00 Cocktail reception

SPOTLIGHT WORKSHOP

11:00 12:40 Spotlight on e-Data: towards a common standard

11:00 11:05 Introduction to the workshop

Workshop chairs (Hans Mulder (Astellas) /David Van Bedaf (Janssen R&D))

11:05 11:25 Jim Brennan (LabWare)

A perspective on paperless operations in a modern bioanalytical laboratory

11:25 11:45 Gerhard Noelken (Allotrope)

Allotrope: An open ecosystem for seamless data management and exchange for Bioanalysis

11:45 12:05 Peter Esch (Novartis)

Electronic Raw Data in a GLP Environment – Swiss AGIT Working Group Guidelines

12:05 12:40 Panel discussion - workshop

Gaps and practical steps towards a common e-standard for bioanalysis

Day 2 - Thursday 20 NOV 2014

PARALLEL SESSIONS 1

08:30 10:10 LC-MS Applications for Large Molecules

08:30 08:50 Kevin Bateman (MSD)

Application of LC-MS for characterization and bioanalysis of therapeutic antibodies

08:50 09:10 Ludovicus Staelens (UCB Pharma)

Internal standard approaches in quantification of proteins by LC-MS/MS

09:10 09:30 Richard Kay (LGC)

Supercharging reagents - revving up peptide LC-MS analyses.

09:30 09:50 Vincent Trinh (inVentiv Health Clinical)

Insulin Glargine: From the Immunoassays to the More Specific LC-MS/MS Assay

09:50 10:10 Erin Chambers (Waters Corporation)

Getting More with Less: Improving Sensitivity and Reducing Sample

Consumption in LC/MS Assays for Endogenous and Injected Glucagon, 6 insulins, and Teriparatide

- 10:10 11:00 Coffee break**
- 11:00 12:40 Diversity of the Bioanalytical Landscape**
- 11:00 11:20 **Ann Lévesque (inVentiv Health Clinical)**
Determination of Testosterone in Plasma instead of Serum: When is it needed? Is it accepted?
- 11:20 11:40 **Susan Pang (LGC)**
The development of robust cortisol assays for sports-based applications
- 11:40 12:00 **Vincenzo Pucci (Merck)**
Merck global bioanalytical strategy to ensure data quality in the discovery space and successful LC-MS/MS methods transfer to preclinical GLP and clinical bioanalytical groups
- 12:00 12:20 **Jonathan Stauber (ImaBiotech)**
Applications of Quantitative Mass Spectrometry Imaging in drug development
- 12:20 12:40 **Mohammed Abrar (Unilabs York Bioanalytical Solutions)**
Vitamin D3 Determination- Automated, Streamlined, Robust and Reliable
- 12:40 14:00 Lunch break**
- 14:00 15:40 Low, Lower, Lowest**
- 14:00 14:20 **William van Dongen (TNO Triskelion)**
Nano-UPLC and Chip-based LC-MS methods for the sensitive determination of therapeutic monoclonal antibodies in serum
- 14:20 14:40 **Mark Wrona (Waters Corporation)**
Integration of microfluidics with High Resolution Mass Spectrometry (HRMS) for DMPK Studies
- 14:40 15:00 **Tom Verhaeghe (Janssen R&D)**
LC-MS/MS as an enabler for a broader application of microdose studies in drug development; the Janssen experience
- 15:00 15:20 **Adrian Pereira (GlaxoSmithKline)**
Validation of a clinical assay with LLoQ of 350 fg/mL by Liquid Chromatography + Accelerator Mass Spectrometry in support of dermal dosing

15:20	15:40	Stephen English (Xceleron) <i>Tiered validation of LC+AMS Assays: Recommendations for best practices</i>
15:40	16:15	Tea break
16:15	17:55	Bioanalytical Assay Robustness
16:15	16:35	Steve White (GlaxoSmithKline) <i>Measuring assay robustness across the life cycle of a bioanalytical method</i>
16:35	16:55	Amanda Wilson (AstraZeneca, on behalf of EBF TT-41) <i>EBF Topic Team-41; Processed Sample Reproducibility and Stability</i>
16:55	17:15	David Bakes (Harlan / Huntington Life Sciences) <i>An industry consensus towards baseline assignment – where do we draw the line?</i>
17:15	17:35	Luc Bouchard (inVentiv Health Clinical) <i>Importance of End-to-End Robustness when dealing with Glucuronide Metabolites</i>
17:35	17:55	Susanne Pihl (Lundbeck, on behalf of EBF TT-47) <i>EBF recommendation on practical management of critical reagents for ligand-binding assays</i>
18:00	19:00	Cocktail reception

PARALLEL SESSIONS 2

08:30	10:10	Day to Day Challenges and Automation in Bioanalysis
08:30	08:50	Raymond Farmen (Celerion) <i>Integrating automated systems for regulated bioanalysis</i>
08:50	09:10	Christophe Zickler (Novartis) <i>Automated bioanalysis of PK, PD and immunogenicity in a GLP/GCLP regulated environment</i>
09:10	09:30	Craig Stovold (LGC) <i>Assessing Carryover in the Immunoassay Laboratory</i>
09:30	09:50	Matt Bentley (Eurofins Pharma Bioanalysis Services) <i>Practical solutions to the optimisation of drug tolerance in ADA method Development</i>

- 09:50 10:10 **Gert Hendriks (PRA Health Sciences)**
Matrix effects in lipemic plasma: practical solutions to additional issues in bioanalytical method development and validation
- 10:10 11:00 Coffee break**
- 11:00 12:40 Immunoassays for Biomarkers**
- 11:00 11:20 **Dominique Gouty (BioAgilytix)**
Selecting the right strategy for Biomarkers
- 11:20 11:40 **Karen Elsby (AstraZeneca)**
The MULTIPLE trials of generating a SINGLE data set: taking biomarker assays through the clinical phases
- 11:40 12:00 **James Lawrence (Harlan / Huntington Life Sciences)**
Adapting Commercial Immunoassay Kits for Pre-Clinical Biomarkers: Challenges and Solutions.
- 12:00 12:20 **Jo Goodman (MedImmune)**
The changing face of the immunoassay landscape for soluble target engagement biomarkers quantification
- 12:20 12:40 **Marianne Scheel Fjording (Novo Nordisk)**
Gold, Silver, Bronze
- 12:40 14:00 Lunch break**
- 14:00 15:40 New Technologies and Applications in Large Molecule Bioanalysis**
- 14:00 14:20 **Michael Przybylski (University of Konstanz)**
Online SAW-Biosensor-Mass Spectrometry: Simultaneous Detection, Structure Determination and Affinity Quantification of Protein-Ligand Interactions
- 14:20 14:40 **Robert Nelson (NovImmune SA)**
Evaluating multiple technology platforms in the development of large molecule bioanalytical assays
- 14:40 15:00 **Clare Kingsley (LGC)**
Ultrasensitivity immunoassays
- 15:00 15:20 **Nick Pearson (CiToxLAB)**
Quantifying short RNA molecules in a regulatory environment

15:20	15:40	Ashleigh Wake (Intertek Life Sciences) <i>Alternative Methods to LC-MSMS and Immunochemistry Based Method in Bioanalysis</i>
15:40	16:15	Tea break
16:15	17:55	Biosimilars
16:15	16:35	Timo Piironen (Syrinx Bioanalytics) <i>Challenges and strategies of developing and validating immunogenicity assays for biosimilars</i>
16:35	16:55	James Munday (Covance) <i>The use of PK, PD and ADA bioanalysis for evaluation of the overall Immunogenicity of biosimilars and the bioanalytical challenges for determining if there are equivalent safety risks.</i>
16:55	17:15	Ricardo Gutierrez-Gallego (Anapharm Biotech) <i>Biosimilarity assessment - impact on safety and efficacy</i>
17:15	17:30	Joseph C. Marini (Janssen R&D, on behalf of AAPS LBABFG) <i>Recommendations from the AAPS LBABFG Biosimilars Action Program Committee on the Development and Validation of PK and ADA assays for Biosimilar Drug Development</i>
17:30	17:45	Birgitte Buur Rasmussen (Ferring Pharmaceuticals, on behalf of EBF) <i>Recommendations from EBF biosimilars evaluation group</i>
17:45	18:00	Panel Discussion
18:00	19:00	Cocktail reception

Day 3 - Friday 21 NOV 2014

PLENARY SESSIONS

08:30	09:00	Consult the Doctor
08:30	08:45	Martijn Hilhorst (PRA Health Sciences) <i>Selectivity issues during the determination of resolvin E1 in human plasma</i>
08:45	09:00	Matt Barfield (Glaxo SmithKline) <i>Issues with transferring Gyrolab preclinical assays to human.</i>

09:00	10:40	"Honey I Shrunk the Sample"
09:00	09:20	Maryann Ngeny (AstraZeneca) <i>Pushing the Boundaries of Microsampling – Realising and Understanding the Full Potential</i>
09:20	09:40	Jo Goodman (MedImmune) <i>One Mouse, One PK: the Magic of Capillary Microsampling in Combination with the Gyrolab™ Assay Platform</i>
09:40	10:00	Beena Punnamoottil (Chimera Biotech) <i>LBA testing in the fraction of a drop: Case studies for ultra-sensitive assays in 1 to 5 microliter sample volume</i>
10:00	10:20	Vera Hillewaert (Janssen R&D) <i>Assessment of capillary microsampling of blood in a healthy volunteer study</i>
10:20	10:40	Zoe Cobb (LGC, on behalf of the EBF Liquid Microsampling Consortium) <i>Feedback from EBF Liquid Microsampling Consortium</i>
10:40	11:15	Young Investigator Award
10:40	10:45	Introduction
10:45	11:15	Presentation by the 2014 Young Investigator Award winner
11:15	11:55	Coffee & Snack break
11:55	12:55	The Regulatory Landscape
11:55	12:15	Michaela Golob (on behalf of EBF) <i>Feedback from AAPS Open Forum</i>
12:15	12:35	Akiko Ishii (National Institute of Health Science) <i>Japan LBA guideline</i>
12:35	12:55	Margarete Brudny-Kloepfel (Bayer Pharma AG, on behalf of EBF) <i>Feedback from China Days knowledge exchange meeting</i>
12:55	13:55	Diversity of the Bioanalytical Techniques

- 12:55 13:15 **Gérard Hopfgartner (University of Geneva)**
Quantification of endogenous and exogenous metabolites in small samples using parallel narrow bore to capillary LC with fast polarity switching MRM
- 13:15 13:35 **Jim Settlege (inVentiv Health Clinical)**
Using Supercritical Fluid Chromatography coupled with Tandem Mass Spectrometry to Provide Easier Solutions to Old Problems and New Solutions to Previously Unsolved Problems
- 13:35 13:55 **Johannes Stanta (Covance)**
Comparing time-of-flight mass spectrometry with triple quadrupole mass spectrometry for small molecule, peptide and oligonucleotide bioanalysis
- 13:55 14:00 Plans for 2015 / Close Out**