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)
Protein Quantification by LBA or LC-MS: Key Criteria for the Definition of the Bioanalytical Strategy

09:00 09:20 Barry van der Strate & Nico van de Merbel (PRA Health Sciences)
Can 1+1 be 3? The combination of LBA and LC-MS to look beyond the horizon of large molecule quantification

09:20 09:40 Rand Jenkins (PPD, Inc.)
Immunogenicity assessments, an important aspect of biotherapeutic drug development: Can LC-MS technology be applied to complement traditional LBA-based approaches?

09:40 10:00 Ronald de Vries (Janssen R&D)
Combined use LBA + LC-MS/MS in drug development of a 4kDa peptide: 1+1=3 or where complementary data made a difference

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)
How to develop Antibody Drug Conjugates – Recommendations from TT43 and survey results

11:20 11:40 Charlotte Hagman (Novartis)
Characterization of Antibody-Drug Conjugates using Affinity Enrichment and High-Resolution Mass Spectrometry

11:40 12:00 Fabio Garofolo (Algorithm Pharma Inc)
Recent Trends in Antibody-Drug Conjugate (ADC) Bioanalysis: Total Antibody Quantification by HRMS
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 Wrorna (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)**  
Tiered validation of LC+AMS Assays: Recommendations for best practices

15:40  16:15  **Tea break**

16:15  17:55  **Bioanalytical Assay Robustness**

16:15  16:35  **Steve White (GlaxoSmithKline)**  
Measuring assay robustness across the life cycle of a bioanalytical method

16:35  16:55  **Amanda Wilson (AstraZeneca, on behalf of EBF TT-41)**  
EBF Topic Team-41; Processed Sample Reproducibility and Stability

16:55  17:15  **David Bakes (Harlan / Huntington Life Sciences)**  
An industry consensus towards baseline assignment – where do we draw the line?

17:15  17:35  **Luc Bouchard (inVentiv Health Clinical)**  
Importance of End-to-End Robustness when dealing with Glucuronide Metabolites

17:35  17:55  **Susanne Pihl (Lundbeck, on behalf of EBF TT-47)**  
EBF recommendation on practical management of critical reagents for ligand-binding assays

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)**  
Integrating automated systems for regulated bioanalysis

08:50  09:10  **Christophe Zickler (Novartis)**  
Automated bioanalysis of PK, PD and immunogenicity in a GLP/GCLP regulated environment

09:10  09:30  **Craig Stovold (LGC)**  
Assessing Carryover in the Immunoassay Laboratory

09:30  09:50  **Matt Bentley (Eurofins Pharma Bioanalysis Services)**  
Practical solutions to the optimisation of drug tolerance in ADA method Development
<table>
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<tr>
<th>Time</th>
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| 09:50 | **Gert Hendriks (PRA Health Sciences)**  
Matrix effects in lipemic plasma: practical solutions to additional issues in bioanalytical method development and validation |
| 10:10 | Coffee break                                                                                                                         |
| 11:00 | Immunoassays for Biomarkers                                                                                                          |
| 11:00 | **Dominique Gouty (BioAgilytix)**  
Selecting the right strategy for Biomarkers                                                                                          |
| 11:20 | **Karen Elsby (AstraZeneca)**  
The MULTiple trials of generating a SINGLE data set: taking biomarker assays through the clinical phases                       |
| 11:40 | **James Lawrence (Harlan / Huntington Life Sciences)**  
Adapting Commercial Immunoassay Kits for Pre-Clinical Biomarkers: Challenges and Solutions.                                        |
| 12:00 | **Jo Goodman (MedImmune)**  
The changing face of the immunoassay landscape for soluble target engagement biomarkers quantification                          |
| 12:20 | **Marianne Scheel Fjording (Novo Nordisk)**  
Gold, Silver, Bronze                                                                                                                   |
| 12:40 | Lunch break                                                                                                                          |
| 14:00 | New Technologies and Applications in Large Molecule Bioanalysis                                                                       |
| 14:00 | **Michael Przybylski (University of Konstanz)**  
Online SAW-Biosensor-Mass Spectrometry: Simultaneous Detection, Structure Determination and Affinity Quantification of Protein-Ligand Interactions |
| 14:20 | **Robert Nelson (NovImmune SA)**  
Evaluating multiple technology platforms in the development of large molecule bioanalytical assays                                    |
| 14:40 | **Clare Kingsley (LGC)**  
Ultrasensitivity immunoassays                                                                                                           |
| 15:00 | **Nick Pearson (CiToxLAB)**  
Quantifying short RNA molecules in a regulatory environment                                                                              |
15:20  15:40  **Ashleigh Wake (Intertek Life Sciences)**  
Alternative Methods to LC-MSMS and Immunochemistry Based Method in Bioanalysis

15:40  16:15  Tea break

16:15  17:55  Biosimilars

16:15  16:35  **Timo Piironen (Syrinx Bioanalytics)**  
Challenges and strategies of developing and validating immunogenicity assays for biosimilars

16:35  16:55  **James Munday (Covance)**  
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.

16:55  17:15  **Ricardo Gutierrez-Gallego (Anapharm Biotech)**  
Biosimilarity assessment - impact on safety and efficacy

17:15  17:30  **Joseph C. Marini (Janssen R&D, on behalf of AAPS LBABFG)**  
Recommendations from the AAPS LBABFG Biosimilars Action Program Committee on the Development and Validation of PK and ADA assays for Biosimilar Drug Development

17:30  17:45  **Birgitte Buur Rasmussen (Ferring Pharmaceuticals, on behalf of EBF)**  
Recommendations from EBF biosimilars evaluation group

17:45  18:00  Panel Discussion

18:00  19:00  Cocktail reception

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**Day 3 - Friday 21 NOV 2014**

**PLENARY SESSIONS**

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<thead>
<tr>
<th>Time</th>
<th>Name</th>
<th>Presentation</th>
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<tbody>
<tr>
<td>08:30</td>
<td>Martijn Hilhorst (PRA Health Sciences)</td>
<td>Selectivity issues during the determination of resolvin E1 in human plasma</td>
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<tr>
<td>08:30</td>
<td>Matt Barfield (Glaxo SmithKline)</td>
<td>Issues with transferring Gyrolab preclinical assays to human.</td>
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09:00 10:40 "Honey I Shrunk the Sample"

09:00 09:20 Maryann Ngeny (AstraZeneca)
Pushing the Boundaries of Microsampling – Realising and Understanding the Full Potential

09:20 09:40 Jo Goodman (MedImmune)
One Mouse, One PK: the Magic of Capillary Microsampling in Combination with the Gyrolab TM Assay Platform

09:40 10:00 Beena Punnamoottil (Chimera Biotec)
LBA testing in the fraction of a drop: Case studies for ultra-sensitive assays in 1 to 5 microliter sample volume

10:00 10:20 Vera Hillewaert (Janssen R&D)
Assessment of capillary microsampling of blood in a healthy volunteer study

10:20 10:40 Zoe Cobb (LGC, on behalf of the EBF Liquid Microsampling Consortium)
Feedback from EBF Liquid Microsampling Consortium

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)
Feedback from AAPS Open Forum

12:15 12:35 Akiko Ishii (National Institute of Health Science)
Japan LBA guideline

12:35 12:55 Margarete Brudny-Kloeppel (Bayer Pharma AG, on behalf of EBF)
Feedback from China Days knowledge exchange meeting

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

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