Program details Open Symposium 2015

Day 1 - Wednesday 18 nov 2015

Plenary session (in auditorium)

08:30 08:40 Welcome

08:40 10:20 Biomarker Validation Strategies

08:40 09:10 ***KeynoteSpeaker: David Perrett, St. Barts Hospital***

Validating Biomarkers in the Clinic: Is it possible?

09:10 09:30 ***Patrick Bennett, PPD***

Biomarkers: not just another bioanalytical challenge

09:30 09:45 ***Christian Herling, on behalf of the EBF TT-50 Clinical analysers***

Clinical Analysers – feedback from EBF topic team

09:45 10:00 ***Philip Timmerman, on behalf of the EBF***

EBF Position on need for regulations in Biomarker Assay validation

10:00 10:20 ***Marianne Scheel-Fjording, on behalf of the EBF***

Feedback from the AAPS Crystal City VI meeting on Biomarkers

10:20 10:40 Panel Discussion

11:00 12:40 Proteins by LC-MS

11:00 11:20 ***Rand Jenkins, onbehalf of the AAPS Bioanalytical Focus Group's Protein***

LC-MS Bioanalysis Subteam

Recommendations for validation of LC-MS/MS bioanalytical methods for protein biotherapeutics

11:20 11:40 ***Erin Chambers, Waters***

Practical Consideraations for LC/MS Bioanalysis of Proteins via the Surrogate
Peptide Approach and Intact Analysis

11:40 12:00 ***Mike Oliver, Thermo Scientific***

Improvement in full workflow capabilities to provide increased reproducibility, speed and throughput for quantitation and characterisation for bio-similars

12:00 12:20 ***Matt Ewles, Covance***

High throughput, robust and cost-effective LC-MS/MS strategies for quantification of therapeutic monoclonal antibodies in human and animal plasma, to support clinical and preclinical studies

12:20 12:40 ***Ichiro Hirano, Shimadzu***

Selective quantification of therapeutic monoclonal antibodies in blood by nano-surface and molecular-orientation limited (nSMOL) proteolysis using LC-MS/MS

14:00 15:20 LC-MS & LBA - two true values!

14:00 14:20 ***Nico van de Merbel, PRA Health Sciences***

Why do LC-MS and LBA results differ? A literature evaluation.

14:20 14:40 ***Daniela Stoellner, on behalf of the EBF TT-20:***

Challenges of total and free macromolecule quantification. An update

14:40 15:00 ***Carsten Krantz, Novartis***

LC-MS for large molecules vs. Ligand Binding Assays-orthogonal readout or contradictory methods?

15:00 15:20 ***Roland Staack, F. Hoffmann-La Roche***

Towards a differentiated PK Analysis for a better understanding of PK/PD/Safety relationship – Challenges and Technologies

16:10 17:50 Analytical Challenges for Novel Constructs

16:10 16:30 ***Neil Henderson, AstraZeneca***

Establishing strategies to meet the bioanalytical needs of Oligonucleotide Therapeutics in Pre-clinical Models and beyond

16:30 16:50 ***Lieve Dillen, Janssen R&D***

Challenges with a LCMS method for quantification of an oligonucleotide

16:50 17:10 ***Rand Jenkins, PPD***

Direct Bioanalysis of ADCs using Affinity Capture-LC-HR/AMS Techniques for Characterization and Quantification—a Progress Update

17:10 17:30 ***Jonathan St-Germain, Algorithme***

Bioanalysis of PEGylated proteins using hybrid LBA/LCMS Method

17:30 17:50 ***Winner of the 2015 - Bioanalysis YIA award: Xiwei (Emmi) Zheng***

Analysis of Solute-Protein Binding in Solution by Ultrafast

Affinity Extraction and Affinity Microcolumns

Workshops

14:00 15:20 Workshop 01: Generic Data Transfer Agreement

14:00 14:20 ***Jose Groenboom – Nieuwenhuijzen, on behalf of the EBF TT-12: Clinical Multi Center Trials***

Introduction: towards a generic data transfer agreement

14:20 14:40 ***Martina Wein, Boeringer Ingelheim***

Introduction to CDISC fort he Bioanalyst

14:40 15:20 Workshop discussion

16:10 17:50 Workshop 02: CRO-Pharma Partnerships

16:10 16:30 ***Vera Hillewaert and Matthew Barfield, on behalf of the EBF***

Importance of Innovation in Pharma-CRO scientific interface – Feedback from the EBF Focus Workshop on Optimizing the Pharma CRO scientific interface in bioanalysis.

16:30 16:50 ***Chris Jones, LGC***

Enhancing the CRO-Pharma relationship with a focus on method transfer.

16:50 17:50 Workshop discussion

Day 2 - Thursday 19 nov 2015

Break out session (in auditorium) .

08:30 10:10 Going Paperless

08:30 08:50 ***Tom Verhaeghe, Janssen R&D***

eLN goes GLP: the journey of implementing an eLN system in a regulated environment - experiences at the bioanalytical lab of Janssen Research and Development.

08:50 09:10 ***Peter Pruim, PRA Health Sciences***

Towards a paperless laboratory – a CRO perspective

09:10 09:30 ***Gerhard Noelken, Allotrope***

How the outcome of the combined EBF/ Allotrope Electronic Data Group can drive implementation of the Allotrope Framework in the Bioanalytical Laboratory?

09:30 09:50 ***David Van Bedaf , on behalf of the EBF - eData team***

EBF – Allotrope Collaboration: towards a common standard on e-data for real.

09:50 10:10 Panel discussion

11:00 12:40 Large Molecule LC-MS Applications

11:00 11:20 ***Michael Blackburn, Covance***

''How low can you go: Driving down limits of quantitation for peptide biomolecules by hybrid IA-LC/MS'

11:20 11:40 ~~***Ann Lévesque, InVentivHealth***~~

~~Hybrid LBA-LC/MS/MS assays: From the new technologies to the high throughput implementation~~

11:40 12:00 ***Matt Barfield, GlaxoSmithKline***

Utilising automation for complex protein assays to increase robustness and reduce cycle times

12:00 12:20 ***Richard Kay, LGC***

Developing LC-MS/MS methods for quantifying mAbs: Transitioning from pre-clinical to clinical matrices.

12:20 12:40 ***Suma Ramagiri, ABSciex***

A Functionalized Assay - Hyphenating LBA with LC/MS: How far can we push to accomplish anything meaningful?

14:00 15:40 Microsampling - Where are we Today?

14:00 14:20 ***Sara Capiau, Ghent University***

Different strategies for coping with the hematocrit effect in dried blood micro-sampling.

14:20 14:40 ***Shinobu Kudoh, Shimadzu Techno-Research***

Introduction of MSW2, a handy and facile device specialized for serum and plasma microsampling

14:40 15:00 ***Hans Stieltjes, Janssen R&D***

Experiences with (non-)capillary microsampling in preclinical GLP studies

15:00 15:20 ***Steve White, on behalf of the EBF LMS Consortium***

Update from the EBF Liquid Microsampling Consortium

15:20 15:40 Panel Discussion

16:20 18:00 Advances in Separation & MS

16:20 16:40 ***Liesbeth Vereyken, Janssen R&D***

Ultra high sensitivity bioanalyis by 2D-microUHPLC to overcome ion suppression with large volume injections.

16:40 17:00 ***Mohammed Abrar, Unilabs***

UPC2 for Bioanalysis – "Providing Diversity for Chromatographic Separation"

17:00 17:20 ***Walid Elbast, Novartis***

Novel quantitative approach for biodistribution of drug-related compounds in tissues using micro Liquid Chromatography - Liquid Extraction Surface Analysis - tandem Mass Spectrometry (mLC-LESA-MS/MS)

17:20 17:40 ***Lester Taylor, Agilent***

2D LC/Q-TOF and SFC/QQQ for Stereospecific Drug Metabolite Analysis

17:40 18:00 ***Diego Rodriguez Cabaleiro, Waters***

Applications of novel acquisition modes and instrument geometries in Time-of-Flight Mass Spectrometer for Targeted Quantitation

18:00 19:00 Cocktail reception incl. celebration of 2015 EBF Best Poster

Break out session (in Jupiter)

08:30 10:10 Biomarkersn & Flow Cytometry

08:30 08:50 ***Afshin Safavi, BioAgilytix***

Assay and Kit Lot Bridging Considerations for Multiplex Biomarker Analysis in Support of Preclinical and Clinical Studies

08:50 09:10 ***Robert Nelson, NovImmune***

Fit-for-purpose inflammatory biomarker assay development and validation

09:10 09:30 ***John Allinson, LGC***

Multiplexed Biomarker Methods – Platforms, methods and special considerations for method validation

09:30 09:50 ***Jennifer Hincks, Harlan / Huntington Life Sciences***

Flow Cytometry Biomarker Assays, Validation Criteria vs. Biology.

09:50 10:10 ***Kurt Sales, Charles River***

Development and Validation of in vitro flow cytometry-based assays for preclinical immunology.

11:00 12:40 New Territories Applied

11:00 11:20 ***Adrian Pereira, GlaxoSmithKline***

The Challenges associated with Dermal Dosing to Humans and Plasma Analysis for a Novel therapeutic agent when administered to Healthy Volunteers

11:20 11:40 ***Esther van Duijn, TNO***

Excellent linearity between automated CO2 combustion AMS and (low level) liquid scintillation counting for plasma, blood, urine and feces samples

11:40 12:00 ***Jonathan Stauber, ImaBiotech***

MALDI Imaging application from preclinical to clinical stages

12:00 12:20 ***Karen Woods, AstraZeneca***

Challenges and Strategies for Bioanalysis following Nanoparticle drug delivery

12:20 12:40 ***Winner 2nd YSS best presentation: James Howard (LGC)***

Slides – See YSS-tab

14:00 15:20 Biomarker Applications

14:00 14:20 ***Raymond Farmen, Celerion***

Further refinement and validation of the only ultrasensitive biomarker method for benzo[a]pyrene exposure by urinary metabolite.

14:20 14:40 ***Richard Hughes, LGC***

Sample volume – does it need to restrict your biomarker strategy?

14:40 15:00 ***Sven Pötzsch, Merck***

Bioanalysis of Metabolic Biomarkers during Drug Discovery and Early Preclinical Development – Challenges and Solutions

15:00 15:20 ***Martine Broekema, PRA Health Sciences***

Immuno-PCR (Imperacer®) in a GLP-Regulated Environment - Examples and Lessons Learned

16:20 17:40 Varying Perspectives on ADAs

16:20 16:40 ***Nicolas White, MedImmune***

CBA, LBA or NA - Regulatory Sense on Non-Sense

16:40 17:00 ***Gregor Jordan, F. Hoffmann-La Roche***

Development of a bioanalytical method for the characterization of immune complexes

17:00 17:20 ***Lydia Michaut, Novartis***

Anti-Vector antibody assays for gene therapy projects: analytical challenges

17:20 17:40 ***Ludovicus Staelens, UCB BioPharma***

Approach to simultaneous detection, (semi-)quantification and isotyping of ADA in plasma samples by LC-MS/MS

Day 3 - Friday 20 nov 2015

Plenary session (in auditorium)

09:00 10:40 Dealing with issues in Clinical Studies

09:00 09:20 ***Jose Groenboom - Nieuwenhuijzen, PRA Health Sciences***

A phase III sample analysis study: challenges and solutions

09:20 09:40 ***Katja Heinig, F. Hoffmann-La Roche***

Stability Issues in Bioanalysis: New Case

09:40 10:00 ***Brigitte Pellerin, InVentivHealth***

Bioanalytical Issues when Dealing with Phase II/III Studies

10:00 10:20 ***Timothy Sangster, on behalf of the EBF TT-45: Defining the right control matrix***

What Matrix, Which Matrix!

10:20 10:40 ***Daniela Stoellner, Novartis***

Incidence of drug treatment in placebo subjects – how bioanalytics helped to understand this case

11:20 13:00 Scientific Validation

11:20 11:40 ***Eva Lindqvist, AstraZeneca***

A journey from Exploratory to Regulatory Bioanalysis

11:40 12:00 ***Yoshihisa Sano*** (***Sunplanet/Eisai, on behalf of the Japan Bioanalysis Forum***

Tiered Approach to Metabolite Quantification: An Outcome from JBF Discussion Group

12:00 12:20 ***Faye Vazvaei, F. Hoffmann-La Roche***

Feedback from the 2015 AAPS Open Forum

12:20 12:40 ***Philip Timmerman, on behalf of the EBF***

EBF Tiered approach final recommendation of Scientific Validation criteria

12:40 13:00 ***Panel Discussion***

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13:00 13:10 Plans for 2016 / Close Out