Day 1 - Wednesday 15 nov 2017

09:00 **Welcome**

Quantitative Imaging – a reality?

09:10 **Keynote Speaker: Steve Hood, GlaxoSmithKline**

Bioimaging – Answering the "What, Where and How Much?" of modern Drug Discovery

09:40 **Pete Watson, Cardiff University**

FWM and CARS microscopy for the quantitative imaging of nanoparticles, drugs and biomarkers in living cells.

10:00 **Delphine Maux, Nestlé Skin Health**

MALDI imaging a new quantitative methodology approach for understanding drug distribution in skin.

10:20 **Coffee break - Poster viewing**

Ambiguities in dealing with regulations

11:00 **Robert Nelson, on behalf of the EBF**

Parallelism – Feedback from the AAPS/EBF/JBF sister meetings

11:20 **Vera Hillewaert, Janssen R&D**

Challenges in dealing with different regulations by different Health Authorities. (A challenge only becomes an obstacle when you bow to it – Ray A. Davis)

11:40 **Magnus Knutsson, on behalf of the EBF**

Co-med stability or interference testing – Feedback from the AAPS/EBF/JBF sister meetings

Why duplicates in PK LBAs?

12:00 **Matthew Barfield, on behalf of the EBF**

Session Introduction including feedback from the AAPS/EBF/JBF sister meetings

12:10 **Enric Bertran, Roche**

Single-Well Analysis in Ligand-Binding Assays: Retrospective Evaluation of Validation and Study Sample Data of PK and ADA Assays using ELISA

12:30 **Johannes Stanta, Covance**

Single analysis in LBA put to the test across analytical designs and platforms

12:50 **Craig Stovold, AstraZeneca**

Right First Replicate?: Assessment of ligand binding assay single well analysis in support of therapeutic oligonucleotides

13:10 **Lunch break**

Parallel breakout session day 1 - 1a

Assay transfer – a two way relationship

14:20 **Luca Ferrari, Roche**

Small molecule bioanalytical method development and transfer: is a “plug and play” approach possible?

14:40 **Nico van de Merbel, PRA Health Sciences**

Transfer or redevelop – that’s the question

15:00 **Alessio Maiolica, Novartis**

Small molecule LC-MS¬/MS assay transfer: A journey through the method cross-validation challenges

15:20 **Debbie McManus, Envigo**

Successful transfer of ligand binding assays between different laboratories

Parallel breakout session day 1 - 1b

Re-visiting immunogenicity strategies

14:20 **Martine Broekema, PRA Health Sciences**

Increased need for ADA assays with enhanced drug tolerance and suggested strategies

14:40 **Szilard Kamondi, Roche**

Evaluation of outlier detection methods for cut-point determination of immunogenicity screening and confirmatory assays

15:00 **Corinna Krinos-Fiorotti, BioAgilytix**

Drug-Reactive Pre-existing Reactivity Assessments: What are the Challenges?

15:20 **James Munday, on behalf of the EBF**

Pre-clinical Immunogenicity assessment, what is the appropriate tiered analysis?

15:40 **Tea break - Poster viewing**

Parallel breakout session day 1 - 2a

New technologies applied 1

16:20 **Anne Kleinnijenhuis, Triskelion**

Multiplex LC-MS analysis to selectively detect different collagen types in fibrotic tissue.

16:40 **Farjana Mahammed, GlaxoSmithKline**

Small & Fast – How to improve bioanalytical throughput whilst maintaining/improving quality

17:00 **EBF Young Scientist introducing the BioA Brain**

YSS Organizers

17:20 **Vibeke Hougaard Sunesen, Leo Pharma**

The fairy-tale of a multi-analyte LC/MS/MS-assay for quantification of low pg/mL levels of active drug compounds and metabolites of a topical fixed dose combination product.

17:40 **Young Investigator Award – Presenter TBC**

Title TBC

Parallel breakout session day 1 - 2b

Biomarker case studies

16:20 **Nick White, MedImmune**

Confuddled by Confounders? That Target Engagement Biomarker Assay can be a Difficult Journey to Overcome

16:40 **Darshana Jani, Pfizer**

Considerations for successful biomarker bioanalysis in regulated environment- Dive in Validation Challenges and Solutions

17:00 **Michael Gröschl, Celerion**

Biomarkers of glucose metabolism in human plasma and saliva

17:20 **John Perkins, Q2 Solutions**

Applying the lessons learned from small molecule biomarker analysis to method development for xenobiotics

17:40 **James Lawrence, Envigo**

The impact of using singlate analysis for the measurement of exploratory biomarker endpoints

18:00 Cocktail reception

Day 2 - Thursday 16 nov 2017

Parallel breakout session day 2 – 1a

“Hybrid” assays – science or just semantics?

08:30 **Rainer Bischoff, University of Groningen**

Immunoaffinity mass spectrometry – The best of both worlds?

08:50 **John Gebler, Waters Corporation**

Protein Biotherapeutic Quantification: A Comparison of LC-MS Techniques for both Digested and Intact Quantification

09:10 **Lorella Di Donato, Caprion Biosciences**

Absolute Quantitation of biotherapeutic drug product and its endogenous protein by immunoaffinity-LC-MS/MS in human plasma

09:30 **Rand Jenkins, PPD**

Addressing method development and validation challenges with high sensitivity assays for antibody fragment drugs using LBA and hybrid LBA/LC-MS technologies

09:50 **Richard Snell, GlaxoSmithKline**

The Utility of Magnetic Beads as an Extraction Technique for Small Molecule Bioanalysis by LC-MS/MS

Parallel breakout session day 2 – 1b

Immunogenicity In action

08:30 **Issa Jyamubandi, LGC**

Approaches to improve the ADA drug tolerance of Monoclonal Antibody Therapeutic.

08:50 **Chris Jones, MedImmune**

Does platform matter for ADA assessment? Validation and sample data revisited across multiple platforms.

09:10 **Lieselot Bontinck, Ablynx**

An innovative approach for detecting neutralizing antibodies directed to antibody-derived therapeutics based on the conventional bridging ADA assay format

09:30 **Marco Michi, Aptuit**

ADA analysis: Use of LC/MS in support to specific case study issues

09:50 **Carles Morte, Kymos Pharma Services**

Assessment of the Immunogenicity of gonadotrophins during Controlled Ovarian stimulation

10:10 Coffee break - Poster viewing

Parallel breakout session day 2 – 2a

Microsampling… What can the future look like?

11:00 **Amanda Wilson, AstraZeneca**

Capillary Plasma Microsampling – Letting the data speak for itself

11:20 **Neil Spooner, in collaboration with the University of Hertfordshire**

Patient centric microsampling – What is it, where are we up to and where might it be leading us?

11:40 **Richard Lucey, LGC**

Optimising recovery from volumetric absorptive microsampling (VAMS) devices, to overcome the hematocrit issue for dried samples

12:00 **Martijn Hilhorst, PRA Health Sciences**

“Pros and cons of conventional and microsampling techniques for quantitative bioanalysis” (TBC)

12:20 **Panel discussion**

Parallel breakout session day 2 – 2b

Can flow fly?

11:00 **Peter Rhein, Merck**

Imaging Flow Cytometry Enhances the Detection of Small Particles and Rare Events Enabling Emerging Applications in Immunology and Oncology

11:20 **Stephanie Traub, Cancer Research UK**

Validation of flow cytometry assays for monitoring of immune cells in hematological malignancies and immuno-oncology trials

11:40 **Richard Hughes, GlaxoSmithKline**

Imaging cytometry: the advantages of hybrid technology in support of drug discovery

12:00 **Richard Heideman, Charles River**

Immunomodulatory Drug Immunotoxicity; Using Scientific Expertise and State of the Art Technology to Address Intractable Problems

12:20 **Hervé Farine, Actelion**

Transfer of a receptor occupancy assay in phase I clinical trial: a sponsor's perspective

12:40 Lunch break

On Thursday afternoon, there will be no plenary nor breakout sessions. Instead, 2 blocks of 5 parallel workshops will be organized. In each of these short workshops, together with the individual workshop moderators, the EBF Open Symposium Organizing Committee is preparing for a discussion around themes relevant to our industry today. For room assignments, see in attached document or ad valvas at the registration desk, in the foyer and at the auditorium entrance from Thursday morning onwards.

From 14:00 until 15:30 Parallel workshop 1-5

WS-1 Life beyond MS-MS

WS-2 Bioanalysis for Biosimilars

WS-3 Validation approaches in ED (usage of surrogate matrix (human) in all nonclinical species)

WS-4 Standardised ADA assays cont´d

WS-5 Pharma/CRO relation – PART 1

From 16:30 until 18:00 Parallel workshop 6-10

WS-6 Approaches on implementing OECD17

WS-7 Complex delivery systems – effect on BA

WS-8 Single vs. Duplicates

WS-9 Calibration concepts in LBA

WS10 Pharma/CRO relation – PART 2

Included in WS-5: **JBF presentation: Masanari Mabuchi, Mitsubishi Tanabe Pharma Corporation/ Japan Bioanalysis Forum**

Relationship between Pharma and CRO in method development and transfer – based on the survey by JBF Discussion Group

18:00 **Cocktail reception**

Day 3 - Friday 17 nov 2017

Parallel breakout session day 3 – 1a

ISR, ISR, ISR

09:30 **Cecilia Arfvidsson, AstraZeneca**

ISR included in every clinical study for 5 years – What have we done … what can we learn …and how do we go from here!?

09:50 **Tom Verhaeghe, Janssen R&D**

ISR: what have we learned after a decade of experience?

10:10 **Morten Anders Kall, on behalf of the EBF**

EBF View on ISR

10:30 **Panel discussion**

Parallel breakout session day 3 – 1b

New technologies applied 2

09:30 **Amanda Wilson, on behalf of the EBF**

Implementation of New Technology – feedback from the EBF mini workshop

09:50 **Pauline Bros, Sanofi**

Innovative combination of ImmunoCapture LC-HRMS approaches for the quantitative analysis of therapeutic monoclonal antibody

10:10 **Ken Cook, Thermo Fisher Scientific**

New Workflows for Biotherapuetic LCMS Analysis

10:30 **Jerome Vialaret, CHU Montpellier**

Comparison of sample preparation for mAbs quantitation by LC-MRM: Protein A cartridges *vs.* nSMOL

10:50 **Tea break – poster focus 4**

Future challenges we cannot deny

11:30 **Tim Sangster, on behalf of the EBF**

Bioanalytical Support to In Vitro Studies

11:50 **Susanne Pihl on behalf of the EBF**

Critical Reagents

12:10 **David Van Bedaf, Janssen R&D**

Future Challenges We Cannot Deny: e-data readability and exchangeability

12:30 **Adam Hughes, GlaxoSmithKline**

“I want to break free” – The implementation of scientific validation

12:50 Plans for 2018 / Close Out