Day 1 - Wednesday 16 nov 2016

08:30 Welcome

Towards Utopia

08:40 Keynote Speaker: Norberto A. Guzman, Princeton Biochemicals
A Rapid, Sensitive and High-Throughput Affinity-Capture-Separation Technique for Bioanalytical Applications - Monitoring Wellness, Disease, and Treatment Effectiveness

09:10 Scott Summerfield, GlaxoSmithKline
LC-MS Bioanalysis: From minutes to seconds

09:30 Renuka Pillutla, Bristol Myers Squibb
Managing the challenges of technology changes in regulated bioanalysis of biotherapeutics

09:50 Ann-Christin Niehoff, Shimadzu
Mass Spectrometry Imaging of Human Brain Tumors Resected by Fluorescence-Guided Surgery

10:10 Coffee break

Regulatory Interpretation

10:50 Paul Morgan, AstraZeneca
Tailoring bioanalytical science strategies to support PKPD understanding at different stages of project lifecycle

11:10 Ian Waterson, MHRA
Bioanalysis and GLP: A Regulatory Perspective

11:30 Yoshiaki Ohtsu, on behalf of the Japan Bioanalysis Forum
Scientific Validation: Feedback from JBF Discussion Group

11:50 Marianne Scheel Fjording, on behalf of the EBF
Feedback from the EBF Focus Workshop on Biomarker Assay validation and analysis

12:10 Philip Timmerman, on behalf of the EBF
What does GLP mean in regulated Bioanalysis or Biomarker Bioanalysis

12:30 panel discussion

12:50 Lunch break
Coping with Rare Matrices

14:00 Hans Stieltjes, Janssen R&D
Evaluation of adsorption of various analytes in cerebrospinal fluid

14:20 Michael Gröschl, Celerion
Saliva – a reliable sample matrix in bioanalytics

14:40 Jamil Hantash, Intertek
Method Development and Validation of Biologics and Small Molecules in Ocular Tissues – Focusing on Bioanalytical Challenges and Foreseeing Regulatory Concerns

15:00 Enric Bertran, F. Hoffmann La Roche
Challenges in Ocular Bioanalysis

15:20 Tea break

Exploring the Challenges of ADCs

16:00 Rand Jenkins, PPD
ADCs Bioanalysis—LBA and LC-MS methods, a changing paradigm?

16:20 Astrid Leegte, PRA Health Sciences
Total and conjugated PK LBA assays and ADA assay for Antibody-Drug Conjugates (ADC)

16:40 Ranbir Mannu, Covance
LC-MS/MS based strategies for quantification of therapeutic antibody drug conjugates in clinical and preclinical studies.

17:00 John Gebler, Waters
LC/MS Quantification of Critical Components of Antibody Drug Conjugates (ADCs)

17:20 Corinna Krinos-Fiorotti, BioAgilytix
Considerations for the development and validation of cell based neutralization assays for antibody-drug conjugates

18:00 Cocktail reception

PARALLEL SESSION ----Day-1

Discussion Forum: OECD17

14:00 David Van Bedaf & Eva Lindqvist, for EBF
Introduction and Feedback from EBF team discussing harmonized implementation of OECD-17

14:20 Moderators: David Van Bedaf & Eva Lindqvist, for EBF
Forum discussion: towards harmonized implementation of OECD-17
15:20  Teabreak

SHOW AND TELL: Feedback from EBF Topic Teams
(pre-registration required when picking up your badge at the registration desk)

Show and tell 1: Towards a harmonized Data Transfer Agreement (DTA), Feedback and recommendation from EBF Topic Team 12

16:00  Introduction
Moderators from TT-12

16:10  Sharing the EBF team recommendation and discussion

Show and tell 2: A harmonized Certificate of Analysis (CoA): Utopia?
Feedback and recommendation from EBF Topic Team 40

16:00  Introduction
moderators: topic team leaders

16:10  Sharing the EBF team recommendation and discussion
Day 2 - Thursday 17 Nov 2016

**Spotlight on Microsampling**

08:30 **Urs Duthaler, UH Basel**
A fully automated extraction method to overcome methodological drawbacks of antiretroviral drug analysis in dried blood spots

08:50 **Karien Bloem, Sanquin**
Dried blood spots obtained by finger prick facilitates therapeutic drug monitoring in adalimumab treated patients

09:10 **Sheelan Ahmad, GlaxoSmithKline**
Will Zero Blood Withdrawal Make SPME a Microsampling Hero?

09:30 **Glen Hawthorne, on behalf of the EBF LMS Consortium**
Update from the EBF Liquid Microsampling Consortium

09:50 **Panel discussion**

10:10 **Coffee break**

**The e-environment**

11:00 **Andreas Henrichs, Sanofi**
Current practice of archiving e-data in the GLP environment at SANOFI

11:20 **David Van Bedaf, Janssen R&D (in collaboration with BSSN-Sciex)**
Strategies for long-term preservation of analytical e-data using the AnIML format

11:40 **Anne Kruse Lykkeberg, Lundbeck**
Study Master: Management of clinical samples in phase III studies using advances Excel.

12:00 **Nicola Stacey, LGC**
A risk-based approach to validation of Commercial off the Shelf (COTS) Computerised Systems in a GxP environment – The challenge of balancing efficiency with integrity.

12:20 **Louise Radzikowski, Novo Nordisk**
SEND implementation in NN – story, status and challenges from a Bioanalytical point of view

12:40 **Lunch break**
What makes Bioanalysis Fun - 1

14:00 Teresa Heslop, GlaxoSmithKline
“Old Dogs, New Tricks!”: HILIC Chromatography with Deuterium Exchange for the Quantification of Ribavirin from Human Plasma and Bronchoalveolar Lavage Fluid

14:20 Morten Funch Carlsen, Leo Pharma
Biosynthesis, structural identification and quantification of low pg/mL levels of a major human metabolite of a dermal drug candidate – a multidisciplinary challenge!

14:40 Amedeo De Nicolò, Università degli Studi di Torino in collaboration with Shimadzu
Evaluation of Internal Standard Normalized Matrix Effects (IS-nME) for mass spectrometry method validation: examples of clinical application..

15:00 Lieve Dillen, Janssen R&D
Standardized approach to assess light stability of drugs in blood and plasma and subsequent impact on pharmacokinetic sampling procedures.

15:20 Sara Stensson, Ferring
Bioanalysis of potent small cyclic peptides – Ways to reach the LLQ Utopia

15:40 Tea break

Large Molecule LC-MS

16:15 Leo Kirkovsky, Pfizer
Dual “Hybrid” and Regular LC-MS/MS Assay for the Quantitation of Unconjugated and Conjugated Calicheamicin in Support of Mylotarg (gemtuzumab ozogamicin) Pediatric Study

16:35 Szabolcs Szarka, LGC
Glu-C – an orthogonal and alternative enzyme for protein quantitation by LC-MS/MS

16:55 Daniel Wilffert, QPS
Antibody-free LC-MS/MS protein analysis of TRAIL

17:15 Nikunj Tanna, Waters
Large Molecule Bioanalysis – Tools and workflows to simplify method development for targeted MRM methods

17:35 Kevin Ray, MilliporeSigma / Merck KGaA
Quantitation of Proteins and Monoclonal Antibodies In Serum by LC-MS/MS Using Full-Length Stable Isotope Labeled Internal Standards

18:00 Cocktail reception
PARALLEL SESSION ----Day-2

Biomarker Parallelism

08:30 Robert Nelson, on behalf of EBF TT-61
Non-parallelism in biomarker assays

08:50 Afshin Safavi, BioAgilytix
Considerations for Evaluation of Parallelism in Biomarker Ligand-Binding Assays: Case Studies of Failed Biomarker Assay Parallelism

09:10 Julie De Gagné, Novartis
The use of parallelism to define biomarker assay parameters: a case study

09:30 Jing Tu, PPD
A Soluble Receptor (sBCMA) Biomarker Parallelism Case Study – Using Parallelism Experiments to Effectively Evaluate Matrix Effects and Selectivity in the Early Stage of LBA Method Development

09:50 Panel discussion

10:10 Coffee break

Pushing the boundaries of Large Molecule Analysis

11:00 Gregor Jordan, F. Hoffmann La Roche
Improved ELISA performance by simple switching from a colorimetric to fluorimetric HRP substrate

11:20 Christian Pieper, Chimera Biotec
Biologics – Biomarker - Bioanalysis. Challenges followed by solution – What to do when new drug programs reach technical limitations in target quantification

11:40 Craig Stovold, AstraZeneca
Amplification Challenge: Comparison of bDNA and PCR-based analytical methods for the determination of nucleotide-based therapeutics

12:00 Bert Rutten, LGC
Comparison of Critical Method Validation Parameters on the Quanterix Simoa and the Singulex Erenna.

12:20 Bioanalysis Zone New Investigator Award Winner

12:40 Lunch break
What makes Bioanalysis fun - 2

14:00  **Roland Staack, F. Hoffmann La Roche**  
Importance of fully characterized bioanalytical methods – the bioanalytical challenges to support the development of a lipidated fusion protein

14:20  **Hanna Ritzen, Mercodia**  
Life cycle management of biomarker assays a route to improved patient outcome.

14:40  **Martine Broekema, PRA Health Sciences**  
Challenges in receptor occupancy determination assays by flow cytometry in drug development

15:00  **Christele Gonneau, Covance CLS**  
Paving the road to Utopia through instrument standardization

15:20  **Anne Incamps, Thermo Fisher Scientific**  
Biomarkers Validation: an Orthogonal approach using Mass Spectrometry and Immunoassays

15:40  **Tea break**

Immunogenicity

16:15  **Jo Goodman, on behalf of the EBF**  
Feedback from the EBF Focus Workshop (September 2016, Lisbon) on Current Analysis of Immunogenicity

16:35  **James Munday, Covance**  
Pre-clinical Immunogenicity assessment – Scientific validation versus Regulatory validation approach. What is the appropriate tiered analysis?

16:55  **Robert Nelson, Novimmune**  
The best-laid schemes o’ mice an’ men: when clinical assumptions go awry

17:15  **Viswanath Devnarayan, Abbvie**  
Clinical Interpretation of ADA

17:35  **Panel discussion**
Day 3 - Friday 18 nov 2016

The Broad Utility of HRMS

09:00 Esther van Duijn, TNO
The combined use of HRMS and AMS for simultaneous metabolite quantification and identification

09:30 Nico van de Merbel, PRA Health Sciences
A practical comparison of triple-quadrupole and high-resolution mass spectrometry for peptide and protein quantification

10:00 Barry Jones, Q2 Solutions
LC-HRMS for Quantitative Bioanalysis in the Regulated Contract Research Laboratory: Small, Medium, and Large Molecule Applications

10:20 Keeley Murphy, Thermo Fisher Scientific
Comprehensive workflows for high performance quantitation utilizing high resolution accurate mass.

PARALLEL SESSION ----Day-3

Abnormal PK

09:00 Daniela Stoellner, on behalf of EBF TT-63
TT-63: Handling of PK data from ADA positive animals

09:20 Nick White, MedImmune
Abnormal PK; Even With Informed Predictions it Happens to the Best of Us!

09:40 Sherri Dudal, UCB BioPharma
Challenge of PKPD of biologics in preclinical disease models: PK and BA perspectives

10:00 Anne Larvor, Amatsigroup
Management of abnormal PK profiles: s BA and PK point of view through several examples.

10:20 Panel discussion

10:40 Coffee break
UTOPIA: THE SCIENCE OF A MODERN GUIDELINE
Interactive session  (Each sub-session consists of a short introduction followed by an interactive discussion involving all conference delegates)

11:25  General Introduction - aim of the session

11:30  The science of a modern guidance - focus on The common themes
       moderated panel session

11:50  The science of a modern guidance - focus on Ligand binding assays
       moderated panel session

12:20  The science of a modern guidance - focus on Chromatography based assays
       moderated panel session

12:50  Closing comments and next steps

12:55  Plans for 2017 / Close Out