



### 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 registraion 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 Ribarvirin 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, Merckodia**  
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 Devanarayan, 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**





**Reaching Utopia**  
The Kaleidoscope of Bioanalysis

**16-18 NOV 2016**  
Hesperia Tower, Barcelona, Spain

**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**