

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

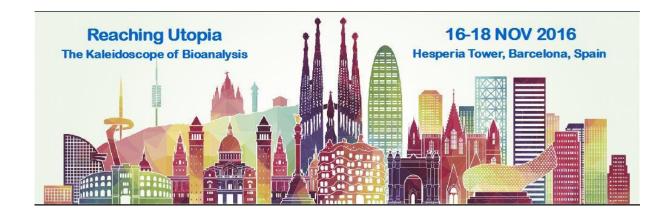
## 17:15 Nikunj Tanna, Waters

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 drugprograms 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?

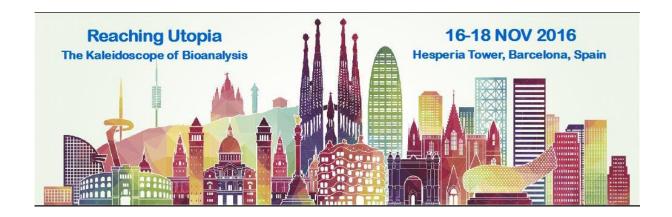
## 16:55 Robert Nelson, Novimmune

The best-laid schemes o' mice an' men: when clinical assumptions go awry

### 17:15 Viswanath 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



## **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