

Program of EBF 5th Open Meeting

(november 14-16, 2012)

Old Battles, New Horizons.

Notice on Global Harmonization

Post conference, EBF will organize a 2h session on the current status of the GBC discussions. In this session, we will engage with the audience to gather input on the items where the GBC harmonisation team require your input because of their importance to the bioanalytical community or their continued ambiguity.

The session will be from 14h00 to 16h00 on Friday Nov. 16th and entrance is free for conference delegates.

Day 0 – 13 November 2012

14.00h 20.00h Registration and Information desk open in hotel lobby

Day 1 – 14 November 2012

7.00h 18.00h Registration and Information desk open

MORNING PLENARY

8.30h 8.45h Welcome and opening remarks

8.45h 10.15h Increasing Challenges in Clinical Studies (Part I)

8.45h 8.50h **Richard Abbott (on behalf of EBF)**
Introduction

8.50h 9.20h **Richard Hucker (A4P Consulting Ltd)**
Meeting the Bioanalytical Challenges of Global Multi-Centre Clinical Trials: Observations and Expectations

9.20h 9.35h **Bernd Matthes (on behalf of the EBF Topic Team)**
Outcome of EBF Survey on Multi-center Trials

9.35h 9.55h **Vera Hillewaert (Janssen Research&Development)**
Global Clinical Trials - Challenges for Bioanalysis

9.55h 10.15h **Hanneke van Assche (Abbott)**
Bioanalytical Challenges from a Clinical Perspective

10.15h 11.00h Coffee Break

11.00h 12.30h Increasing Challenges in Clinical Studies (Part II)

- 11.00h 11.20h **Carolyn Mailer (on behalf of EBF TT12)**
Case Example Highlighting Multi-center Clinical Trial Issues
- 11.20h 11.40h **Franck Picard (Novartis)**
The Pre-Advance Platform: Sample Management and Processing by Mouse Click
- 11.40h 11.55h **Katja Heinig (on behalf of the EBF Topic Team)**
Stabilisation of Clinical Samples
- 11.55h 12.15h **Philip Timmerman (on behalf of EBF)**
EBF Recommendation on Method Establishment and Bioanalysis of Biomarkers in Support of Drug Development
- 12.15h 12.30h **Discussion**

12.30h 14.00h Lunch and poster session

AFTERNOON PLENARY SESSIONS

14.00h 16.00h A progress update since Large meets Small

- 14.00h 14.20h **Nico van de Merbel (PRA)**
It's only just begun: The Importance of Sample Preparation for Protein Quantification by LC-MS
- 14.20h 14.40h **Kenneth Fountain (Waters)**
Challenges in the Development of a Bioanalytical Method for the Simultaneous Quantification of Synthetic Insulin Analogs in Human Plasma
- 14.40h 15.00h **Lieve Dillen (Janssen Research&Development)**
Bioanalysis of Peptides and Proteins in Drug Research and Development: from Strategy into Practice
- 15.00h 15.20h **Michael Blackburn (Covance Laboratories Ltd)**
Quantitation of a Therapeutic Insulin Analogue by Immuno-Affinity Extraction - LC-MS/MS
- 15.20h 15.40h **Magnus Knutsson (on behalf of the EBF Topic Team)**
EBF Experiences on LC-MS/MS Analysis of Large Molecules
- 15.40h 16.00h **Discussion**

16.00h 16.30h Coffee break

16.30h 18.00h Technology updates I

- 16.30h 17.00h **Richard Kay (Quotient Bioresearch)**
Development of an Immunoprecipitation and LC-MS/MS based Method for Quantifying the 105 kDa Recombinant Protein SXN101959 in Plasma
- 17.00h 17.30h **Luc-Alain Savoy (SGS Life Science Services)**
Selected Reaction Monitoring (SRM) for Quantification of Steroid and Peptide Biomarkers: Challenges & Benefit
- 17.30h 18.00h **Catalin Duneanu (Waters)**
A Universal Strategy for Quantification of Therapeutic Monoclonal Antibodies in Serum using Extended Isotopically Labeled Peptide Standards and 2DLC-SRM

18.00h 19.00h Cocktail Reception (sponsored by ABSciex)

Enjoy a few drinks and the opportunity to discuss bioanalytical topics in a relaxed atmosphere

Day 2 – 15 November 2012

07.00h 18.00h Registration and Information desk open

MORNING BREAKOUT SESSIONS

Breakout sessions I and II are in parallel

8.30h 10.15h Breakout session I

Micro sampling I - Updates on DBS

8.30h 8.50h **Christoph Stove (Ghent University)**

Prediction of the Hematocrit of Dried Blood Spots via Potassium Measurement on a Routine Clinical Chemistry Analyzer

8.50h 9.10h **Karl Sköld (Denator AB)**

Heat Stabilization of Blood Spots for Metabolically Unstable Drugs

9.10h 10.00h **Feedback from the EBF DBS/Micro sampling Consortium**

Ben van Baar

Internal Standard Addition in DBS

Zoe Cobb

Homogeneity and Stability: The Results

Ronald de Vries

EBF and Dried Blood Spots – Status Update from the Hematocrit EBF Topic Sub-Team

10.00h 10.15 **Panel Discussion**

8.30h 10.15h Breakout session II

Biosimilars

8.30h 9.00h **Huub Schellekens (Utrecht University)**

EU regulations of biosimilars: will developments in quality testing reduce the need for clinical data?

9.00h 9.20h **James Munday (on behalf of EBF)**

Outcome of EBF Survey on Biosimilars

9.20h 9.40h **Gregor Schaffar (Sandoz)**

Pharmacokinetic and Immunogenicity Assessing of Biosimilars in Clinical and Pre-Clinical Studies

9.40h 10.00h **Melody Sauerborn (TNO Triskelion)**

How safe is your Biosimilar? The Tiered Approach to Measure Immunogenicity of Biologics - also the Right Approach for Biosimilars?

10.00h 10.15h **Panel Discussion**

10.15h 10.45h Coffee break

MORNING BREAKOUT SESSIONS (CONTINUED)

Breakout sessions III and IV are in parallel

10.45h 12.30h Breakout session III

Micro sampling II - Recent developments

- 10.45h 11.05h **Sue Sparrow (GlaxoSmithKline)**
Microsampling – Toxicology Considerations
- 11.05h 11.20h **Bart Remmerie (Janssen Research & Development)**
Can finger-prick sampling replace venous sampling ? A Pharmacokinetic Perspective
- 11.20h 11.40h **Timothy Sangster (Charles River Laboratories)**
Global Implementation of Microsampling – A Case Study
- 11.40h 12.00h **Michael Spreadborough (AstraZeneca)**
Plasma Microsampling – have we already reached the Horizon?
- 12.00h 12.15h **Pierre Picard (Phytonix Technologies Inc)**
Less than a Microliter needed: Blood PK Study, Microsomal Samples and other Matrices analyzed by LDTD-MS/MS
- 12.15h 12.30h **Panel Discussion**

10.45h 12.30h Breakout session IV
Emerging Technologies and Innovative Applications for Large Molecules

- 10.45h 11.10h **Jamie Sawyer (SQI Diagnostics, Inc.)**
Ig_gplex: a Novel Automated Platform for Bioanalytics
- 11.10h 11.35h **Julie de Gagné (Novartis)**
Challenges in Developing a Sensitive PD Assay – from Tool Selection to Technologies Evaluation
- 11.35h 12.00h **Rohan de Silva (University of London)**
Do Pathological Changes in Tau Protein Isoforms manifest in Cerebrospinal Fluid of Tauopathy Patients? Development and Validation of Sensitive Immuno-PCR Assays
- 12.00h 12.25h **Clare Kingsley (Quotient Bioresearch)**
Analytical Strategies for PK and Immunogenicity Testing for a Novel Recombinant Decoy Biopharmaceutical
- 12.25h 12.30h **Discussion**

12.30h 14.00h Lunch and poster session

AFTERNOON BREAKOUT SESSIONS AND ELN WORKSHOP

Breakout session V and VI as well as ELN workshop are in parallel

14.00h 15.30h Breakout session V
Is Quantitative Bioanalysis ready for High Resolution Mass Spectrometry

- 14.00h 14.30h **Kevin Bateman (Merck & Co)**
HRMS in Regulated Bioanalysis ?
- 14.30h 14.50h **William van Dongen (TNO Triskelion)**
LC–MS Systems for Quantitative Bioanalysis
- 14.50h 15.10h **Mark Wrona (Waters / Vertex Pharmaceuticals)**
Accurate Mass Quantitation of in Vivo Plasma Samples using High Resolution QToF and MSE Data Analysis
- 15.10h 15.30h **Fabio Garofolo (Algorithme Pharma)**
Challenges and Solutions in Large Molecule Regulated Bioanalysis using High Resolution Mass Spectrometry

**14.00h 15.30h Breakout session VI
Wanted and unwanted Immunogenicity**

- 14.00h 14.25h **Stefan Kostense (Crucell)**
Challenges of Wanted and Unwanted Immunogenicity Assays
- 14.25h 14.40h **Nicolas Sabarth (Baxter)**
Assessing Immunogenicity of Influenza Vaccines
- 14.40h 14.55h **Sylvain Fleury (Mymetics Corporation)**
Phase-I “Proof of Principle”: Immunization with Virosome-Gp41-Derived Antigen Induces Mucosal Antibodies with Antiviral Properties to Reduce Risk of HIV-1 Infection
- 14.55h 15.10h **Clare Kingsley (Quotient Bioresearch)**
Development and Validation of Neutralising Anti-Drug Antibody (Nabs) Assays
- 15.10h 15.30h **Panel Discussion**

**14.00h 15.30h Breakout session VII
ELN Workshop**

This session will be a workshop without plenary lectures. The aim of the workshop is to provide a forum for questions and discussion on ELN, and share the outcome of an EBF survey on ELN with the participants as well as experience of EBF members who already have implemented an ELN. As seats are limited for the workshop participants who would like to join will have to fill-in a dedicated registration form at the registration desk in Barcelona.

15.30h 16.00h Coffee break

16.00h 16.30h Young Scientist Award

- 16.00h 16.05h **EBF Steering Committee member**
Introduction of Award winner
- 16.05h 16.30h **Award winner**
Presentation

16.30h 18.00h Technology updates II

- 16.30h 17.00h **Lester Taylor (Agilent Technologies)**
The expanding Role of Triple Quadrupole Mass Spectrometry for Bioanalytical Applications
- 17.00h 17.30h **Simon Szwandt (Thermo Fisher Scientific)**
A Validated Method for the Definitive Quantitation of Heparin-25 in Rat Serum by LC/MS/MS using High Resolution, Accurate Mass MS
- 17.30h 18.00h **Mauro Aiello (AB Sciex)**
IonDrive Technology: A diversified Approach to Peptide Quantitation

18.00h 19.00h Cocktail Reception (sponsored by ABSciex)

Enjoy a few drinks and the opportunity to discuss bioanalytical topics in a relaxed atmosphere

Day 3 – 16 November 2012

MORNING BREAKOUT AND PLENARY SESSIONS

Breakout session VIII and IX are in parallel

9.00h 10.30h Breakout VIII

BA Clinic - Consult the doctor

9.00h 9.15h *David Neville (Quotient Bioresearch)*

Right Brain Thinking in a Left Brain Environment; Troubleshooting Bioanalytical Methods

9.15h 9.30h *Fabio Garofolo (Algorithme Pharma)*

A Current Hot Topic in Regulated Bioanalysis: Impact of Hemolysis on Drug Stability

9.30h 9.45h *Tom Verhaeghe (Janssen Research&Development)*

Evaluation of Hemolysis in Assay Validation and the Impact on the Analysis of Study Samples

9.45h 10.00h *Alex Muntendam (ABL B.V.)*

Betahistine in Human Plasma by LC-MS/MS: An Example of a Low Range Analytical Range, with a Low Molecular Weight Compound and its Peculiarities

10.00h 10.15h *Iris Vanwelkenhuysen (Janssen Research&Development)*

Which Steps to Take if Re-Analysis Results do not Confirm the Result of the First Analysis?

10.15h 10.30h *Panel Discussion*

9.00h 10.30h Breakout IX

Tiered Approach in Practice - are our Minds Ready for it?

9.00h 9.30h *David Jones (MHRA)*

GLP or Not GLP, That Is The Question! (How to handle non-GLP data in Regulatory Submissions)

9.30h 9.50h *Brigitte Buscher (on behalf of the EBF Topic Team)*

Plasma Protein Binding Studies including Bioanalysis in Drug Discovery and Development

9.50h 10.10h *John Smeraglia (Huntingdon Life Sciences)*

Method Validation Status versus Regulatory Compliance Status

10.10h 10.30h *Philip Timmerman (on behalf of the EBF Topic Team)*

Towards an EBF Recommendation on Quantification of Drugs and Metabolites in Tissues

10.30h 11.15h Coffee break

PLENARY SESSIONS

11.15h 13.30h Updates from the globe

11.15h 11.30h *Michaela Golob (on behalf of GBC)*

Updates from the GBC Activities & Progress

11.30h 12.00h *Noriko Katori (National Institute of Health Sciences)*

Regulated Bioanalysis Status in Japan and Notable Points of the Draft Japanese BMV Guideline

12.00h 12.30h *Joao Tavares (ANVISA)*

New BMV Guideline in Brazil

12.30h 13.00h *Hu Pei (PUMCH)*

Title to be announced

13.00h 13.25h *Peter van Amsterdam (on behalf of EBF)*
Feedback on EMA Guideline Workshop

13.25h 13.40h *Panel discussion*

13.40h 13.50h EBF plans for 2013 and 2014, close out and adjourn

POST EBF CONFERENCE EVENT GBC ROUND TABLE

14.00h 16.00h GBC Round table

In this session, we will engage with the audience to gather input on the items where the GBC Harmonisation Teams require your input because of their importance to the bioanalytical community or their continued ambiguity.

Entrance to this session is free for registered conference delegates.

The discussion points will become available on the GBC website (www.globalbioanalysisconsortium.com) from end of October onwards.