Day 1 - Wednesday 20 NOV 2013

PLENARY SESSION

08.30h 08.35h Welcome

08.35h 10.30h Assay transfer - Expectations & Practicalities

08.35h 08.55h ***Cheryl McAlpine (Merck-Millipore)***
Challenges in assay transfer of complex assay formats

08.55h 09.15h ***Fabienne Deckert-Salva (Novartis)***
Outsourcing and assay transfer strategies for biologics programs

09.15h 09.35h ***Graeme Smith (Huntingdon Life Sciences)***
Fit for purpose method transfer

09.35h 09.55h ***Ronald de Vries (Janssen R&D)***
Janssen strategy for bioanalytical assay transfer

09.55h 10.15h ***Steve White (GlaxoSmithKline)***
Assay cross validation - Recent experiences in transfering bioanalytical assays from sponsor to CRO partners and between CROs

10.15h 10.30h ***Panel Discussion***

10.30h 11.00h Coffee break

11.00h 12.15h From biomarker to diagnostics or personalized medicine: is there a role for regulated bioanalysis?

11.00h 11.25h ***John Mills (AstraZeneca)***
Delivering on the Promise of Personalized Healthcare

11.25h 11.50h ***Suntje Sander and Peter van Amsterdam (Abbott)***
Successful treatment of maldigestion due to pancreatic exocrine insufficiency: diagnosis, clinical picture and the challenges of measurements involved

11.50h 12.15h ***Joan-Carles Arce and Birgitte Buur Rasmussen (Ferring)***
Individualized dosing regimen for fertility treatment based on a biomarker

12.15h 12.45h Bioanalysis Young Investigator Award

12.15h 12.20h ***Peter van Amsterdam (on behalf of EBF)***
Announcing the Young Investigator Award Winner

12.20h *12.45h* ***Young Investigator (TBD)***
Young Investigator Award Winning Presentation

12.45h 14.00h Lunch break

14.00h 15.35h Interpretation and implementation of guidance on haemolysed / hyperlipedemic plasma and co-administrated drugs

14.00h *14.20h* ***Benno Ingelse (on behalf of EBF TT-15)***
How to deal with haemolysed and hyperlipidaemic samples: an EBF perspective

14.20h *14.35h* ***Fabio Garofolo (Algorithme Pharma)***
Criteria for performing a scientifically meaningful lipemic plasma test during LC-MS/MS bioanalytical method validation (BMV): which type to choose?

14.35h *14.50h* ***Martina Wein (Boehringer-Ingelheim)***
How to investigate in the influence of hyperlipidemic samples on bioanalytical assays

14.50h *15.05h* ***Tom Verhaeghe (Janssen R&D)***
Co-stability assessment for fixed dose combinations: an additional burden to bioanalytical method validation

15.05h *15.20h* ***Berthold Lausecker (on behalf of EBF TT-31)***
Interaction compounds & comedication testing

15.20h *15.35h* ***Panel Discussion***

15.35h 16.15h Coffee break

16.15h 18.00h Peptide and protein analysis with LC-MS

16.15h *16.35h* ***Nico van de Merbel (RUG)***
The usefulness of LC-MS as a platform for protein quantification: from theory to practice

16.35h *16.55h* ***Rand Jenkins (PPD Inc)***
Application of LC-MS/MS and LBA methods in concert for bioanalysis of monoclonal antibody oncology drugs and associated soluble target receptors

16.55h *17.15h* ***William van Dongen (TNO Triskelion)***
Low ng/ml bioanalysis of monoclonal antibody therapeutics using immuno extraction and LC-MS

17.15h *17.30h* ***Anders Sonesson (Ferring)***
LC-MS/MS bioanalysis of peptides - How to manage non specific binding?

17.30h *17.45h* ***Mireia Fernandez Ocaña (Pfizer)***
Sensitive peptide immunoaffinity LC-MS/MS quantification of a membrane-bound target receptor from clinical biopsies

17.45h *18.00h* ***Erin Chambers (Waters)***
Ultra-sensitive simultaneous LC-MS/MS quantification of human insulin, glargine, lispro, aspart, detemir and glulisine in human plasma using 2D-LC and a novel high efficiency column

18.00h **19.00h** **Cocktail reception**

Day 2 - Thursday 21 NOV 2013

SPOTLIGHT WORKSHOP: CONTINUED DEVELOPMENTS IN DBS

08.30h **10.30h** **Continued developments in DBS**

08.30h *08.40h* ***Philip Timmerman***
(on behalf of the EBF Consortium)
Introduction and recap of EBF Recommendation on DBS

08.40h *09.00h* ***Bert Ooms (Spark Holland)***
Towards unbiased Dried blood spot analysis using temperature-enhanced flow-through desorption coupled online to solid phase extraction and mass spectrometry

09.00h *09.20h* ***Kevin Bateman (Merck & Co.)***
Dried blood spot (DBS) sample collection for drug development: recent experience at Merck

09.20h *09.40h* ***Jack Henion (Quintiles Bioanalytical and ADME Labs)***
Recent Developments in Dried Plasma Spot Analysis Using a Novel Red Blood Cell Filtration Card

09.40h *10.00h* ***Ynze Mengerink (Chemelot)***
New Ht independent dried blood spot cards

10.00h *10.30h* ***Workshop discussion (coffee will be served in workshop room)***
Moderator: Steve White (on behalf of the EBF Consortium)

SPOTLIGHT WORKSHOP: DEFINING RAW DATA IN REGULATED BIOANALYSIS

13.30h **15.40h** **Defining raw data in regulated bioanalysis**

13.30h *15.40h* *Introduction to the Workshop: categorizing raw data*

13.40h *13.55h* *Proposed way forward on* ***'Organization/system related Data (non-laboratory)'***

13.55h *14.10h* *Proposed way forward on* ***'Non-study related Data (general laboratory equipment/tools)'***

14.10h *14.25h* *Proposed way forward on* ***'Study related Data (non-laboratory)'***

14.25h *14.40h* *Proposed way forward on **'Study related Data (laboratory)'***

14.40h *15.10h* *Discussion*

15.10h *15.40h* *Prerequisites for successful use of e-data (in regulated bioanalysis)*

SPOTLIGHT WORKSHOP: IS VALIDATION REALLY NEEDED FOR ALL ASSAYS: TAKING TIERED APPROACH OUTSIDE THE WORLD OF MIST

16.15h **18.00h** **Is validation really needed for all assays: taking tiered approach outside the world of MIST**

16.15h *16.35h* ***Philip Timmerman (on behalf of EBF)***
The MIST concept taken beyond metabolite quantification: overview of EBF discussions on applying tiered approach

16.35h *16.55h* ***Jaap Wieling (QPS)***
Can we validate an assay for a biomarker that we have not identified ?

16.55h *17.15h* ***Vera Hillewaert***
A complex problem: what (and how) should we quantify?

17.15h *17.35h* ***Neil Henderson (AstraZeneca)***
Characterising the performance of in situ hybridisation (ISH) methodologies in order to demonstrate fit-for-purpose assays for clinical deployment

17.35h *18.00h* ***Panel Discussion***

BREAKOUT SESSIONS
SMALL MOLECULES / CHROMATOGRAPHY BASED

08.30h **10.00h** **Consult the doctor**

08.30h *08.45h* ***Alex Muntendam (ABL)***
Positive control group samples in a toxicity study. Now what?

08.45h *09.00h* ***Ann Lévesque (inVentiv Health clinical)***
How problematic situations can become positive ones: case studies of bioanalytical Issues

09.00h *09.15h* ***David Neville (Quotient Bio Analytical Sciences)***
Non-specific binding, Non-linearity or Nonsense?

09.15h *09.30h* ***Iain Love (Huntingdon Life Sciences)***
Viewing the big picture through a keyhole: providing context to Bioanalytical challenges

09.30h *09.45h* ***Nico van de Merbel (PRA)***
Blood is no plasma: failing long-term frozen stability results for cyclosporin A in diluted whole blood

09.45h *10.00h* ***First Aid: last minute submitted cases (Panel)***

10.45h 12.30h Interpretation and implementation of Guidance expectations: Internal Standard variability

10.45h 11.05h ***Olivier Le Blaye (ANSM)***
Examples of IS variations seen during inspections

11.05h 11.20h ***Aimin Tan (BioPharma Services Inc)***
Leveraging Successful Troubleshooting Experiences for the Prevention or Reduction of Internal Standard Response Variations during LC-MS Bioanalysis

11.20h 11.35h ***John Allanson (Unilabs York Bioanalytical Solutions)***
Challenges and solutions in the application IS variability criteria

11.35h 11.50h ***Luc Bouchard (inVentiv Health clinical)***
Internal standard variation during routine sample analysis: investigation of case studies

11.50h 12.10h ***Steve White (on behalf of EBF TT-07)***
Dealing with internal standard variability - Towards a recommendation

12.10h 12.30h ***Panel Discussion***

12.45h 14.00h Lunch break

14.00h 15.40h Innovative applications in sampling & extraction

14.00h 14.20h ***Kathryn Chapman (NCR3s)***
Overcoming the barriers for uptake of microsampling techniques in regulatory toxicology

14.20h 14.40h ***Stephen Williams (Charles River)***
Small samples, large molecules and bigger benefits

14.40h 15.00h ***Neil Spooner (GlaxoSmithKline)***
Latest developments in microsampling for regulated quantitative bioanalysis

15.00h 15.20h ***Craig Aurand (Supelco/Sigma-Aldrich)***
Investigation of solid phase micro extraction as an alternative to dried blood spot

15.20h 15.40h ***Ranbir Mannu (Covance)***
Development of a capillary micro-sample bioanalytical method for quantification of an phosphorothioated 18-mer oligonucleotide in human plasma using LC-MS/MS

15.40h 16.15h Coffee break

16.15h 17.55h Innovative applications in separation & quantification

16.15h 16.35h ***Gert Hendriks (PRA)***
Old school derivatization in modern LC-MS analysis

16.35h *16.55h* ***Jim Settlage (inVentiv Health clinical)***
The re-emergence of GC-MS/MS as a tool for the analysis of small molecule biomarkers

16.55h *17.15h* ***Paul Rainville (Waters)***
Critical evaluation of common sample preparation techniques for bioanalysis on microfluidic LC/MS performance

17.15h *17.35h* ***Lester Taylor (Agilent Technologies)***
High-Throughput SPE-MS/MS - A Viable Approach For Validated Bioanalytical Analysis?

17.35h *17.55h* ***Sega Ndiaye (Innate Pharma / Proteomic Platform Innovation Technologic Timone PIT2) - Shimadzu***
Free MMAE toxin quantitation by triple quadrupole in Antibody drug Conjugate analysis

BREAKOUT SESSIONS
LARGE MOLECULES / LIGAND BINDING BASED

08.30h **10.00h** **Analysis of parallelism for biomarkers and therapeutic proteins**

08.30h *08.50h* ***Edwin Janssen (on behalf of EBF TT-35)***
Validation of ligand-binding assays: the Importance parallelism

08.50h *09.10h* ***Ulrich Kunz (Boehringer-Ingelheim)***
Case studies of non-parallelism in various biomarker assays

09.10h *09.30h* ***Bruno Boulanger (Arlenda)***
How to develop and assess the parallelism in a bioassays: a fit-for-purpose strategy

09.30h *09.50h* ***Speaker to be confirmed***
Title to be confirmed

09.50h *10.00h* ***Panel Discussion***

10.00h **10.45h** **Coffee break**

10.45h **12.30h** **Challenges for flow cytometry in regulated bioanalysis**

10.45h *10.55h* ***Barry van der Strate (on behalf of EBF TT-32)***
Short introduction the increased use of flow cytometry to support clinical studies

10.55h *11.15h* ***Minesh Patel (Merck-Millipore)***
Challenges for Flow Cytometry in regulated Bioanalysis

11.15h *11.35h* ***Nora Bachmayer (Crucell)***
Encountered challenges during the standardization of the ICS assay

11.35h *11.55h* ***Robin Longdin (Quotient Bio Analytical Sciences)***
Challenges for flow cytometry in regulated Bioanalysis; quality assurance and regulatory considerations

11.55h *12.15h* ***Virginia Litwin (Covance)***
Analytical Method Validation: Perspectives from the Flow Cytometry Action Programming Committee of the AAPS

12.15h *12.30h* ***Panel Discussion***

12.30h 14.00h Lunch break

14.00h 15.30h Interferences & surprises ligand binding assay method development

14.00h *14.20h* ***Helen Young (Quotient Bio Analytical Sciences)***
Implementation of Critical Reagent Monitoring in a Clinical Laboratory

14.20h *14.40h* ***Martin Nemansky (PRA)***
Guidelines at work - Examples of theoretical considerations versus practical solutions in Immunogenicity assays

14.40h *15.00h* ***Matthew Bentley (Merck-Millipore)***
Immunogenicity analysis challenges and solutions for PEGylated biopharmaceuticals

15.00h *15.20h* ***Roland Staack (F. Hoffmann-La Roche)***
Free analyte QC concept - a novel approach for qualification/validation of free drug assays

15.20h *15.40h* ***Open Discussion***

15.40h 16.15h Coffee break

16.15h 18.00h Analytical challenges of antibody-drug conjugates (ADCs)

16.15h *16.35h* ***Bernhard Beckermann (Bayer)***
Introduction

16.35h *16.55h* ***Steffen Groß (Paul-Ehrlich-Institut)***
Regulatory expectations for the characterisation of ADCs

16.55h *17.10h* ***Stefanie Fischmann (AbbVie)***
Strategy for bioanalysis of ADCs along project development stages

17.10h *17.25h* ***Marie-Hélène Pascual (Sanofi)***
Selective immunoassay of the naked antibody as a new tool for pharmacokinetic interpretation of an antibody drug conjugate

17.25h *17.40h* ***Jasja Wolthoorn (TNO Triskelion)***
Novel Platform Using LC-MS and Ligand Binding Assays for Characterization and PK analysis of ADCs

17.40h *18.00h* ***Panel discussion***

Day 3 - Friday 22 NOV 2013

BREAKOUT SESSIONS

08.30h 10.20h Promises of new technology: sense and nonsense of HR-MS

08.30h 08.50h ***Suma Ramagiri (AB SCIEX)***
ADC quantitation using HRMS

08.50h 09.15h ***Lieve Dillen (Janssen R&D)***
High resolution mass spectrometry for bioanalysis at Janssen. Current experiences and future perspectives

09.15h 09.40h ***Mark Wrona (Waters)***
Moving forward on Quan-Qual, perspectives on using TOFs for bioanalytical work

09.40h 10.00h ***Mohammed Abrar (Unilabs York Bioanalytical Solutions)***
The comparison of high resolution MS with triple quadrupole MS for the analysis of oligonucleotides

10.00h 10.20h ***Hongxia Wang (Thermo Fisher Scientific)***
Quantification of protein biotherapeutics by a universal LC-high resolution/accurate mass based approach: intact protein or proteolytic peptides?

08.30h 10.20h Issues & solutions in sample logistics

08.30h 08.50h ***Jose Groenboom (on behalf of EBF TT-12)***
Sample logistics: problems and solutions in multi-center clinical trials

08.50h 09.10h ***Rebecca Sleigh (on behalf of EBF TT-12)***
Proposed generic lab manual

09.10h 09.300h ***Scott Vincent (A4P Consulting)***
Bio-logistical considerations in planning and executing early phase bioanalytical components

09.30h 09.50h ***Jean-Guy de Gruben (World Courier)***
Issues within the context of Clinical Trials Logistics. Practical examples and solutions

09.50h 10.10h ***Bärbel Wilke (LKF - Laboratorium für Klinische Forschung)***
Logistics within a Central Laboratory - From Specimen Receipt to Result Reporting

10.10h 10.20h ***Introducing the Focus Workshop***

10.20h 11.00h Coffee break

PLENARY SESSIONS

11.00h	**14.15h**	**2013 draft FDA Guidance for Industry on Bioanalytical Method Validation - preparing for Crystal City V**
		Each session will consist of a short introduction summarizing the EBF consolidated comments on the draft Guidance on the specific chapter, followed by plenary discussion. Timing of the sessions is indicative and depends on extent of comments.
11.00h	*11.15h*	*Introduction and background*
11.15h	*12.00h*	*Chromatographic methods*
12.00h	*12.45h*	*Ligand Binding Assays*
12.45h	*13.00h*	*Incurred Sample Reanalysis*
13.00h	*13.30h*	*Additional issues: endogenous compounds, biomarkers, diagnostic kits and new technologies*
13.30h	*14.00h*	*Documentation and glossary*
14.00h	*14.15h*	*Wrap up*
14.15h	**14.30h**	**Plans for 2014 and adjourn**