Program

15 NOVEMBER 2011

14:00 20:00 **Registration and Information Desk Open**

Day 1 – 16 November 2011

07.00 18:00 **Registration and Information Desk Open**

MORNING PLENARY SESSIONS

08.30 08.45 **Welcome And Opening Remarks**

08.45 10.40 **Biomarker Validation Recommendation**
Chair: Arjen Companjen (Crucell)

08.45 09.00 **Philip Timmerman (on behalf of EBF)**
Introduction to biomarker validation recommendation session

09.00 09.20 **Christian Herling (on behalf of EBF)**
EBF reflections on biomarker validation

09.20 09.40 **Alexandre Avrameas (Novartis)**
Validation of immunoassay for protein biomarkers: bioanalytical study plan implementation

09.40 10.00 **Barry Jones (Advion)**
LC/MS biomarker assay validation strategies using surrogate matrix and surrogate analyte approaches

10.00 10.20 **Richard Houghton (Quotient Bioresearch)**
Challenges of validating small molecule LC-MS/MS biomarker methods

10.20 10.40 **John Chappell (ICON Development Solutions)**
Biomarker Measurement- maximum information from limited volume

10.40 11.20 **Coffee Break and Poster Session**

11.20 12.45 **How To Implement The EMA Guideline On Bioanalytical Method Validation**
Chair and Moderator: Silke Luedtke (Boehringer-Ingelheim)

11.20 11.25 **Peter van Amsterdam (on behalf of EBF)**
Introduction

11.25 11.35 **Olivier Le Blaye (afssaps)**
< Title to be confirmed >

11.35 11.45 **Timothy Sangster (Charles River Laboratories)**
EMA – have our prayers been answered!

11.45 11.55 **Daniela Stoellner (Novartis)**
New EMA guideline on method validation and how it translates into best practice for Ligand Binding Assays

11.55 12.05 **Graeme Smith (Huntingdon Life Sciences)**
Partial Validation when is enough, enough?

12.05 12.15 **Morten Rohde (Lundbeck)**
Matrix Effects in Bioanalysis, when established procedures become obsolete.

12.15 12.45 **Panel Discussion**

12.45 13:50 Lunch And Poster Session

Day 1 – 16 November 2011

AFTERNOON PLENARY SESSIONS

13.50 16.00 Updates From The Globe
Chair: Philip Timmerman (Janssen Research & Development)

13.50 14.05 **Rafael Barrientos (Magabi for ACBio)**
ANVISA guideline on bioanalytical method validation updates

14.05 14.20 **Shinobu Kudoh (Shimadzu for Japan Bioanalysis Forum)**
Introducing the Japan Bioanalysis Forum (JBF)

Global Harmonization – Updates And Feedback From GBC Harmonization Teams

14.20 14.30 **Philip Timmerman (on behalf of GBC)**
Global Bioanalysis Consortium status update

14.30 14.45 **John Smeraglia (on behalf of GBC Harmonisation Team A1)**
Harmonization team A1 (scope and regulations) update

14.45 15.00 **Nico van de Merbel (on behalf of GBC Harmonisation Team A6)**
Harmonization team A6 (stability) update

15.00 15.15 **Michaela Golob (on behalf of GBC Harmonisation Team L6)**
Harmonization team L6 (immunogenicity effect on PK) update

15.15 15.30 **Ben Gordon (on behalf of GBC Harmonisation Team S1)**
Harmonization team S1 (run acceptance) update

15.30 16.00 **Panel Discussion**
Moderators: Michaela Golob (EU), Shinobu Kudoh (APAC), Rafael Barrientos (LA) and Fabio Garofolo (NA)

16.00 16.30 Coffee Break and Poster Session

16.30 18.00 Technology Session I
Chair: Margarete Brudny-Kloeppel (Bayer HealthCare)

16.30 17.00 **Patrick Bennett (Thermo Scientific)**
Applying proven proteomics workflows and tools for quantitative bioanalysis of large molecules

17.00 17.30 **Barry van der Strate (PRA International)**
Flow cytometry for determination of efficacy in phase I

17.30 18.00 **Andrew Roberts (Quotient Bioresearch)**
Challenges in developing anti-drug antibody ligand binding assays

18.30 20.00 Conference Reception I in Exhibition and Poster Hall
Sponsored by Advion
Discover Catalunyan cava: enjoy a few drinks and savour traditional food during this great networking opportunity

Day 2 – 17 November 2011

07.00 18:00 Registration and Information Desk Open

MORNING PLENARY SESSIONS

08.30 10.00 Technology Session II
Chair: Richard Abbott (Shire)

08.30 09.00 **Mauro Aiello (AB Sciex)**
Differential ion mobility spectrometry, creating a new dimension of selectivity for LC/MS/MS analysis

09.00 09.30 **Robert S. Plumb (Waters Corporation)**
Beyond sensitivity: improving the performance, productivity and compliance of the bioanalytical assay process

09.30 10.00 **Lester Taylor (Agilent Technologies)**
Automation and optimization of an on-line extraction system for dried blood spot analysis

10.00 10.20 Bioanalysis Young Investigator Award

10.00 10.05 **Peter van Amsterdam (representing EBF Steering Committee)**
Introduction

10.05 10.20 **Award winner**
Presentation

10.20 11.00 Coffee Break and Poster Session

11.00 12.30 Relationship Between Incurred Sample Reproducibility (ISR) And Incurred Sample Stability (ISS)
Chair & Moderator: Silke Luedtke (Boehringer-Ingelheim)

11.00 11.20 **Morten Anders Kall (on behalf of EBF)**
Feedback on EBF survey on Incurred Sample Stability (ISS)

11.20 11.40 **Theo de Boer (QPS)**
Incurred sample accuracy assessment: design of experiments based on standard addition

11.40 12.00 **Ronald de Vries (Janssen Research & Development)**
Assessment of ISS using an efficient standardized stepwise "black box" process.

12.00 12.30 **Panel Discussion**

12.30 14.00 Lunch and Poster Session

Day 2 – 17 November 2011

AFTERNOON PLENARY SESSIONS

14.00 15.40 **Plenary Microdosing /Microtracer**
Chair: Philip Timmerman (Janssen Research & Development)

14.00 14.40 **Keynote Speaker: Malcolm Rowland (School of Pharmacy and Pharmaceutical Sciences, University of Manchester)**
Microdosing: a simple idea with big results

14.40 15.00 **Microdosing /Microtracer Plenary Session With Focus On AMS (Plenary)**
Graeme Young (GSK)
"LC+AMS" in support of microdose/microtracer clinical studies at GSK – an evolving science

15.00 15.20 **David Higton (on behalf of EBF)**
Towards a recommendation of bioanalytical qualification or validation of microdosing and microtracer studies – part 1 – LC+AMS

15.20 15.40 **Stuart Best (Xceleron)**
What are the critical factors determining the performance of an LC+AMS assay?

15.40 16.20 **Coffee Break and Poster Session**

AFTERNOON BREAKOUT SESSIONS

Main Auditorium

16.20 18.00 **I: Microdosing /Microtracer Plenary Session With Focus On High Sensitivity LC-MS/MS**
Chair: Richard Abbott (Shire)

16.20 16.40 **David Higton (on behalf of EBF)**
Towards a recommendation of bioanalytical qualification or validation of microdosing and microtracer studies – part 2 – LC-MS/MS

16.40 17.00 **Richard Abbott (Shire)**
Microdosing and cold LC-MS/MS: bioanalysis and its evolving role in strategic drug development

17.00 17.20 **Alberto Guenzi (Hoffmann-La Roche)**
Microdosing with LC-MS analysis: variations on the theme

17.20 17.40 **Magnus Knutsson (Ferring)**
Drug development of highly potent therapeutic peptides - A bioanalytical challenge with micro-dosing plasma levels at therapeutic doses

17.40 18.00 **Panel Discussion**
Moderators: Graeme Young (GSK), Richard Abbott (Shire) and David Higton (AstraZeneca)

Breakout Room

16.20 18.00 **II: Stability Issues In Ligand Binding Assays**
Chair: Arjen Companjen (Crucell)

16.20 16.30 **Arjen Companjen (on behalf of EBF)**
Introduction

16.30 16.50 **Jenny Hendriks (Crucell)**

Binding and activity of anti-vaccine antibodies in short and long term stability studies

16.50 17.10 **Ulrich Kunz (Boehringer-Ingelheim)**
Case studies of issues with stability of antibody reagents

17:10 17:30 **Susanne Pihl (on behalf of EBF)**
Long term stability investigation of macromolecules in an isochronic study design

17:30 18.00 **Panel Discussion**
Moderator: Margarete Brudny-Kloeppel (Bayer HealthCare)

18.30 20.00 **Conference Reception II in Exhibition and Poster Hall**
Sponsored by Icon Development Solutions
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Day 3 – 18 November 2011

MORNING BREAKOUT SESSIONS

Main Auditorium

8.30 10.45 **III. Updates On Dried Blood Spots, Blood Analysis And Microsampling**
Chair: Ben Gordon (for Servier)

8.30 8.45 **Philip Timmerman (on behalf of EBF)**
Moving forward from the EBF Recommendation

8.45 9.45 **Feedback and status of EBF Dried Blood Spot Consortium**
EBF June 2011 DBS workshop – where are we today?
All presentations are on behalf of the EBF DBS consortium

8.40 – 8.45	**Steve White** Introduction
8.45 – 9.00	**Liz Thomas** Sample Dilution
9.00 – 9.15	**Zoe Cobb** Stability/recovery
9.15 – 9.30	**Dieter Zimmer** Internal Standard
9.30 – 9.45	**Steve White** Haematocrit

9.45 10.00 **Eric Fluhler (Pfizer, on behalf of AAPS Bioanalytical Focus Group)**
Feedback from the AAPS APQ Open Forum: "DBS and microsampling: moving past the hype to knowledge and implementation" 27-Oct-2011, Washington D.C.

10.00 10.20 **Ove Jonsson (AstraZeneca)**
Capillary micro sampling (CMS): handling and analysis of small volumes of blood, plasma and other biofluids

10.20 10.45 **Panel Discussion**
Moderator: Steve White (GSK)

Breakout Room

8.30 10.45 **IV. Challenge Of "Free" And "Total" Macromolecule Quantification**
Chair: Daniela Stoellner (Novartis)

8.30 9.00 **Daniela Stoellner (on behalf of EBF)**

EBF overview

9.00 9.25 **Lindsay King (Pfizer)**
Risk assessment for the measurement of Free and Total drug and target

9.25 9.50 **Roland Staack (Hoffmann-La Roche)**
Mathematical simulation tools in bioanalytical assay development

9.50 10.15 **Philip Lowe (Novartis)**
Integration of physiological and biochemical concepts into the development of biopharmaceuticals

10.15 10.45 **Panel Discussion**
Moderator: Michaela Golob (Merck-Serono)

10.45 11.15 Coffee Break and Poster Session

Day 3 – 18 November 2011

PLENARY SESSIONS

11.15 13.00 Anomalous Results
Chair & Moderator: Peter van Amsterdam (Abbott Healthcare Products)

11.15 11.25 **Magnus Knutsson (on behalf of EBF)**
Updates from EBF survey on unexpected results

11.25 11.45 **Fabio Garofolo (Algorithm Pharma)**
An in-depth bioanalytical investigation to determine the root cause of abnormal results

11.45 12.00 **Silke Luedtke (Boehringer-Ingelheim)**
Unexpected results in a bioanalytical laboratory – a safety and compliance issue?

12:00 12:15 **Rachel Green (Quotient Bioresearch)**
Use of a CAPA system in handling anomalous results – with a focus on maintaining GCP compliance

12.15 12.35 **Andreas Henrichs (Sanofi-Aventis)**
GCP in a bioanalytical laboratory

12.35 13.00 **Panel Discussion**

13.00 14.00 2011-2012 EBF Feedback on planned and ongoing activities
Chair: Peter van Amsterdam (Abbott Healthcare Products)

13.00 13.20 **Arjen Companjen (on behalf of EBF)**
Overview of 2011 activities and plans for 2012

13.20 13.30 **Speaker to be announced (on behalf of EBF Topic Team-16)**
Feedback from topic team 16: formulation analysis

13.30 13.40 **Philip Timmerman (on behalf of EBF Topic Team -09)**
Feedback from topic team 9: alternative techniques

13.40 14.00 **Silke Luedtke (representing EBF SC)**
<< EBF Special Event >>

14.00 Adjourn