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 - 12.05 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?
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 Bioreserach)
Challenges in developing anti-drug antibody ligand binding assays
Open Symposium – Less is More
Defining Modern Bioanalysis: Use Less Compound to Obtain More Information

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  Diego Rodriguez Calabeiro (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

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

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
Discover Catalunyan red: enjoy a few drinks and savor traditional food during this great networking opportunity

Day 3 - 18 November 2011

Morning Breakout Sessions

Main Auditorium

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)

8.30 10.45 **Breakout Room**

**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**