



### **Day 0 - 30 NOVEMBER 2010**

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

---

### **Day 1 - 1 DECEMBER 2010**

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

**08.30 08.40** **Welcome and opening remarks**

### **MORNING PLENARY SESSIONS**

**08.40 10.00** **Bioanalysis – Thinking Outside the “Commodity” Box**

08.40 09.00 **Ian Wilson (AstraZeneca)**

What You Can't See Can Hurt You: Looking at Bioanalysis by LC-MS From the Outside

09.00 09.20 **John Pugh (University of Sheffield)**

Elemental imaging via LA-ICP-MS - New opportunities in the life sciences

09.20 09.40 **Robert Plumb (Waters)**

High Sensitivity Analysis of Biotherapeutics Using Capillary LC

09.40 10.00 **Martyn Hemsley (Covance)**

Considerations and Experiences in Developing Bioanalytical Assays for the Quantitative Determination of Oligonucleotides

10.00 10.30 Coffee Break

**10.30 12.30** **Practical Solutions to Bioanalytical Challenges : Blood - the original bioanalytical matrix?**

10.30 11.00 **Keynote Speaker : Albert Wolthuis (KCL)**

The Blood Matrix: A Dynamic Mirror

11.00 11.20 **Achiel Van Peer (Janssen Research and Development)**

Blood and Plasma: "A Magic Twin or Single in Human Pharmacokinetics ?"

11.20 11.35 **John Perkins (Advion BioServices)**

Long Term Stability Issues Observed during Validation of an LC-MS/MS assay for Clopidogrel and Metabolites

11.35 11.50 **Ronald de Vries (Janssen Research and Development)**

Analyte Instability Issues in Blood

11.50 12.10 **Achim Freisleben (Merck-Serono for EBF)**

EBF Current Thinking on the Conduct of Whole Blood Stability

12.10 12.30 **Panel Discussion**

**12.30 13.30** **Lunch and poster session**

---

### **Day 1 - 1 DECEMBER 2010**

### **AFTERNOON PLENARY SESSIONS**

**13.30 16.00** **Towards Global Harmonization**

13.30 13.50 **Philip Timmerman (Janssen Research and Development for EBF and GBC)**

GBC-Harmonization Initiative and EBF Perspective

13.50 14.10 **Jérôme Barré (afssaps)**

EMA Perspective on Global Harmonization

14.10 14.30 **Rafael Barrientos (Magabi for ACBio)**

South America perspective



14.30	14.50	<b>Daniel Tang (Frontage for BBDS and SBDS)</b> APAC Perspective on Global Harmonization
14.50	15.10	<b>Mark Arnold (Bristol Meyers Squibb for AAPS)</b> AAPS Perspective on Global Harmonization
15.10	15.30	<b>C.T. Viswanthan (FDA/CDER)</b> FDA Perspective on Global Harmonization
15.30	16.00	<b>Panel Discussion</b>
16.00	16.30	Coffee Break
<b>16.30</b>	<b>18.00</b>	<b><u>Pt Sponsor session I</u></b>
16.30	17.00	<b>Gary Harland (Waters)</b> Addressing The Challenge of Sensitivity and Metabolite Detection in Bioanalytical Studies
17.00	17.30	<b>Mauro Aiello (AB SCIEX)</b> Overcoming the Data Analysis Bottleneck with Next Generation Quantitative Software
17.30	18.00	<b>Pat Bennett (Thermo Scientific)</b> Future of the Triple Quadrupole: What is Possible and what is Practical?
<b>18.30</b>	<b>20.00</b>	<b><u>Conference Reception I</u></b> Discover Catalunyan Reds : Enjoy a Few Drinks and Savor Traditional Food During this Great Networking Opportunity

---

## **Day 2 - 2 DECEMBER 2010**

<b>07.00</b>	<b>18:00</b>	<b><u>Registration and Information Desk Open</u></b>
		<b>MORNING PLENARY SESSIONS</b>
<b>08.30</b>	<b>10.00</b>	<b><u>Pt Sponsor session II</u></b>
08.30	09.00	<b>Lester Taylor (Agilent)</b> Use of an Ion Funnel Triple Quadrupole LC/MS Instrument for HighSensitivity Quantitation.
09.00	09.30	<b>Martin Nemansky (PRA International)</b> Comparison of various platforms for large molecule analysis - Introduction of the Imperacer® technology
09.30	10.00	<b>Iain Shaw (Quotient Bioresearch)</b> C14 enabled drug development
10.00	10.30	Coffee Break
<b>10.30</b>	<b>12.30</b>	<b><u>Technologies and Comparison of Assay Platforms</u></b>
10.30	10.50	<b>Stefanie Fischmann (Abbott)</b> Comparison of Data from ECL and Hyphenated LC-MS Platforms on Quantitation of mAb from Serum Samples
10.50	11.10	<b>Fritz Poulsen (NovoNordisk)</b> Wash AlphaLISA - An Extension of the AlphaLISA/LOCI Technology
11.10	11.30	<b>Ronald Schmidt (Sanofi-Aventis)</b> Quantitative LC-MS/MS Analysis of Synthetic Insulins
11.30	11.50	<b>Craig Stovold (Quotient Bioresearch)</b> Appliation of the Gyrolab to bioanalytical, pharmacodynamic and immunogenicity analysis in a regulated laboratory
11.50	12.10	<b>Birgit Jaitner (Novartis)</b> An approach to measure total drug levels in human serum samples while overcoming target interference
12.10	12.30	<b>Panel Discussion</b>



12.30 14.00 Lunch and Poster Session

---

## **Day 2 - 2 DECEMBER 2010**

### **AFTERNOON BREAKOUT SESSIONS**

- 14.00 15.30 Ia - Reconnect on Dried Blood Spots**
- 14.00 14.30 **Philip Timmerman (Janssen Research and Development for EBF and GBC)**  
EBF recommendation on Method Validation for Dried Blood Spots
- 14.30 14.50 **Julian Haynes (Pfizer)**  
Application of a Simple 2D-LC-MS/MS System to Control Ion Suppression Effects from DBS Samples
- 14.50 15.10 **Rohan Takur (Taylor Technology)**  
DBS and HRMS for in vivo Fast PK studies – The Value and Advantage for Pre-Clinical Studies.
- 15.10 15.30 **Panel Discussion**
- 14.00 15.30 Ib - FDA Draft Guideline on "Assay Development for Immunogenicity Testing of Therapeutic Proteins" and Related Topics**
- 14.00 14.20 **Susan Kirshner (FDA)**  
US FDA Draft Guidance on Immunogenicity Testing
- 14.20 14.40 **Arjen Companjen (Crucell for EBF)**  
The EBF Perspective on the FDA draft guidance on Assay Development for Immunogenicity Testing of Therapeutic Proteins
- 14.40 15.00 **Robin Thorpe (NIBSC)**  
European Guidance on Unwanted Immunogenicity of Biologicals
- 15.00 15.30 **Panel Discussion**
- 15.30 16.00 Coffee Break
- 16.00 18.00 IIa - Continuation from Break Out Session 14.00-15.30 on Immunogenicity Guideline and Related Topics**
- 16.00 16.30 **Geoff Hale (Merck/Millipore)**  
The utility and futility of cut points for assessing unwanted immunogenicity
- 16.30 17.00 **Janka Ryding (Ferring)**  
Case Study: Neutralization Assay Design and Qualification.
- 17.00 17.30 **Andrea Kiessling (Novartis)**  
Integrated Approach of PK/PD/Immunogenicity Analysis
- 17:30 18:00 **Panel Discussion**
- 16.00 18.00 IIb - Practical Solutions to Bioanalytical Challenges : Matrix Effects**
- 16.00 16.30 **Keynote Speaker : Vincenzo Pucci (Merck & Co Inc)**  
Strategies for Reducing Phospholipid-based Matrix Effects in LC-ESI-MS Bioanalysis
- 16.30 16.50 **Curtis Sheldon (Celerion)**  
Haemolysed Sample Evaluation : A Variety of Issues for a Variety of Situations
- 16.50 17.10 **Carl-Johan Sennbro (Active Biotech for EBF)**  
Choice of Anticoagulant and Comparison of Counter-Ions - Results from Two EBF Surveys
- 17.10 17.25 **Tom Verhaeghe (Janssen Research and Development)**  
Matrix Effects in Practice : Sense and Nonsense of Internal Standard Response Acceptance Criteria
- 17.25 17.40 **Magnus Knutsson (Ferring)**  
Experiences of Assessing Matrix Effects by Monitoring Internal Standard Response in Study Samples
- 17.40 18.00 **Panel Discussion**



**18.30 20.00** **Conference Reception II**  
The Catalunya Cava Experience: Enjoy a Few Drinks and Savor Traditional Food During this Great Networking Opportunity

---

### **Day 3 - 3 DECEMBER 2010**

#### **MORNING PLENARY SESSIONS**

**8.30 10.30** **Finding the Right Level**

8.30 8.40 **Margarete Brudny-Kloeppel (Bayer Schering Pharma AG for EBF)**  
Introduction

8.40 9.10 **Fabio Garofolo (Algorithme Pharma Inc.)**  
When and How Much do Anomalous Results Need to be Investigated?

9.10 9.40 **Silke Lüdtke (Boehringer-Ingelheim for EBF)**  
Handling of Anomalous Results in Europe – Feedback from EBF Survey

9.40 10.10 **EBF Speaker(s) to be announced**  
Case Studies

10.10 10.30 **Panel Discussion**

10.30 11.00 Coffee Break

**11.00 12.00** **EBF Feedback**

11.00 11.30 **Peter van Amsterdam (Abbott for EBF)**  
Update on New Organization

11.30 12.00 **Margarete Brudny-Kloeppel (Bayer Schering Pharma AG for EBF)**  
Feedback from EBF 2010 Surveys and Activities

**12.00 13.40** **Biomarkers**

12.00 12.20 **Liesbeth Vereyken (Janssen Research and Development)**  
Challenges with Nucleoside Triphosphate Method Development and Analysis during the Life Cycle of a HCV Program

12.20 12.40 **Mark Spengler (Chimera)**  
Using Ligand-Binding Assay Sensitivity for Improved Matrix Tolerance and Related Parameters by Tailored Sample Dilution.

12.40 13.00 **Anna Valeri (MHRA)**  
Title to be Confirmed

13.00 13.20 **Jan Moack (Slovak University of Technology, Bratislava)**  
Effective use of Combination of Lung Malignancy Marker

13.20 13.45 **Panel Discussion**

**13.45 14.00** **Close out Discussion, Ideas for 2011**

**14.00** **Adjourn**

---