



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

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

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### **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 **Speaker to be announced**

Title to be announced

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**

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### **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 of 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



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|--------------|--------------|---|
| 14.30        | 14.50        | <b>Daniel Tang (Frontage for BBDS and SBDS)</b><br>APAC Perspective on Global Harmonization   |
| 14.50        | 15.10        | <b>Mark Arnold (Bristol Meyers Squibb for AAPS)</b><br>AAPS Perspective on Global Harmonization   |
| 15.10        | 15.30        | <b>C.T. Viswanthan (FDA/CDER)</b><br>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><br>Addressing The Challenge of Sensitivity and Metabolite Detection in Bioanalytical Studies                                     |
| 17.00        | 17.30        | <b>Mauro Aiello (AB SCIEX)</b><br>Overcoming the Data Analysis Bottleneck with Next Generation Quantitative Software  |
| 17.30        | 18.00        | <b>Pat Bennett (Thermo Scientific)</b><br>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><br>The Catalunya Cava Experience: Enjoy a Few Drinks and Savor Traditional Food During this Great Networking Opportunity |

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

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| <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><br>Use of an Ion Funnel Triple Quadrupole LC/MS Instrument for HighSensitivity Quantitation.                           |
| 09.00        | 09.30        | <b>Martin Nemansky (PRA International)</b><br>Comparison of various platforms for large molecule analysis - Introduction of the Imperacer® technology |
| 09.30        | 10.00        | <b>Iain Shaw (Quotient Bioresearch)</b><br>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><br>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><br>Wash AlphaLISA - An Extension of the AlphaLISA/LOCI Technology  |
| 11.10        | 11.30        | <b>Ronald Schmidt (Sanofi-Aventis)</b><br>Quantitative LC-MS/MS Analysis of Synthetic Insulins  |
| 11.30        | 11.50        | <b>Presenter to be confirmed (Quotient Bioresearch)</b><br>Title to be Confirmed  |
| 11.50        | 12.10        | <b>Birgit Jaitner (Novartis)</b><br>Title to be Confirmed   |
| 12.10        | 12.30        | <b>Panel Discussion</b>   |
| 12.30        | 14.00        | Lunch and Poster Session  |



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

### **AFTERNOON BREAKOUT SESSIONS**

- 14.00 15.30** **I - 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** **IIa - 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 **Presenter to be Confirmed (Company for EBF)**  
EBF Perspective on the Draft Immunogenicity Guideline
- 14.40 15.00 **Speaker to be announced**  
Title to be announced
- 15.00 15.30 **Panel Discussion**
- 15.30 16.00 Coffee Break
- 16.00 18.00** **IIb - Continuation from Break Out Session 14.00-15.30 on Immunogenicity Guideline and Related Topics**
- 16.00 16.30 **Geoff Hale (Merck/Millipore)**  
Screening Cutpoint / Confirmatory Cutpoint
- 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** **III - 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**  
Discover Catalunan Reds : Enjoy a Few Drinks and Savor Traditional Food During this Great Networking Opportunity
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### **Day 3 - 3 DECEMBER 2010**

#### **MORNING PLENARY SESSIONS**

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| <b>8.30</b>  | <b>10.30</b> | <b><u>Finding the Right Level</u></b>   |
| 8.30         | 8.40         | <b>Margarete Brudny-Kloeppel (Bayer Schering Pharma AG, for EBF)</b><br>Introduction  |
| 8.40         | 9.10         | <b>Fabio Garofolo (Algorithme Pharma Inc.)</b><br>When and How Much do Anomalous Results Need to be Investigated?   |
| 9.10         | 9.40         | <b>Silke Lüdtkke (Boehringer-Ingelheim for EBF)</b><br>Handling of Anomalous Results in Europe – Feedback from EBF Survey   |
| 9.40         | 10.10        | <b>Speaker to be announced</b><br>Title to be confirmed   |
| 10.10        | 10.30        | <b>Panel Discussion</b>   |
| 10.30        | 11.00        | Coffee Break  |
| <b>11.00</b> | <b>12.00</b> | <b><u>EBF Feedback</u></b>  |
| 11.00        | 11.30        | <b>Peter van Amsterdam (Abbott, for EBF)</b><br>Update on New Organization  |
| 11.30        | 12.00        | <b>Margarete Brudny-Kloeppel (Bayer Schering Pharma AG, for EBF)</b><br>Feedback from EBF 2010 Surveys and Activities   |
| <b>12.00</b> | <b>13.40</b> | <b><u>Biomarkers</u></b>  |
| 12.00        | 12.20        | <b>Liesbeth Vereyken (Janssen Research and Development)</b><br>Challenges with Nucleoside Triphosphate Method Development and Analysis during the Life Cycle of a HCV Program |
| 12.20        | 12.40        | <b>Mark Spengler (Chimera)</b><br>Using Ligand-Binding Assay Sensitivity for Improved Matrix Tolerance and Related Parameters by Tailored Sample Dilution.                    |
| 12.40        | 13.00        | <b>Presenter (MHRA)</b><br>Title to be Confirmed  |
| 13.00        | 13.20        | <b>Jan Moack (Slovak University of Technology, Bratislava)</b><br>Effective use of Combination of Lung Malignancy Marker  |
| 13.20        | 13.45        | <b>Panel Discussion</b>   |
| <b>13.45</b> | <b>14.00</b> | <b>Close out Discussion, Ideas for 2011</b>   |
| <b>14.00</b> |              | <b><u>Adjourn</u></b>   |

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