

## Day 2 - 2 December 2010

**07:00 - 18:00** Registration and Information  
Desk Open

### MORNING PLENARY SESSIONS

#### 08:30 - 10:00 - Platinum Sponsor session II

- 08:30 - 09:00** - Lester Taylor (Agilent) p. 16  
*Use of an Ion Funnel Triple Quadrupole LC/MS Instrument for High Sensitivity Quantitation.*
- 09:00 - 09:30** - Martin Nemansky (PRA International) p. 17  
*Comparison of various platforms for large molecule analysis - Introduction of the Imperacer® technology*
- 09:30 - 10:00** - Iain Shaw (Quotient Bioresearch) p. 17  
*C14 enabled drug development*
- 10:00 - 10:30** - Coffee Break

#### 10:30 - 12:30 - Technologies and Comparison of Assay Platforms

- 10:30 - 10:50** - Stefanie Fischmann (Abbott) p. 18  
*Comparison of Data from ECL and Hyphenated LC-MS Platforms on Quantitation of mAb from Serum Samples*
- 10:50 - 11:10** - Fritz Poulsen (NovoNordisk) p. 19  
*Wash AlphaLISA - An Extension of the AlphaLISA/LOCI Technology*
- 11:10 - 11:30** - Ronald Schmidt (Sanofi-Aventis) p. 19  
*Quantitative LC-MS/MS Analysis of Synthetic Insulins*
- 11:30 - 11:50** - Craig Stovold (Quotient Bioresearch) p. 20  
*Application of the Gyrolab to bioanalytical, pharmacodynamic and immunogenicity analysis in a regulated laboratory*
- 11:50 - 12:10** - Birgit Jaitner (Novartis) p. 20  
*An approach to measure total drug levels in human serum samples while overcoming target interference.*
- 12:10 - 12:30** - Panel Discussion
- 12:30 - 14:00** - Lunch and Poster Session

### AFTERNOON BREAKOUT SESSIONS

- 14:00 - 15:30** - Breakout Ia  
**Reconnect on Dried Blood Spots**
- 14:00 - 14:30** - Philip Timmerman p. 21  
(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) p. 21  
*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- 14:00 - 15:30** - Breakout Ib - FDA Draft Guidance on «Assay Development for Immunogenicity Testing of Therapeutic Proteins» and Related Topics
- 14:00 - 14:20** - Susan Kirshner (FDA) p. 22  
*US FDA Draft Guidance on Immunogenicity Testing*
- 14:20 - 14:40** - Arjan Companjen (Crucell on behalf of EBF) p. 22  
*The EBF perspective on the FDA draft guidance on Assay Development for Immunogenicity Testing of Therapeutic Proteins*
- 14:40 - 15:00** - Robin Thorpe (NIBSC) p. 23  
*European Guidance on Unwanted Immunogenicity of Biologicals*
- 15:00 - 15:30** - Panel Discussion
- 15:30 - 16:00** - Coffee Break
- 16:00 - 18:00** - Breakout IIa - Continuation from Break Out Session 14.00-15.30 on Immunogenicity Guidance and Related Topics
- 16:00 - 16:30** - Geoff Hale (Milipore BioPharma Services) p. 23  
*The utility and futility of cut points for assessing unwanted immunogenicity*
- 16:30 - 17:00** - Janka Ryding (Ferring) p. 24  
*Case Study: Neutralization Assay Design and Qualification*
- 17:00 - 17:30** - Andrea Kiessling (Novartis) p. 24  
*Integrated Approach of PK/PD/Immunogenicity Analysis*
- 17:30 - 18:00** - Panel Discussion
- 16:00 - 18:00** - Breakout IIb - Practical Solutions to Bioanalytical Challenges : Matrix Effects
- 16:00 - 16:30** - Keynote Speaker : Vincenzo Pucci (Merck & Co Inc) p. 25  
*Strategies for Reducing Phospholipid-based Matrix Effect in LC-ESI-MS Bioanalysis*
- 16:30 - 16:50** - Curtis Sheldon (Celerion) p. 25  
*Haemolysed Sample Evaluation : A Variety of Issues for a Variety of Situations*
- 16:50 - 17:10** - Carl-Johan Sennbro (Active Biotech for EBF) p. 26  
*Choice of Anticoagulant and Comparison of Counter-Ions - Results from Two EBF Surveys*
- 17:10 - 17:25** - Tom Verhaeghe (Janssen Research and Development) p. 27  
*Matrix Effects in Practice : Sense and Nonsense of Internal Standard Response Acceptance Criteria*
- 17:25 - 17:40** - Magnus Knutsson (Ferring) p. 27  
*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 Savour Traditional Food During this Great Networking Opportunity*



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