

PROGRAM

Day 1 - 12 June 2012

MORNING PLENARY SESSIONS

Introduction and aim of the meeting

- Philip Timmerman (on behalf of EBF)
Welcome and introduction, aim of the meeting
- CT. Viswanathan (CT Viswanathan & Associates, Inc.)
Keynote: Bringing New Technologies into Regulatory Space

Special Topics and Interesting Techniques

- William van Dongen (TNO Triskelion)
iHUMITE: A cost efficient and accurate human drug metabolite profiling workflow
- Martijn Hilhorst (PRA International)
Advantages and recent developments in the use of photo-spray ionisation for quantitative bioanalysis
- Bruce Thompson (AB Sciex)
Pushing the limits of increased selectivity, dynamic range and sensitivity for bioanalytical applications

Alternative MS-techniques for quantitative bioanalysis

- Benno Ingelse (MSD)
Keynote: Towards High Resolution MS in Regulated Bioanalysis
- Jaap Wieling (QPS)
Application of ICP-MS and LC-ICP-MS in Drug Development
- Erik Baltussen (WIL)
ICPMS and tailored sample preparation for unusual bioanalytical applications
- Steven Watt (A&M)
High Resolution and Accurate Mass Spectrometry for Specific and Sensitive Quantification of Target Compounds in Complex Matrices
- Fabio Garofolo (Algotihm Pharma)
HR-MS in High Throughput Regulated Bioanalysis: A thorough and Practical Evaluation of Performance, Roubustness and Return on Investment

- Diego Rodriguez Cabaleiro (Waters Europe)
Accurate Mass MS/MS an Attractive Option For the Quantification of Biotherapeutics in DMPK Studies

AFTERNOON PLENARY SESSIONS

Miniaturization and/or automation of sample preparation techniques?

- Kevin Bateman (MSD)
Keynote presentation: Development of Quantitative Nanoscale Techniques for Ultra Trace Analysis of Biological Microsamples
- Lieve Dillen (Janssen R&D)
Blood microsampling and bioanalysis in preclinical species
- Ove Jonsson (AstraZeneca)
Capillary Microsampling: "Better science - Fewer animals"
- Brigitte Buscher (TNO Triskelion)
Microdialysis as a tool in drug research and development
- Sheelan Ahmad (GSK)
The Application of Solid - Phase Micro-Extraction and Micro-Sampling/ a Multipurpose Micro-Technique for Bioanalysis

Tissue Analysis

- Markus Stoeckli (Novartis)
Keynote presentation: We Can See - Mass Makes the Difference
- Jonathan Stauber (ImaBiotech)
Maldi imaging of small histological tissue applied to ophthalmology: qualitative and quantitative approach in drug discovery
- Andrew McEven (Quotient Bioresearch)
MALDI Tissue Imaging: More than Just a Pretty Picture?
- Hermann Mascher (Pharm-Analyte Labor)
Some practical aspects in tissue analysis
- Nathalie Mokrzycki (MSD)
EBF Topic team on tissue analysis: plans

Day 2 - 13 June 2012

MORNING BREAKOUT SESSIONS

Focus on Large molecules: Emerging platforms in support of LBA

- John Allinson (ICON Development Solutions)
Keynote presentation: New and Automated Technology Platforms in Bioanalysis
- Karen Dowers (CRL)
A Hybrid LBA-QPCR Technique (Proseek) for Improved Assay Sensitivity
- Denise Sickert (Novartis)
Homogeneous immunoassay using AlphaLISA technology - the "no wash" high-throughput alternative to ELISA for PK, PD and immunogenicity measurement during drug development
- Bryan Krastins (ThermoFisher Scientific)
Mass Spectrometric Immunoassays
- Graig Stovold (Quotient Bioresearch)
Going round again: Lessons learnt from establishment and validation of methods on the Gyrolab Workstation

Focus on Small molecules: Miniaturization and diversification in LC-MS interfacing

- Sabeth Verpoorte (University of Groningen)
Keynote: Incorporating Multifunctionality into Microchip Separations
- Marc De Meulder (Janssen R&D)
Hatching sensitivity in Bioanalysis The promise of chip based micro LC/MS
- Paul Rainville (Waters Corporation)
Capillary Scale LC/MS/MS for High Sensitivity Bioanalysis Is This A Reality and Where Are The Pit Falls
- Tina Settineri (Eksigent)
Micro LC/MS: Miniaturizing LC for LC/MS applications in bioanalysis

MORNING PLENARY SESSIONS

Applications and validation approaches for Emerging platforms in support of LBA

- Jenny Hendriks (Crucell)
Keynote presentation: Challenges in Development and Validation of an Intracellular Cytokine Staining assay
- Carsten Lindemann (EUFETS GmbH)
Validation of a PCR for the quantification of residual plasmid DNA in samples from a biodistribution study for a therapeutic RNA vaccine
- Jan Detmers (Chimera Biotec GmbH)
Case Studies on ultra-sensitive immunoanalytics based on Imperacer® (Immuno-PCR) in clinical settings.
- Jason Cook (AstraZeneca)
Validation of a multiplexed cytokine panel in human serum using a Randox Evidence analyser and comparison to other platforms (Luminex and MSD)
- Philip Timmerman and C.T. Viswanathan
Panel discussion connecting back on scope of FM

AFTERNOON PLENARY SESSIONS

GBC feedback

- Peter van Amsterdam (on behalf of GBC)
Feedback from GBC Harmonization team leaders Face to face (March 2012)
- Philip Timmerman (Janssen R&D)
Feedback and input A2 - Tiered approaches to method validation
- Ben Gordon (on behalf of Servier)
S1 - Small molecule specific run acceptance harmonization team progress report
- Steve White (GSK)
S2 - Small molecule specific assay operation
- Stuart McDougall (Covance)
S3 - Chromatographic run quality assessment
- Chris Beaver (Pharmanet)
L1 - Large molecule specific run operation
- Chris Beaver (Pharmanet)
L2 - Large molecule specific assay operation
- John Smeraglia (HLS)
L3 - Assay Formats
- Tom Verhaeghe (Janssen Research and Development)
A8 - Documentation