

Day 0 – 20 JUNE 2011

16:00 20:00 **Registration and Information Desk Open**

Day 1 - 21 JUNE 2011

07.30 12:30 **Registration and Information Desk Open**

08.45 09.00 **Welcome and Introduction**

09.00 12.30 **New Technology Developments for Analysis of Large Molecules**

09.00 10.30 **Session 1: New Instrument Developments**

Chair: Berthold Lausecker, CRS Mannheim

09.00 09.30 **Comparison of different MS platforms for peptide quantification**
Lieve Dillen, Janssen R&D

09.30 09.50 **Implementation of a common high pH LC/MS/MS platform for small molecules and large molecules**
Robert Plumb, Waters Corporation

09.50 10.10 **Introducing a novel bench top Orbitrap for highly selective peptide/protein quantitation**
Kai Scheffler, Thermo Fisher Scientific

10.10 10.30 **High Sensitivity Protein Quantitation Using a Triple Quadrupole with a Dual Ion Funnel**
Lester Taylor, Agilent Technologies

10.30 11.00 **Coffee Break**

11.00 15.00 **Cutting Edge Analytical Approaches**

11.00 12.30 **Session 2a: Cutting Edge Analytical Approaches - Peptides**

Chair: Silke Luedtke, Boehringer-Ingelheim

11.00 11.30 **Strategies for the analysis of therapeutic peptides in biofluids**
Lee Goodwin, Covance

11.30 11.50 **Comparison of clinical analyser and LC-MS/MS based approaches for quantification of serum IGF-I levels**
Rachel Green, Quotient Bioresearch

11.50 12.10 **Quantitative LC-MS/MS analysis of polypeptides: glucagon**
Veniamin Lapko, Celerion

12.10 12.30 **Quantification of selected peptides in biological fluids e.g. plasma**
Hermann Mascher, pharm-analyt Lab. GmbH

Day 1 - 21 JUNE 2011

12.30 13.30 Lunch

13.30 15.00 Session 2b: Cutting Edge Analytical Approaches - Peptides
Chair: Silke Luedtke, Boehringer-Ingelheim

13.30 14.00 **The importance of sample preparation for the analysis of proteins and peptides by liquid chromatography with mass spectrometric detection**
Gerard Hopfgartner, University of Geneva

14.00 14.30 **LC-MS/MS bioanalysis of therapeutic peptides in plasma at low pg/mL levels**
Magnus Knutsson, Ferring Pharmaceuticals A/S

14.30 15.00 **A selective SPE/LC-MS/MS assay for simultaneous quantitation of multiple amyloid beta peptides in cerebrospinal fluid**
Erin Chambers, Waters Corporation

15.00 15.30 Coffee Break

15.30 18.00 Validation Requirements for Large Molecule Analysis with MS Techniques

15.30 18.00 Session 3: Regulatory Challenges and Acceptance Criteria
Chair: Berthold Lausecker, CRS Mannheim

15.30 15.50 **First EBF reflections on Method validation criteria for peptide/protein analysis with LC-MS based techniques**
Philip Timmerman, Janssen R&D

15.50 16.20 **Validation of an immunoprecipitation, digestion and immunoaffinity LC-MS/MS assay for human NGF biomarker and implementation in support of clinical trials**
Gary Schulz, Advion Bioservices

16.20 16.40 **The use of internal standards for macromolecule quantification by LC-MS: lessons learned from small molecule assays**
Nico van de Merbel, PRA International

16.40 17.00 **Issues of specificity, recovery, and accuracy in LC-MS/MS assays for peptides and proteins (working title)**
Ben van Baar, QPS

17.00 18.00 **Panel Discussion**

18.00 19.00 Cocktail Reception

Day 2 - 22 JUNE 2011

- 08.30 12.00 Cutting Edge Analytical Approaches - Proteins**
- 08.30 10.00 Session 4a: Cutting Edge Analytical Approaches - Proteins**
Chair: Begona Barroso, Astellas
- 08.30 09.00 **The powers of using MRM3 and high resolution MS with fast scan rates to conquer previously difficult large molecule compounds**
Yong-Xi Li, Medpace Bioanalytical Laboratories
- 09.00 09.30 **LC-MS/MS quantification of proteins and peptides in biological fluids: towards a generic approach**
Olivier Heudi, Novartis Pharma AG
- 09.30 10.00 **High throughput method for the quantitative analysis of therapeutic antibody in the low ng/mL range from serum samples via affinity enrichment coupled LC-MS/MS to support clinical and preclinical PK/TK evaluation**
Stephanie Fischmann, Abbott
- 10.00 10.30 Coffee Break**
- 10.30 12.00 Session 4b: Cutting Edge Analytical Approaches - Proteins**
Chair: Begona Barroso, Astellas
- 10.30 10.50 **Sample preparation for protein quantification by LC-MS/MS**
Ejvind Mørtz, Alphalyse
- 10.50 11.10 **Challenges in validating protein and peptide LC-MS/MS methodologies**
Ian Ward, Quotient Bioresearch
- 11.10 11.30 **Comparison of quantitative assays for a large protein: ELISA vs. LC-MS/MS**
Alberto Guenzi, Hoffmann-La Roche
- 11.30 12.00 **Development and validation of an immunoaffinity-LC-MS/MS assay for 22 KDa somatropin in human serum (working title)**
Rand Jenkins, PPD

Day 2 - 22 JUNE 2011

- 11.50 13.00 Lunch**
- 13.00 14.30 Analytical Strategy**
- 13.00 14.30 Session 5: Analytical Strategies on Combining LBA and LC-MS(/MS) for Large Molecules**
Chair: Peter van Amsterdam, Abbott Healthcare Products
- 13.00 13.30 **The sense and nonsense of quantitative analysis of biologics - or why should we care**
Martin Nemansky, PRA International
- 13.30 14.00 **Ligand Binding Assay critical reagent characterization via LC-MS**
Brian Geist, Centocor
- 14.00 14.30 **Highly sensitive Cytokine Quantification using Imperacer®, an Immuno-PCR based Ligand-Binding Assay System**
Michael Adler, Chimera Biotec GmbH
- 14.30 15.00 Coffee Break**
- 15.00 16.30 Proteins in the MIST**
- 15.00 16.30 Session 6: Proteins in the MIST**
Chair: Peter van Amsterdam, Abbott Healthcare Products
- 15.00 15.30 **Ion mobility mass spectrometry: New molecular tool for the analysis of reactive intermediates in the oligomerization-aggregation of "misfolding"-aggregating proteins**
Michael Przybylski, University of Konstanz
- 15.30 15.50 **Strategies for quantifying plasma protease susceptible peptides by LC-MS/MS**
Richard Kay, Quotient Bioresearch
- 15.50 16.10 **Bioanalytical LC-MS of therapeutic oligonucleotides**
William van Dongen, PROXY laboratories
- 16.10 16.30 **Extracting metabolite ions of peptide drugs out of an in vivo matrix background**
Filip Cuyckens, Janssen R&D
- 16.30 Closing Remarks and Adjourn**