



Focus Meeting – Large Meets Small

Connecting strategies on analyzing large molecules with small molecule technologies

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**

Session with focus on new mass spectrometer instrumentation features in the field of large molecule quantitation including oligonucleotides (TOF, Ion-Trap, High Resolution, Ion Mobility,)

10.30 11.00 **Coffee Break**

10.30 12.30 **Session 2: Cutting Edge Analytical Approaches - Peptides**

Session with focus on analysis of peptides; strategy presentations and case studies are welcome here
Biomarkers can be part of this session as long as they are fitting into the molecular size

12.30 13.30 **Lunch**

13.30 18.00 **Validation Requirements for Large Molecule Analysis with MS Techniques**

13.30 15.00 **Session 3: Regulatory Challenges and Acceptance Criteria**

Session with focus on drivers of validation and acceptance criteria: molecular size or type of analysis
4-6-15, 4-6-20 or other? Standard or tailored approach (fit for purpose)?
Biomarkers are not part of this session.

15.00 15.30 **Coffee Break**

15.30 17.00 **Session 4: Cross Validation with and/or Data Comparison to LBA Assays**

Session with focus on cross validation and data interpretation aspects
Is a 1/1 correlation needed/wanted/expected? Do we get complementary data out from the different approaches?
Biomarkers are not part of this session, unless to highlight the difference in approach.

17.00 18.00 **Panel Discussion**
Session to conclude the validation sessions and plan towards a recommendation

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 5: Sample Preparation for the Analysis of Proteins (digestions, alkylation, hydrolization, automation,...)**
Session with focus of analysis of proteins after different digestion techniques and other sample pre-treatment including selective extraction and special requirements for the chromatography of proteins/peptides
Biomarkers can be part of this session

10.00 10.30 Coffee Break

10.30 12.00 **Session 6: Derivatisation - Tagging of Proteins/Peptides**
Session with focus of analysis of proteins using tagging and the comparison of absolute and relative quantification. Techniques as MALDI-TOF could be included in this session.
Both proteins and biomarkers can be part of this session

12.00 13.00 Lunch

13.00 14.30 Analytical Strategy

13.00 14.30 **Session 7: Analytical Strategies on Combining LBA and LC-MS(/MS) for Large Molecules**
Here we are expecting one to three presentations with a subsequent panel discussion on analytical strategies for a drug life cycle. How do BA strategies differ for LBA vs. Large Molecule MS vs. Small molecule MS? Can LC-MS(/MS) used at the start of a project and later on ELISA, or could we start with a generic ELISA and switch to a specific as the compounds further develops?

14.30 15.00 Coffee Break

15.00 16.30 Proteins in the MIST

15.00 16.30 **Session 8: Proteins in the MIST**
New technology developments in Metabolite ID and quantification for peptides and proteins. What are the requirements of MIST for therapeutic proteins/peptides? Are ADAs the MIST of proteins/peptides?

16.30 Closing Remarks and Adjour