



EBF Cyberconnect Events:
Focus Workshop: Peptides & Proteins with (LC-)MS
 17-18 June 2021

Day 1

12:30	12:45	Coming online
12:45	13:00	Getting started - Welcome Philip Timmerman - EBF
13:00	13:20	Introduction to the workshop Matthew Barfield - on behalf of the EBF <i>Why this workshop?</i>
13:20	14:40	Session 1 - Scientific Challenges (e.g. reagents, free total, intact vs digested)
13:20	13:40	Carsten Krantz - Novartis <i>Hybrid LBA-LCMS for ADA detection</i>
13:40	14:00	Daniel Vidler or Michael Blackburn - Arcinova <i>Identifying Peptide Markers From Mycobacterial Protein Digests – Development of a High-Resolution LC-MS Assay</i>
14:00	14:20	Matthias Sury - Celerion <i>Key Reagent Release Testing by LC-HRMS</i>
14:20	14:40	Chris Williams - QPS <i>Development of a hybrid method for quantification of a therapeutic protein differing by a single amino acid from the endogenous form</i>
14:40	15:10	Break
15:10	18:00	Session 2: Scientific developments (new tools)
15:10	15:30	Julien Peltier - GlaxoSmithKline <i>Characterisation and Quantification of Therapeutic Antibodies by Incorporating Response Bias Correction using Affinity Capture and Intact Protein LC-MS.</i>
15:30	15:50	Ke Li - Frontage Labs <i>Development and validation of a LC/MS method for the quantification of fascin in human serum</i> Thomas Schneider - BiognoSYS AG <i>Context of Use Validation of a Data Independent Acquisition based Deep Proteome Quantification Approach</i>
15:50	16:10	Lei Xiong - Sciex <i>Improved LC-MRM workflow for cyclic peptide quantification on natriuretic peptide family</i>
16:10	16:20	Short Q&A logistic break
16:30	16:50	James Marr - MSD <i>Improvements in Immunoprecipitation and Digestion Efficiencies for Monoclonal Antibodies in Pharmacokinetic Studies using LC-MS/MS for Analysis</i>
16:50	17:10	Szabolcs Szarka - LGC <i>Utilizing high-resolution mass spectrometry to improve the sensitivity of a therapeutic protein assay</i>
17:10	17:30	Anton Rosenbaum - AstraZeneca <i>Comparison of Bioanalytical Methods for Pharmacokinetic Assessments of ADC</i>

17:30 18:00 Session 2 Q&A

18:00 **End of Day 1**

Day 2

12:45 13:00 **Coming online**

13:00 15:00 **Session 3: how to interpret the data” (e.g. biological specificity vs. analytical specificity, which data are ‘true’?**

13:00 13:10 Philip Timmerman - EBF
Introduction to the session: Turning Scientific challenges challenges into opportunities

13:10 13:30 Oriol Peris Serrano - CRL
Theme: Stakeholders perspective on acceptance criteria - title tbc

13:30 13:50 Gregor Jordan - F. Hoffmann-La Roche
Is correct quantification of free/active drug concentrations by hybrid LC-MS possible? An evaluation applying the “free analyte QC concept”

13:50 14:10 Nico van de Merbel - PRA-HS/U. Groningen
Analytical consequences of the in vivo deamidation of trastuzumab and pertuzumab: comparison of the results of three bioanalytical platforms

14:10 14:30 Session 3 Q&A and panel discussion

14:30 14:50 *Break*

14:50 18:00 **Session 4 - Defining a bioanalytical strategy for peptide/protein: which assay when and why?**

14:50 15:00 Iain Love - on behalf of the EBF
Introduction to the session: Questions to consider when building a bioanalytical strategy for proteins

15:00 15:20 Rita Martello - Merck KGaA
How to develop a bioanalytical strategy for therapeutic proteins

15:20 15:40 Shashank Gorityala - Covance
LCMS-based strategies for the quantitation of protein biotherapeutics

15:40 16:00 Emmanuel Njumbe Ediage, Janssen R&D
Challenges in developing an LC-MS/MS assay for the quantification of Pegasys; what are we measuring?

16:00 16:20 Session 4 Q&A and panel discussion

16:20 16:40 *Break*

16:40 18:00 **Session 5 - Regulatory challenges – experience and industry recommendations**

16:40 17:00 Amanda Wilson - on behalf of the EBF
Introduction to the session: EBF FB from the survey

17:00 17:30 Case studies on scientific and regulatory challenges on combining MS and LBA based technologies in one project
Case study 1, title tbc - Presenter tbc, Comac Medical
Case study 2, title tbc - Presenter: Benno Ingelse, Byondis
Case study 2, open slot

17:30 18:00 Closing Panel discussion: where regulatory and scientific challenges for protein analysis meet.

18:00 Adjourn



Organising Committee:

Matthew Barfield (Roche), Iain Love (Charles River Laboratories), Amanda Wilson