



## EBF 2021 Cyberconnect Events:

### Focus Workshop: Peptides & Proteins with (LC-)MS

17-18 June 2021

#### Day 1 (all times in CET, Brussels Time Zone)

12:30	12:45	Coming online
12:45	13:00	<b>Getting started - Welcome</b> Philip Timmerman - EBF
13:00	13:20	<b>Introduction to the workshop</b> Matthew Barfield - on behalf of the EBF <i>Why this workshop?</i>
13:20	14:40	<b>Session 1 - Scientific Challenges (e.g. reagents, free total, intact vs digested)</b>
13:20	13:40	Carsten Krantz - Novartis <i>Hybrid LBA-LCMS for ADA detection</i>
13:40	14:00	Daniel Vidler - Arcinova – A Quotient Sciences Business <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	18:30	<b>Session 2: Scientific developments (new tools)</b>
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>
15:50	16:10	Thomas Schneider - BiognoSYS AG <i>Context of Use Validation of a Data Independent Acquisition based Deep Proteome Quantification Approach</i>
16:10	16:30	Lei Xiong - Sciex <i>Improved LC-MRM workflow for cyclic peptide quantification on natriuretic peptide family</i>
16:30	16:40	Short Q&A
		Short logistic break
17:00	17:20	James Marr - MSD <i>Improvements in Immunoprecipitation and Digestion Efficiencies for Monoclonal Antibodies in Pharmacokinetic Studies using LC-MS/MS for Analysis</i>
17:20	17:40	Szabolcs Szarka - LGC <i>Utilizing high-resolution mass spectrometry to improve the sensitivity of a therapeutic protein assay</i>
17:40	18:00	Anton Rosenbaum - AstraZeneca <i>Comparison of Bioanalytical Methods for Pharmacokinetic Assessments of ADC</i>
18:00	18:30	Session 2 Q&A
18:30		<b>End of Day 1</b>

## Day 2 (all times in CET, Brussels Time Zone)

12:45	13:00	Coming online
13:00	14:30	<b>Session 3: how to interpret the data (e.g. biological specificity vs. analytical specificity, which data are 'true'?)</b>
13:00	13:10	Philip Timmerman - EBF <i>Introduction to the session: Turning Scientific challenges challenges into opportunities</i>
13:10	13:30	Oriol Peris Serrano - Charles River Laboratories <i>The Impact of Assay Acceptance Criteria on Derived Data – Pharmacokinetic Assessment Through Simulation</i>
13:30	13:50	Gregor Jordan - F. Hoffmann-La Roche <i>Is correct quantification of free/active drug concentrations by hybrid LC-MS possible? An evaluation applying the "free analyte QC concept"</i>
13:50	14:10	Nico van de Merbel - PRA-HS/U. Groningen <i>Analytical consequences of the in vivo deamidation of trastuzumab and pertuzumab: comparison of the results of three bioanalytical platforms</i>
14:10	14:30	Session 3 Q&A and panel discussion
14:30	14:50	Break
14:50	16:20	<b>Session 4 - Defining a bioanalytical strategy for peptide/protein: which assay when and why?</b>
14:50	15:00	Iain Love - on behalf of the EBF <i>Introduction to the session: Questions to consider when building a bioanalytical strategy for proteins</i>
15:00	15:20	Rita Martello - Merck KGaA <i>How to develop a bioanalytical strategy for therapeutic proteins</i>
15:20	15:40	Shashank Gorityala - Covance <i>LCMS-based strategies for the quantitation of protein biotherapeutics</i>
15:40	16:00	Emmanuel Njumbe Ediage, Janssen R&D <i>Challenges in developing an LC-MS/MS assay for the quantification of Pegasys; what are we measuring?</i>
16:00	16:20	Session 4 Q&A and panel discussion
16:20	16:40	Break
16:40	18:20	<b>Session 5 - Regulatory challenges – experience and industry recommendations</b>
16:40	17:00	Amanda Wilson - on behalf of the EBF <i>Introduction to the session: EBF FB from the survey</i>
17:00	17:20	Case studies & scientific and regulatory challenges on combining MS and LBA Tsvetelina Ivanova, Comac-Medical <i>Pharmacokinetic analysis using LBA and MS concentration data – was this a real challenge?</i>
17:20	17:40	William Mylott, PPD <i>Bioanalytical Method Validations: Taking a 'Hybrid Approach'</i>
17:40	18:00	Eric Thomas, Covance by Labcorp <i>Perspectives on Performance and Requirements for Protein MS Assays</i>
18:00	18:20	<b>Closing Panel discussion:</b> where regulatory and scientific challenges for protein analysis meet.
18:20		Closing comments and Adjourn



### Organising Committee:

Matthew Barfield (F. Hoffmann-La Roche), Iain Love (Charles River Laboratories), Amanda Wilson (AstraZeneca), Nico van de Merbel (PRA-HS) and Philip Timmerman (EBF)