



BEBPA's 5<sup>th</sup> Annual

## Host Cell Protein Conference

Best Practices for Immunoassay & LC-MS/MS Assessments of Product Purity

May, 10-12, 2017

[The Sheraton at Fisherman's Wharf](#)

San Francisco, CA

### Pre-Conference Workshops, May 10, 2017

#### Workshop 1: LC-MS/MS for HCP Analysis

**Instructor:** Kevin Van Cott, University of Nebraska

**Morning Session: An introduction to HCP Analysis by Mass Spectrometry** Introductory primer for those who have little or no MS experience

**Afternoon Session: From Standard Proteomics Methods to HCP Analysis**

Methods, technologies, and applications for experienced MS users

#### Workshop 2: Host Cell Proteins 101

**Instructor:** Denise Krawitz, CMC Paradigms LLC

A full day workshop on the many considerations needed to define, control, and monitor the HCP population in a drug substance

Workshop Adjourns at 5:00

#### Day 1, May 11, 2017

8:50 Welcome to the Conference

##### Session 1: Host Cell Protein Impurities & Product Quality

9:00 Case Study: Clinical perspectives on Phospholipase

B-Like 2 Protein, a Host Cell Impurity in Lebrikizumab Clinical Material– John Matthews, **Genentech**

9:30 Identification and quantification of HCP's by SWATH LC MS for process development of novel biologics– Thomas Kofoed, CEO, **Alphalyse** & Lars Skriver, **Savara**

10:00 Host Cell Proteins Seen as Critical Quality Attributes– Thomas Waerner, **Boehringer Ingelheim**

10:30-11:00 Morning Break

11:00 Monitoring & Identifying Critical HCPs During CHO Cell Bioprocessing: Do They Exist & Why We Shouldn't Have to Reclibrate HCP Assays Between Projects

Mark Smales, **University of Kent**

11:30 Knowledge Based HCP Risk Control Strategy During Downstream Process Development with Recent Case Studies

Fengqiang Wang, **Merck**

12:00 Lessons Learned: HCP Analysis of a Variety of Biologics and Biosimilars using LC-MS/MS– Laura McIntosh, **Caprion**

12:30-2:00 Lunch

##### Session 2: Immunoassay Development & Integration with LC-MS

2:00 Anti-HCP Antibody Reagents and Assay Development From a CRO Perspective: Industry Wide Data, Trends and Recommendations– Tobey Gooding, Research Associate, **Covance**

2:30 CHO Strain vs. Culture Process: Comparing HCP Reagent Made From Different CHO Lines On Measurement of HCPs in the Same Products– Lea Hagigi, **Biogen**

3:00 Case Study: HCP Antigen Stability

Emily Menesale, **Biogen**

3:30-4:00 Afternoon Break

4:00 Quantitative Investigation of HCP Impurities: Bridging the Gap Between ELISA & Orthogonal LC-MS/MS Analysis

Ying Zhang, **Pfizer**

4:30 An LC-MS/MS Workflow for Identification & Quantification of E. Coli Residual HCP's to Support Biotherapeutic Purification Process Development– Xian Huang, **Bristol-Myers Squibb**

5:00 Increased Throughput and Accuracy in Host Cell Protein Quantitation using Spectral Library Searches

Martha Stapels, **Sanofi Genzyme**

5:30: Conference Adjourns

#### Day 2, May 12, 2017

8:50 Welcome to the Conference

##### Session 3: Utilizing Mass Spectrometry for Host Cell Protein Characterization

9:00 The 2017 Chinese Haster Reference Genome  
Kelvin Lee, **University of Delaware**

9:30 Case Study for a Validation of a MS Based HCP Quantification Method - Requirements and Limitation– Ingo Lindner, **Roche**

10:00 An Effective SWATH-MS Workflow for the Analysis of CHO HCPs– Bi Xuezhi, **BioProcessing Technology Institute**

10:30-11:00 Morning Break

##### Session 4: Host Cell Protein Control Strategies for Pre- and Post-Marketed Products

11:00 A holistic phase appropriate strategy for HCP-limits and HCP characterization– Markus Haindl, **Roche**

11:30 HCP Control Strategy Reassessment for a CHO-derived Protein Therapeutic–John Rolf, **Amgen**

12:00 HCP ID and levels – Seeking Post Approval Changes in a Marketed Product– Feny Gunawan, **Genentech**

12:30-2:00 Lunch

##### Session 4: Quality & Regulatory Aspects of HCP Impurity Specifications

*Regulators from FDA, Health Canada and various EU Authorities have been invited.*

3:30-4:00 Afternoon Break

4:00 Roundtable Discussion on Specification Setting

Denise Krawitz, Consultant–Moderator ● Svetlana Bergelson, **Biogen**

● Ned Mozier, **Pfizer**

● Michael Wiedman, **Roche**

● Thomas Waerner, **Boehringer Ingelheim**

5:30 Conference Adjourns

3 Ways to Register: Online at [BEBPA.org](http://BEBPA.org)– Phone: 916-729-0109– Email: [bebpa@surewest.net](mailto:bebpa@surewest.net)