Host Cell Protein Conference

Presenters from:

AbbVie
Alphalyse
Amgen
Biogen
BioProcessing Technology Institute
Boehringer Ingelheim
Caprion Biosciences
Covance
CMC Paradigms LLC
FDA
Genentech
Health Canada
Merck
Novo Nordisk
Paul-Ehrlich-Institut
Pfizer
Roche
Sanofi Genzyme
Savara
University of Delaware
University of Kent
University of Nebraska

What's in your product? Come hear the latest advances in the field of biopharmaceutical HCP testing

- **Latest technology developments of LC-MS/MS of HCPs:** Hear the latest on HCP characterization and quantification methods with mass spectrometry. Day one will include a workshop with a morning session focused on an introduction to HCP analysis with MS and the afternoon will include talks by experts looking for the needle in the haystack.
- **Making the right choices in HCP immunoassay development:** Experts in development and characterization of immunoassays will speak about the latest technologies to ensure your HCP immunoassay is optimized for your product and for long-term use.
- **Clinical case study:** What happens when a host cell protein is discovered after the start of Phase III? Hear a clinicians perspective on managing risk.
- **Modern HCP control strategies:** Hear from Amgen, Roche, and Genentech on strategies to monitor, control, and characterize HCPs for pre- and post-marketed products
- **Implementing HCP monitoring to improve process development:** Experts from academia and industry will speak about technologies and risk-based approaches for HCP monitoring during purification process development.
- **Representation from FDA, Health Canada, and Paul-Erlich-Institut:** Hear the latest perspectives and expectations on HCP monitoring and control from Health Authorities world-wide.

For more information: www.bebpa.org

HCP Conference, May 10-12, 2017
Sheraton at Fisherman's Wharf, San Francisco, CA

HCP Workshop, May 10, 2017

To view abstracts, click on the titles of the talks

The workshops are brought to you based on popular demand. Attendees from last year's conference requested that primers be included as part of our program. These are designed for "non-experts" to allow you to understand the technology of your colleagues. Therefore if you are an expert in immunoassays sign up for the LC-MS course and vice versa. Here is your chance.

Workshop 1: LC-MS/MS for HCP Analysis

Track A

Morning session: An Introduction to HCP Analysis by Mass Spectrometry

This session is designed as an introductory primer for those who have little to no experience in mass spectrometry. After completion of this workshop, the participants should be familiar with basic MS technology and terminology, they should understand the HCP analysis workflow and how HCPs are identified, and they should understand how MS analysis can complement other methods to produce a comprehensive understanding of the purity of their products.

Afternoon Session: From Proteomics to HCPs – State of the Art in HCP Analysis by Mass Spectrometry

The afternoon workshop will build on information presented in the morning session. The goal is to present specific case studies and applications of new methods and technologies to HCP analysis. This session will be appropriate for those who attended the morning session, as well as those who have general LC-MS/MS proteomics experience and would like to learn what is different about HCP analysis. The session will close with a panel discussion and Q&A session that will be open to all aspects of HCP analysis by MS.

Instructor: Dr. Kevin Van Cott, University of Nebraska

8:30-10:00: Morning Session

10:00-10:30 Morning break

10:30: 12:00: Morning Session 2

12:00-1:30: Lunch

Facilitator: Dr. Kevin Van Cott, University of Nebraska

1:30 Performance of Host Cell Protein LC-MS/MS scaled from nanoflow to standard LC flow using a Thermo QExactive Plus mass spectrometer
Jonas Borch-Jensen**, NovoNordisk**

2:15 Advanced Mass Spectrometry workflows for Relative and Absolute Quantitation of Host Cell Proteins"
Eric Johansen**, Abbvie**

3:00-3:30: break

3:30 Data Analysis, Quantitation and Reporting for Mass Spectrometry-Based HCP Studies
Michael Schirm**, Caprion Biosciences**

4:15 Panel and Q&A Discussion

Workshop Adjourns

Workshop 2: Host Cell Proteins 101

Track B

Production of biopharmaceuticals in recombinant cells requires that manufacturers ensure process-related impurities, such as host cell proteins (HCPs) are minimized and controlled. HCPs are a particularly complex impurity because of the heterogeneity of the host cell protein population and lack of standards across the biotechnology industry. This course is intended to be a full day introduction to the many considerations needed to define, control, and monitor the HCP population in a drug substance. It will also be a thorough update on the HCP landscape for individuals returning to HCP work after an extended break

Instructor: Denise Krawitz, CMC Paradigms LLC

8:30-10:00 Morning Session

10:00-10:30: Morning Break

10:30-12:00: Morning Session 2

12:00-1:30: Lunch

1:30-3:00: Afternoon Session

3:00-3:30: Afternoon Break

3:30-5:00: Afternoon Session 2

5:00 Conference Adjourns

HCP Conference, Day 1, May 11, 2017

To view abstracts, click on the titles of the talks

Session 1: Host Cell Protein Impurities & Product Quality

Session Chair: Denise Krawitz, CMC Paradigms, LLC

8:50 Welcome to the Conference

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

Session Chair: Svetlana Bergelson, Biogen

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 Increased Throughput and Accuracy in Host Cell Protein Quantitation using Spectral Library Searches
Martha Stapels, **Sanofi Genzyme**

5: 00: Conference Adjourns

Join us for BioGenes Hosted Reception

Day 2, May 12, 2017

Session 3: Utilizing Mass Spectrometry for Host Cell Protein Characterization

Session Chair: Kevin Van Cott, University of Nebraska

8:20 Welcome to the Conference

8:30 Monitoring Contaminating Proteins in Biological Samples: HCPs and Beyond–
Kevin Van Cott, **U of Nebraska**

9:00 Case Study for a Validation of a MS Based HCP Quantification Method - Requirements and Limitation– Ingo Lindner, **Roche**

9:30 An Effective SWATH-MS Workflow for the Analysis of CHO HCPs– Bi Xuezhi, **BioProcessing Technology Institute**

10:00-10:30 Morning Break

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

Session Chair: Markus Haindl, Roche

10:30 A holistic phase appropriate strategy for HCP-limits and HCP characterization– Markus Haindl, **Roche**

11:00 HCP Control Strategy Reassessment for a CHO-derived Protein Therapeutic–John Rolf, **Amgen**

11:30 HCP ID and levels – Seeking Post Approval Changes in a Marketed Product– Feny Gunawan, **Genentech**

12:00-1:30 Lunch

Session 5: Quality & Regulatory Aspects of HCP Impurity Specifications

Session Chair: Ned Mozier, Pfizer

1:30: Regulating HCPs – Framework & Flexibilities
Erika Friedl, **Paul-Erlich-Institut**

2:00 Common Approaches to Host Cell Protein Analysis & Control in Europe - Focus Monoclonal Antibodies
Joerg Engelsberg, **Paul-Erlich-Institut**

2:30 Host Cell Protein Control Strategies and Case studies: CDER Experiences.
Emily Jing, **US-FDA**

3:00 Regulatory Expectations for the Control of Host Cell Proteins in Recombinant Therapeutic Proteins: Health Canada's Perspective– Erin Ewing, **Health Canada**

3:30-4:00 Afternoon Break

Continued to next page

HCP Conference Day 2, May 12, 2017

To view abstracts, click on the titles of the talks

4:00 Roundtable on Specification Setting
Denise Krawitz, CMC Paradigms, LLC– Moderator

- **Ned Mozier, Pfizer**
- **Svetlana Bergelson, Biogen**
- **Michael Wiedmann, Roche**
- **Thomas Waerner, Boehringer Ingelheim**

5:30 Conference Adjourns

Posters Titles:

Optimization of Downstream Processing, Based on Identification & Quantification of HCPs Using SWATH LC-MS
Ejvind Mortz, **Alphalyse**

Following the Identity of Host Cell Proteins from Host Cell Culture Fluid to the Drug Substance using a Mass Spectrometry-Based Shotgun Proteomics Approach
Dr. Yu Zhou, **BioMarin Pharamceuticals**

Generation and Purification of E. coli HCP Critical Reagents: From Impurity to ELISA
Lisa Wong, **Genentech**

A Novel Data Acquisition Mode for Identification and Quantification of Low-Abundance Host Cell Proteins in Biopharmaceuticals
Dr. Catalin Doneanu, **Waters**

3-Channel 2D-DIGE Coupled to Antibody Affinity Extraction for Investigation of Host Cell Protein Populations in In-process and Drug Substance Samples
Eric Bishop, **Cygnus Technologies**

Phospholipase related Impurities in Therapeutic mAbs
Dr. Harbhahan Dhillon, **Bristol-Myers Squibb**

Epitope mapping of Sandwich ELISA Reagents by Hydroxyl Radical Footprinting-Mass Spectrometry (HRF-MS)
Margaret Lin, **Genentech**

Tracking Host Cell Proteins While Biopharmaceutical Manufacturing: Advanced Methodologies to Improve Product Quality
Dr. Stefanie Wohlrab, **Roche Diagnostics GmbH**

Robust HCP Coverage Analysis with Dedicated Melanie Software
Dr. Sonja Voordijk, **GeneBio SA**

Mass Spectrometry as a Powerful Tool Box for Host Cell Protein Analysis
Dr. Thomas Flad, **Protagen Protein Services GmbH**

Enhanced HCP Coverage Analysis utilizing Multiplexed 2D Electrophoresis
Dr. David Chimento, **Rockland Immunochemicals**

Practical Considerations and Insights In the Use of Immunogold Labeling-Electron Microscopy for the Detection of HCPs in REOLYSIN
Julia Transfiguracion, **Human Health Therapeutics, National Research Council Canada**

Characterization & Quantification of Residual HCP Proteins in CHO using a Stable Isotope Labeled Standard
Dr. Jeff Turner, **MilliporeSigma**

BioPhorum Development Group: Consolidated Biotech Industry Review on Host Cell Protein (HCP) Risk Management and Control
Dr. Fengqiang Wang, **Merck**

Bridging Immunodetection to Identification for Host Cell Protein Analysis
Dr. Nicolas Lebesque, **Novartis**

Enhanced Analysis of Host Cell Proteins from CHO Cell Cultured mAb Using Agilent 6545XT AdvanceBio LC/Q-TOF
Linfeng Wu, **Agilent Technologies**

Comments from last year's conference:

Finally a relevant conference focused on host cell proteins that brings everyone up to date on all the best Approaches.
Georgeen G., Abbvie

Excellent talks over a wide range of topics, but orchestrated so that the sessions flowed.
Rick C, GSK

Very high quality of information in a very "familiar" atmosphere. One of the most useful workshops I ever visited. Asked many of my burning questions or give new ideas where to continue. Highly actual state of the art.
Anke F., Glycotope

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