12th Annual Host Cell Protein Conference

May 14-16, 2024

Hybrid Conference
In-Person: College Park Marriott
Hotel & Conference Center
College Park, Maryland

All times are in Eastern Time
Slides not available for distribution are highlighted in RED

Day 1 | Tuesday, May 14

8:00 Check In for In-Person Attendees

Session 1A: Regulatory Perspective

(All Attendees Welcome)
Session Chair: *Alexey Khrenov, CMC Reviewer, FDA*
Location: *Vessey Ballroom*

9:00 Welcome and Logistics

9:15 Session Introduction and Audience Survey

9:30 Keynote Speaker
HCPs Then and Now: What Has Changed, What Remains the Same
Nadine Ritter, President, Global Biotech Experts

10:15 Morning Break

10:45 A Comprehensive Guidance to Assess Clinical Safety Risks Upon Identification of Individual HCPs, Incorporating Regulatory Considerations and Industry Experience
Fengqiang Wang, Global Change Facilitator, Merck and Co. Inc., and Ying Zhang, Director, Sarepta Therapeutics

11:15 HCP Control Strategies and Regulatory Requirements
Erika Friedl, Senior Quality Expert, Paul-Ehrlich-Institut

11:45 Q&A Panel Discussion

12:15 Lunch
Location: *Vessey Foyer*

12:45 ***Diamond Exhibitor Hosted Luncheon Talk: Cygnus Technologies***
Past, Present, and Future of HCP Analytics: Making the Case for Using Advanced Technologies and Methods to Monitor and Control HCP
Eric Bishop, Vice President, Research & Development

Session 1B: ELISA Development

(All Attendees Welcome)
Session Chair: *Catherine Shoemaker-Ramsey, Associate Director of Analytical Development, Biogen*
Location: *Vessey Ballroom*

1:45 HEK293 Total Host Cell Protein ELISA Development to Support AAV Gene Therapy Programs
Jianming Kang, Senior Scientist, Regeneron

2:15 Choice of Animal for HCP Antibody Generation and Different ELISA Formats
Midori Greenwood-Goodwin, Principal Scientist, Genentech

2:45 Individual Immunoassay Development to Detect High Risk Host-Cell Protein in Protein Therapeutic
Bharathi Govindarajan, Associate Director, Sanofi

3:15 Q&A Panel Discussion

3:45 Afternoon Break

Session 1C: HCP and Product Stability

(All Attendees Welcome)
Session Chair: *Ned Mozier, Retired, Pfizer*
Location: *Vessey Ballroom*

4:15 Assessing and Mitigating Particle Risks in Drug Products: A Prospective Approach to Identifying and Characterizing Polysorbate-Degrading HCPs
Inn Yuk, Senior Director, Genentech

4:45 Developing a High-Sensitivity Method for Detection and Quantification of Host Cell Proteins in Biopharmaceuticals by Mass Spectrometry: A Company Perspective on an Industry-Wide Challenge
Marius Felix, Post-Doc Boehringer Ingelheim Pharma GmbH

5:15 Q&A Panel Discussion

5:45 Platinum Exhibitor Introduction
TotalLab

6:00 Conference Day 1 Adjourns

6:15 TotalLab Hosted Welcome Networking Reception

BEBPA — Biopharmaceutical Emerging Best Practices Association

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Day 2 | Wednesday, May 15

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Session 2A: Bioprocessing

(All Attendees Welcome)
Session Chair: *Denise Krawitz, Principal Consultant, CMC Paradigms LLC*
Location: *Vessey Ballroom*

9:00 Session Introduction and Audience Survey

9:15 Talk To Be Announced
Speaker To Be Announced

9:45 Q&A

10:00 Morning Break

10:30 Host Cell Protein (HCP) Removal in Biomanufacturing Operation by Flow-Through Affinity Chromatography
Stefano Menegatti, Associate Professor, NC State University

11:00 Applying UHPLC-HRAM MS/MS2 Method to Assess Host Cell Protein Clearance during the Purification Process Development of Therapeutic mAbs
Reiko Kiyonami, Senior Product Applications Specialist, Thermo Fisher Scientific

11:30 Lunch
Location: *2nd Floor (2110/2111/2112)*

1:00 What You Can Learn from HCP Analysis of 500 Projects Using LC-MS
Victor Chrone, Bioinformatics Scientist, Alphalyse A/S

1:30 Q&A Panel Discussion

Session 2B: HCP Analysis

(All Attendees Welcome)
Session Chair: *Alexey Khrenov, CMC Reviewer, FDA*
Location: *Vessey Ballroom*

2:00 USP Resources to Support Host Cell Protein Analysis by Mass Spectrometry
Niomi Peckham, Director, Pipeline Development, United States Pharmacopeia

2:30 Strategy to Harmonize the Quantitation and Reporting of MS-based HCP Results for Process and Method Development Understanding Across Projects and Their Long Lifecycles
Brian Gau, Sr. Principal Scientist, Pfizer

3:00 Q&A Panel Discussion

3:30 Afternoon Break

Session 2C: HCP Challenges

(All Attendees Welcome)
Session Chair: *Catherine Shoemaker-Ramsey, Associate Director of Analytical Development, Biogen*
Location: *Vessey Ballroom*

4:00 From Identification of a Potentially Critical HCP to IMPD and Beyond: Analytical Perspective
Petr Obrdlik, Associate Director, Novartis

4:30 Navigating the Challenges in Evaluation of Residual Host Cell Proteins in Lentiviral Vectors
Shilpa Suravajhala, Senior Scientist, bluebird bio, Inc.

5:00 Control Strategy for Lentivirus Vector-derived HCPs Impurity in CAR-T Final Drug Product
Roman Drews, Head of Regulatory Affairs, Arcellx, Inc.

5:30 Q&A Panel Discussion

6:00 Conference Day 2 Adjourns

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Day 3 | Thursday, May 16

9:00 In-Person Interest Groups

10:10 Morning Break

10:40 In-Person Interest Groups

11:40 Lunch
Location: *2nd Floor (2110/2111/2112)*

Session 3A: Mass Spectrometry

(All Attendees Welcome)
Session Chair: *Ying Zhang, Director, Sarepta Therapeutics*
Location: *Vessey Ballroom*

1:00 Session Introduction and Audience Survey

1:15 HCP Profiling of mAbs and AAV Gene Therapy Vectors using Data Independent LC-MS/MS on Orbitrap Astral MS
Jonathan Bones, Principal Investigator and Director, NIBRT

1:45 Analysis of Host-Cell Proteins in In-Process Samples by Next-Generation Proteomics Combined with Targeted Absolute Quantitation
Sabrina Liberatori, R&D Manager, Omics and Informatics, LONZA

2:15 Host Cell Proteome Dynamics: Identification, Quantitation by Mass Spectrometry
Nandakumar Sundaramoorthy, Director, Stelis Biopharma

2:45 Q&A Panel Discussion

3:15 Afternoon Break

Session 3B: Regulatory Discussion

(All Attendees Welcome)
Session Chair: *Alexey Khrenov, CMC Reviewer, FDA and Ying Zhang, Director, Sarepta Therapeutics*
Location: *Vessey Ballroom*

3:45 Wide Ranging Q&A with our Regulatory Participants

4:45 Closing Comments & Summary

5:00 Conference Concludes

In-Person Interest Groups

(In-Person Attendees Only)

Interest Group 1: USP 1132.1
Leaders: *Fengqiang Wang, Merck & Co., Ying Zhang, Sarepta Therapeutics and Ned Mozier, Retired, Pfizer*
Location: *Meeting Room 1105*

The USP <1132.1> interest group will provide an overview of the special considerations on the use of LC-MS/MS methods for HCP identification and quantitation and cover best practices as well as the orthogonality between LC-MS and ELISA methods and how to interpret the differences observed among the two methods. Multiple case studies will be provided to drive an interactive conversation about use of LC-MS at different phases of biopharmaceutical development.

Interest Group 2: ELISA Development
Leaders: *Catherine Shoemaker-Ramsey, Associate Director, Analytical Development, Biogen*
Location: *Meeting Room 1101/1102*

9:00 Introduction and Survey

9:10 SureKit® Stabilized Host Cell Protein Assay Kits: A User-Friendly Alternative to Traditional HCP ELISAs and Frozen Reagent Storage
Mary Retzlaff, Chief Scientific Officer, Upkara, Inc

9:30 Long-term HCP Antibody Stability Analysis
Xing Wang, President, Array Bridge Inc.

9:50 Process-Specific Calibrators in a Generic Host Cell Protein ELISA
Andrew Hamilton, Senior Scientist Cytiva

10:10 Break

10:40 Enhancing Efficiency and Flexibility in Host Cell Protein ELISA Through End-to-End Automation Using Hamilton Systems
Daniela Olszova, Research Scientist, Gilead Sciences Inc.

11:00 Q&A Panel Discussion

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The TotalHCP Project: Building a More Comprehensive Understanding of HCPs Using Software
Steven Dodd, Head of Sales and Business Development, TotalLab Ltd.

LC-MS for Improving Decision Making and Mitigating Risk in Process Development
Henry Fisher, R&D Scientist, Labcorp

Comprehensive Assessment of Immunogenicity Risk of Host Cell Proteins in Biologics Using in silico and in-vitro Methods
Kirk Haltaufderhyde, Scientist, EpiVax Inc.

MS Quantification of Lipases in Biosimilars and Process Changes
Jared Isaac, Associate Director, Cygnus Technologies

Improved Analytical Testing of HCP Impurities with an Automated Immunoassay Platform
Ellen Lee, Field Application Scientist, Gyros Protein Technologies

Characterization and Comparison of Host Cell Protein Profiles Derived from Two Host Cell Lines
Guojie Mao, Principal Scientist, Lonza

Evaluation of Antibody Affinity Extraction and Native Digestion as Sample Preparation Methods for LC-MS Detection of HCPs in Drug Substance
Stephen Stahlschmidt, Lab Technician II, Cygnus Technologies

Development of a Specific HCP-Assay for the Evolving Chicken Embryo Fibroblast (CEF) Expression System
Thorsten Strahl, GmbH Supervisor Protein and Olaf Stamm, Technical Business Development Director, Charles River Laboratories Germany GmbH

A Case Study on Development of a Platform Process-Specific CHO HCP ELISA
Mahima Tank, Senior Scientist, Takeda Pharmaceuticals

Evaluation of Search Engines for HCP Analysis by Mass Spectrometry
Kevin Van Cott, Associate Professor, University of Nebraska

Custom Automated CHO HCP ELISA-Like Technology for Routine Sample Testing
McKenna Vettori, Senior Scientist, GSK

Gold Exhibitors

BioPhorum
GYROS PROTEIN Technologies
ICL ANTIBODIES Are Our Business
ROCKLAND

Silver Exhibitors

ALPHALYSE™
charles river
cytiva
labcorp

Virtual Exhibitors

FasTrain Training for Busy Professionals