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 Standard Time

Day 1 | Tuesday, May 14

8:00 Check In for In-Person Attendees

Session 1A: Regulatory Perspective

(All Attendees Welcome)
Session Chair: *To Be Announced*

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
Sapphire Sloan, Global Change Facilitator, BioPhorum

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

Session 1B: ELISA Development

(All Attendees Welcome)
Session Chair: *To Be Announced*

2:00 HEK293 Total Host Cell Protein ELISA Development to Support AAV Gene Therapy Programs
Jianming Kang, Senior Scientist, Regeneron

2:30 Choice of Animal for HCP Antibody Generation and Different ELISA Formats
Florian Semmelmann, Senior Scientist, Roche

3:00 Individual Immunoassay Development to Detect High Risk Host-Cell Protein in Protein Therapeutic
Bharathi Govindarajan, Associate Director, Sanofi

3:30 Q&A Panel Discussion

4:00 Afternoon Break

Session 1C: HCP and Product Stability

(All Attendees Welcome)
Session Chair: *To Be Announced*

4:30 Polysorbate Degrading Enzymes Assessing and Mitigating Particle Risks in Drug Products: A Prospective Approach to Identifying and Characterizing Polysorbate-Degrading HCPs
Inn Yuk, Senior Director, Genentech

5:00 Specific Removal of Critical HCPs in the Polishing Steps of Downstream Processing
Daniel Lakatos, Labhead, Boehringer Ingelheim Pharma GmbH & Co.KG

5:30 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

6:00 Q&A Panel Discussion

6:30 Conference Day 1 Adjourns

6:45 Hosted Welcome Networking Reception

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Day 2 | Wednesday, May 15

Session 2A: Bioprocessing

(All Attendees Welcome)
Session Chair: *To Be Announced*

9:00 Session Introduction and Audience Survey

9:15 Talk To Be Announced
Speaker To Be Announced

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

1:15 What You Can Learn from HCP Analysis of 500 Projects Using LC-MS
Victor Chrone, Bioinformatics Scientist, Alphalyse A/S

1:45 Q&A Panel Discussion

Session 2B: HCP Analysis

(All Attendees Welcome)
Session Chair: *To Be Announced*

2:15 USP Resources to Support Host Cell Protein Analysis by Mass Spectrometry
Niomi Peckham, Director, Pipeline Development, United States Pharmacopeia

2:45 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

3:15 Q&A Panel Discussion

3:45 Afternoon Break

Session 2C: HCP Challenges

(All Attendees Welcome)
Session Chair: *To Be Announced*

4:15 From Identification of a Potentially Critical HCP to IMPD and Beyond: Analytical Perspective
Petr Obrdlik, Associate Director, Novartis

4:45 Navigating the Challenges in Evaluation of Residual Host Cell Proteins in Lentiviral Vectors
Shilpa Suravajhala, Senior Scientist, bluebird bio, Inc.

5:15 Control Strategy for Lentivirus Vector-derived HCPs Impuriy in CAR-T Final Drug Product
Roman Drews, Head of Regulatory Affairs, Arcellx, Inc.

5:45 Q&A Panel Discussion

6:15 Conference Day 2 Adjourns

BIOPHARMACEUTICAL EMERGING BEST PRACTICES ASSOCIATION

BEBPA

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Day 3 | Thursday, May 16

9:00 In-Person Interest Groups

10:10 Morning Break

10:30 In-Person Interest Groups

11:30 Lunch

Session 3A: Mass Spectrometry

(All Attendees Welcome)
Session Chair: *To Be Announced*

1:15 Session Introduction and Audience Survey

1:30 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

2:00 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

2:30 Host Cell Proteome Dynamics: Identification, Quantitation by Mass Spectrometry
Nandakumar Sundaramoorthy, Director, Kemwell Biopharma Private Limited

3:00 Q&A Panel Discussion

3:30 Afternoon Break

Session 3B: Regulatory Discussion

(All Attendees Welcome)
Session Chair: *To Be Announced*

4:00 Wide Ranging Q&A with our Regulatory Participants

6:10 Closing Comments & Summary

6:30 Conference Concludes

In-Person Interest Groups

(In-Person Attendees Only)

Interest Group 1: USP 1132.1
Leaders: *Fengqiang Wang, Merck & Co. and Ying Zhang, Sarepta Therapeutics*

During the manufacture of protein-based biotherapeutics, host cell proteins (HCPs) are coproduced with the desired product as a significant class of heterogenic process-related impurities that need to be adequately removed due to their potential impact to product quality, safety, and efficacy. The enzyme-linked immunosorbent assay (ELISA) has been commonly used as the industry standard to monitor the removal of HCP during downstream processing and measure the residual HCP content in final drug substance, with the best practices to develop and validate HCP ELISA being well-covered in USP general chapter <1132>.

Interest Group 2: ELISA Development

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

10:30 Case Study – Characterization of Critical Reagents for HCP ELISA Development by Different Orthogonal Methods
Pia Paarmann, Head of 2D Analytics, BioGenes GmbH

10:50 Enhancing Efficiency and Flexibility in Host Cell Protein ELISA Through End-to-End Automation Using Hamilton Systems
Daniela Olszova, Research Scientist, Gilead Sciences Inc.

11:10 Q&A Panel Discussion

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TotalLab
LIFE SCIENCE ANALYSIS

Gold Exhibitors

BioPhorum

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