

- Qualification of a Generic CHO HCP Assay by Orthogonal Methods and Recommendations 16:10 for Management of Critical Reagent Supply for the Validated HCP-ELISA Robert Hooper, Senior Research Scientist, Rockland Immunochemicals, Inc.
- In-House CHO HCP ELISA Platform Feasibility Study 16:40 Elisa Giordano, Research Associate, Merck Serono S.p.A.

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17:10 Case Study - Challenges and Solutions in Specific HCP ELISA Development for the Physcomitrium patens (Moss) Plant-Based Expression System Stefan Sommerschuh, Head of Assay Department, BioGenes GmbH 222

17:40 - 17:55 Break

17:55-18:40 Panel Discussion: Sessions 1 & 2

18:40 Conference Day 1 Adjourns

19:00 Networking Happy Hour

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11th Annual **Host Cell Protein** Conference May 22-24, 2023

> **Hybrid Conference In-Person: President Valamar Hotel** Dubrovnik, Croatia

\*\*Slides not available for distribution are highlighted in **RED**\*\*

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Workshop 2: ELISA & Critical Reagent Development



# 11th Annual Host Cell Protein Conference May 22-24, 2023

Hybrid Conference In-Person: President Valamar Hotel Dubrovnik, Croatia

**Day 2** Tuesday, May 23, 2023

#### \*\*Slides not available for distribution are highlighted in **RED**\*\*

## Morning Workshops - For In-Person Attendees Only

Workshops

9:00-11:30 Workshop 3: <u>Phase-Specific HCP Strategy</u> Workshop 4: <u>Intro to MS</u>

## Afternoon Presentations: For Online and In-Person Attendees

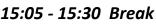
Session 3: Alternatives to ELISA for HTP and Routine HCP Testing Session Chair: Thomas Wärner, Senior Principal Scientist, Boehringer Ingelheim

- 12:45 Session Introduction & Audience Survey
- **13:00** Using GyroLab for HCP Analysis from Microbial Derived Samples Martin Voigtmann, Scientist, Boehringer Ingelheim RCV GmbH & Co
- **13:30** <u>The Use and Implementation of Bio-layer Interferometry for Host Cell Protein Detection</u> Nicklas Skjoldager, Senior Research Scientist, Novo Nordisk
- 14:00 <u>High Throughput Platform for Multiplex Analysis of Total and Specific Host Cell Proteins</u> (HCPs) Content to Support mAb Process Development Suzana Petrovic, Scientist, Sanofi
- 14:30 <u>LUMINEX An Innovative Method for Host Cell Protein Quantification with Multiplexing</u> <u>Capabilities</u> <u>Joromy Oska</u>, Sanior Scientist, Marsk

Jeremy Osko, Senior Scientist, Merck

📁 15:00 - 15:05 Book Giveaway 🍭







Session 4: Methods for Detection of Low Abundance HCP's Session Chair: Stefanie Wohlrab, Senior Scientist, Roche Diagnostics GmbH

- 15:30 Session Introduction & Audience Survey
- **15:40** Assessing Methods for Detecting Low Abundant HCPs Thomas Wärner, Senior Principal Scientist, Boehringer Ingelheim
- 16:10 Identification and Absolute Quantification of a Problematic HCP with Lipase Activity to Support Therapeutic Protein Development Sook Yen (Kelly) E, Senior Scientist, Regeneron Pharmaceuticals
- 16:40 <u>Probing Residual Host Cell Proteins in Monoclonal Antibody and its High Molecular</u> <u>Weight Species: A Different Way to Study Difficult-to-Remove HCPs</u> *Yunli Hu, Staff Scientist, Regeneron Pharmaceuticals*

17:10 - 17:30 Break



17:30-18:15 Panel Discussion: Sessions 3 & 4

18:15 Conference Day 2 Adjourns

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### Morning Workshops - For In-Person Attendees Only

Wednesday, May 24, 2023

<u>Workshops</u>

Day 3

9:00-11:30 Workshop 5: <u>Risk Assessment</u>

Afternoon Presentations: For Online and In-Person Attendees

Session 5: Guidance

Session Chair: Fengqiang Wang, Principal Scientist, Merck

- 12:30 Session Introduction & Audience Survey
- **12:45** <u>HCP Impurity Control Covering Various Product Classes</u> Erika Friedl, Senior Quality Expert, Paul-Ehrlich Institut
- **13:15** USP Standards to Support Host Cell Protein Analysis by Mass Spectrometry Niomi Peckham, Director, Pipeline Development, United States Pharmacopeia
- 13:45 <u>Comprehensive Assessment of Immunogenicity Risk of Host Cell Proteins in Biologics</u> <u>Using In Silico and in Vitro Methods</u> *Katie Porter, Associate Director, EpiVax, Inc.*

14:15-14:35 Panel Discussion: Sessions 5



14:35 - 15:00 Break

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Session 6: HCP Critical Reagent Characterization Methods Session Chair: Frieder Kröner, Group Head - Impurities, Novartis Pharma AG

- 15:00 Session Introduction & Audience Survey
- 15:15 <u>Comprehensive Characterization of In-House ELISA Host Cell Protein Reagents by</u> <u>IAC & LCMS</u>

Suli Liu, Principal Scientist, Biogen

- **15:45** <u>ELISA Reagent Characterization Using Advanced LC-MS Methods</u> *Ejvind Mørtz, COO, Alphalyse*
- **16:15** <u>Case Studies Using LC-MS to Mitigate Problematic HCPs</u> Jared Isaac, Associate Director, Cygnus Technologies



16:45 - 17:00 Break 17:00-17:20



17:00-17:20 Panel Discussion: Sessions 6

17:20-17:45 Closing Remarks & Gift Basket Giveaway Denise Krawitz, Principal Consultant, CMC Paradigms LLC

BEBPA.org PO Box 4458 Bremerton WA, 98312 17:45 Conference Concludes

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## Morning Workshops - For In-Person Attendees Only

### Day 1 Monday, May 22, 2023

#### Workshop 1: Advanced MS Topics

- 9:00-10:10 AM, Part 1
- 10:30-11:30 AM, Part 2

Leaders: Ying Zhang, Sarepta Therapeutics & Kevin Van Cott, University of Nebraska-Lincoln

**Overview:** Focus on quantitation of HCPs by LC-MS/MS, data analysis, reporting of HCP results, and discussion of how MS results should be considered in the context of HCP ELISA results to facilitate better product and process understanding.

#### Workshop 2: ELISA Critical Reagent Generation & Qualification

- 9:00-10:10 AM, Part 1
- 10:30-11:30 AM, Part 2
- **Leaders:** Denise Krawitz, CMC Paradigms LLC, Robert Hooper, Rockland Immunochemicals, Stefan Sommerschuh, BioGenes GmbH & Eric Bishop, Cygnus Technologies

**Overview:** Join us for a deep dive into HCP ELISA critical reagent generation, qualification, and lifecycle management. Experts from BioGenes, Cygnus, and Rockland/Cytiva will discuss best practices followed by an extended Q&A.

### Day 2 Tuesday, May 23, 2023

#### Workshop 3: Phase-Specific HCP Strategy

- 9:00-10:10 AM, Part 1
- 10:30-11:30 AM, Part 2

Leaders: Fengqiang Wang, Merck and Co. Inc., Oliver Anderka,

Novartis Pharma AG & Stefanie Wohlrab, Roche Diagnostics GmbH **Overview:** Focus on the strategy to apply different analytical methods for the control and characterization of HCPs in biopharmaceuticals at different phases

of research, development, and commercialization.

#### Workshop 4: Intro to Mass Spectrometry for HCP Analysis

- 9:00-10:10 AM, Part 1
- 10:30-11:30 AM, Part 2
- Leaders: Frieder Kröner, Novartis Pharma AG & Denise Krawitz, CMC Paradigms LLC

**Overview:** This workshop will cover how mass spectrometry is used as an orthogonal method for HCP characterization and ELISA reagent qualification, as well as the basics of MS data analysis, interpretation, and application to development programs.

### Day 3 Wednesday, May 24, 2023

#### Workshop 5: Risk Assessment

• 9:00-10:10 AM, Part 1

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• 10:30-11:30 AM, Part 2

Leaders: Christina de Zafra, Seagen, Denise Krawitz, CMC Paradigms LLC & Fengqiang Wang, Merck and Co. Inc Overview: Coming soon! 9:00-10:10 Workshops 5: Part 1

过 10:10 - 10:30 Break 🗰

10:30-11:30 Workshops 5: Part 2

11:30 - 12:30 Lunch

🚻 10:10 - 10:30 Break 🎬

8:00-9:00

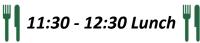
**Check-in For** 

**In-Person Attendees** 

9:00-10:10

Workshops 1 & 2: Part 1

10:30-11:30 Workshops 1 & 2: Part 2



9:00-10:10 Workshops 3 & 4: Part 1

🚻 10:10 - 10:30 Break 🎬

10:30-11:30 Workshops 3 & 4: Part 2



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#### on, **[] 11.30** - **12.30** s, and A.



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**Posters** 

Poster Title	Presenter	Company	Presentation Schedule
<u>High Risk Host Cell Proteins – Establishing a</u> Comprehensive Control Strategy	Sapphire Sloan	BioPhorum	Monday, 22 May 10:10 - 10:20
Optimization of Two Dimensional Difference Gel Electrophoresis for Host Cell Protein Analysis	Guojie Mao	Lonza Biologics plc	Monday, 22 May 15:05 - 15:15
Fast and Robust Quantitation of Host Cell Proteins withSub ppm Sensitivity using dia-PASEF and VIP- HESI	Christian Albers	Bruker Daltonics GmbH & Co. KG	Monday, 22 May 15:20 - 15:30
A Generic ELISA Kit for CHO HCP Quantification Assay Development and Validation	Joe Hirano	Cytiva	Monday, 22 May 17:45 - 17:55
Automation of Host Cell Protein Analysis by Mass Spectrometry: Increased Speed and Reproducibility, from Sample Preparation to Report	Griffin Moran	Novo Nordisk A/S	Tuesday, 23 May 15:05 - 15:15
Tackling HCPs Responsible for Polysorbate Degradation: Using Activity-Based Protein Profiling (ABPP) to Generate an Activity Map of the CHO Cell Culture Fluid Proteome with Different Probes	Marius Felix	Boehringer Ingelheim Pharma GmbH & Co.KG	Tuesday, 23 May 15:20 - 15:30
Evaluation of Search Engines and Results Curation Options for HCP Analysis	Kevin Van Cott	University of Nebraska- Lincoln	Tuesday, 23 May 17:10 - 17:20
Comprehensive Identification and Quantitation of Host Cell Proteins in Monoclonal Antibody Products Utilizing a Fully Automated Multi-Nanoparticle Proteomics Methodology	Shao-Yung (Eric) Chen	Seer Inc.	<b>REVISED!</b> Wednesday, 24 May 10:10 - 10:20
An Agile Analytical Workflow to Monitor Residual Host Cell Proteins and Facilitate Decision-Making in Purification Process Development	Sabrina Liberatori	Lonza Biologics R&D	<b>REVISED!</b> Wednesday, 24 May 10:20 - 10:30
When is a Process Specific HCP ELISA Assay Required for HCP Monitoring? Case Study on the Impact of Cross-Reactivity Against the Drug	Emilie Bodin	Agro-Bio	<b>REVISED!</b> Wednesday, 24 May 14:35 - 14:45
HCP Profiler: Another Way for HCP Identification and Quantification in DSP Evaluation by LC-MS/MS	Xavier Homo-Prault	ANAQUANT	<b>REVISED!</b> Wednesday, 24 May 14:45 - 14:55
Impact of Cell Line and Culture Harvest Method on CHO HCP Profiles	Sonja Voordijk	SIB (Swiss Institute of Bioinformatics)	<b>REVISED!</b> Wednesday, 24 May 16:45 - 16:55
PrismA ELISA™ kit - Quantification of a Process Related Impurity	Joe Hirano	Cytiva	Visit the Cytiva booth for more details!

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