

May 22-24, 2023

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Hybrid Conference

In-Person: President Valamar Hotel

Dubrovnik, Croatia

All Times are in CENTRAL EUROPEAN SUMMER TIME

Day 1 Monday, May 22, 2023

Slides not available for distribution are highlighted in RED

Morning Workshops - For In-Person Attendees Only

('Refresh Page' to see latest updates!)

9:00-11:30

[Workshops](#)

Workshop 1: [Advanced MS Topics](#)

Workshop 2: [ELISA & Critical Reagent Development](#)

Afternoon Presentations: For Online and In-Person Attendees

12:30 Welcome Comments, Introduction & Audience Survey

Denise Krawitz, Principal Consultant, CMC Paradigms LLC

Session 1: HCP Profiling During Process Development

Session Chair: Denise Krawitz, Principal Consultant, CMC Paradigms LLC

12:45 Session Introduction & Audience Survey

13:00 [Analyzing CHO Host Cell Proteins: Impact of Cell Age and of Digest Conditions](#)

Kelvin Lee, Professor & Director, University of Delaware

13:30 [A Multi-Angled Approach for Host Cell Protein Population Analysis Provides a Holistic View of Upstream Process Influence](#)

Todd Wright, Senior Scientist, Seagen

14:00 [HCP Case Study in Biosimilar Development: Effect of Different HCP Populations on Comparative Forced Degradation Studies](#)

Jon Valgeirsson, VP ARD, Alvotech

14:30 [Analysis of Host Cell Proteins in Protein A Eluates of mAb-based Therapeutic Proteins](#)

Sherin Panikulam, PhD Student, Univ. of Applied Sciences & Arts NW Switzerland

 15:00 - 15:05 Book Giveaway 



15:05 - 15:30 Break



Session 2: Implementation of HCP ELISAs:

Commercial, Platform, and Process-Specific Assays

Session Chair: Denise Krawitz, Principal Consultant, CMC Paradigms LLC

15:30 Session Introduction & Audience Survey

15:40 [HCP Control Strategy - Experiences from an "Off Gel" Road](#)

Margarita Sabater, Senior CMC Specialist, Genmab A/S

16:10 [Qualification of a Generic CHO HCP Assay by Orthogonal Methods and Recommendations for Management of Critical Reagent Supply for the Validated HCP-ELISA](#)

Robert Hooper, Senior Research Scientist, Rockland Immunochemicals, Inc.

16:40 [In-House CHO HCP ELISA Platform Feasibility Study](#)

Elisa Giordano, Research Associate, Merck Serono S.p.A.

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



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

Hosted by BEBPA



BEBPA.org

PO Box 4458
Bremerton WA, 98312

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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**

9:00-11:30

[Workshops](#)Workshop 3: [Phase-Specific HCP Strategy](#)Workshop 4: [Intro to MS](#)**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** [The Use and Implementation of Bio-layer Interferometry for Host Cell Protein Detection](#)*Nicklas Skjoldager, Senior Research Scientist, Novo Nordisk***14:00** [High Throughput Platform for Multiplex Analysis of Total and Specific Host Cell Proteins \(HCPs\) Content to Support mAb Process Development](#)*Suzana Petrovic, Scientist, Sanofi***14:30** [LUMINEX - An Innovative Method for Host Cell Protein Quantification with Multiplexing Capabilities](#)*Jeremy Osko, Senior Scientist, Merck***15:00 - 15:05 Book Giveaway****15:05 - 15:30 Break****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** [Probing Residual Host Cell Proteins in Monoclonal Antibody and its High Molecular Weight Species: A Different Way to Study Difficult-to-Remove HCPs](#)*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



BEBPA

11th Annual Host Cell Protein Conference

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Day 3 Wednesday, May 24, 2023

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

Morning Workshops - *For In-Person Attendees Only*

[Workshops](#)

9:00-11:30

Workshop 5: [Risk Assessment](#)

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 **HCP Impurity Control Covering Various Product Classes**

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 **Comprehensive Assessment of Immunogenicity Risk of Host Cell Proteins in Biologics Using In Silico and in Vitro Methods**

Katie Porter, Associate Director, EpiVax, Inc.

14:15-14:35

Panel Discussion: Sessions 5



14:35 - 15:00 Break



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 **Comprehensive Characterization of In-House ELISA Host Cell Protein Reagents by IAC & LCMS**

Suli Liu, Principal Scientist, Biogen

15:45 **ELISA Reagent Characterization Using Advanced LC-MS Methods**

Ejvind Mørtz, COO, Alphalyse

16:15 **Case Studies Using LC-MS to Mitigate Problematic HCPs**

Jared Isaac, Associate Director, Cygnus Technologies



16:45 - 17:00 Break



17:00-17:20

Panel Discussion: Sessions 6

17:20-17:45

Closing Remarks & Gift Basket Giveaway

Denise Krawitz, Principal Consultant, CMC Paradigms LLC

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.

8:00-9:00

Check-in For
In-Person Attendees

9:00-10:10

Workshops 1 & 2: Part 1

☕ 10:10 - 10:30 Break ☕

10:30-11:30

Workshops 1 & 2: Part 2

🍴 11:30 - 12:30 Lunch 🍴

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.

9:00-10:10

Workshops 3 & 4: Part 1

☕ 10:10 - 10:30 Break ☕

10:30-11:30

Workshops 3 & 4: Part 2

🍴 11:30 - 12:45 Lunch 🍴

Day 3 Wednesday, May 24, 2023

Workshop 5: [Risk Assessment](#)

- 9:00-10:10 AM, Part 1
- 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

☕ 10:10 - 10:30 Break ☕

10:30-11:30

Workshops 5: Part 2

🍴 11:30 - 12:30 Lunch 🍴

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Posters

Poster Title	Presenter	Company	Presentation Schedule
High Risk Host Cell Proteins – Establishing a 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.	REVISED! 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	REVISED! 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	REVISED! 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	ANQUANT	REVISED! 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)	REVISED! Wednesday, 24 May 16:45 - 16:55
Prisma ELISA™ kit - Quantification of a Process Related Impurity	Joe Hirano	Cytiva	<i>Visit the Cytiva booth for more details!</i>

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