

# Host Cell Protein Conference



## Presenters from:

Alphalyse  
Biogen Idec  
Boehringer Ingelheim  
Caprion Proteomics  
Charles River Laboratories  
Cygnus Technologies  
Eli Lilly  
Ernst-Moritz-Arndt University  
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Janssen Infectious Diseases  
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Paul Ehrlich Institute  
Pfizer  
Protagen Protein Services  
Roche  
Rockland Immunochemicals  
Stemcentrx  
University of Delaware  
University of Kent  
University of Nebraska  
Waters Corporation

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

- **Making the right choices in HCP immunoassay development:** Impact of species immunized, antibody purification strategies, and assay format on the final HCP values. First day Workshop will cover HCP immunoassay basics and how to avoid common pitfalls.
- **Latest technology developments of LC-MS/MS of HCPs:** Hear the latest on instrumentation, data bases to search, and strategies for quantitative analysis of trace impurities. First day Workshop will cover the basics of LC-MS/MS of HCPs for non-Mass Spec experts.
- **Polysorbate degradation** in final products have been linked to an HCP impurity – find out which one.
- **Working on a BioSimilar?** Have different HCPs than in the originators product? Hear examples of how companies have dealt with this problem.
- **Integrating LC-MS/MS data and immunoassay data in a comprehensive overall Quality System.** How to balance input from two very different data sources over product life span. How to use HCP characterization assays in registration, site changes, and version changes.
- **US Pharmacopeia and EU Pharmacopeia expert panelists,** who recently published monographs on HCP analysis, will discuss key points of both texts and provide guidance on expectations for science-based HCP impurity analysis as part of overall Quality Systems.

For more information: [www.bebpa.org](http://www.bebpa.org)

HCP Conference, May 17-19, 2016  
Sana Metropolitan–Lisbon, Portugal

# HCP Workshop, May 17, 2016

To view abstracts, click on the titles of the talks



The morning 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: Introduction to HCP Analysis by LC-MS

### Track A

**9:00-12:00: [Effective Use of Mass Spectrometry in the Analysis of HCPs](#).** In recent years, the use of mass spectrometry (MS) methods in HCP analysis has grown. While MS methods have not yet matured to the point of being used as release assays, they have the potential to complement and clarify the information obtained by HCP ELISAs and other analytical methods. The target audience for this workshop is scientists with little or no direct experience in MS analysis. After completion of this tutorial, participants should be familiar with MS technology and terminology, understand how to critically review MS results, and envision how MS methods can complement other HCP analysis methods.

**Kevin van Cott, University of Nebraska**

**12:00-1:00: Lunch**

## Workshop 2: Introduction to HCP Analysis by Immunoassay

### Track B

**9:00-12:00: [Key Concepts in the Development of Immunoassays for the Analysis of HCPs](#).** This workshop will cover the steps involved in the development of immunoassays for HCP analysis. Choice of immunogen, standard, species to immunize, purification of antibodies and choices in assay format will be covered. Common mistakes and how to avoid them will be reviewed based on the instructors 20-years of experience. Cygnus Technologies is a leading global supplier of both assay kits based on platform reagents, and custom development of anti-HCP assays. Assay qualification for specific applications will be discussed.

**Eric Bishop, Cygnus Technologies**

**12:00-1:00: Lunch**

## Afternoon Workshop: USP Monograph of HCP Analysis & EUP Monograph on HCP Analysis

Recently, both the US Pharmacopeia and the EU Pharmacopeia assembled panels of experts to draft guidance documents on strategies for Host Cell Protein Impurity Analysis. In 2015, both groups issued monographs with recommendations. Members of both expert panels will present the key thinking behind, and the main take-away messages from, the final documents. Workshop attendees will be able to see the areas of common agreement between the two groups and places where the two groups differed in their recommendations.

### **1:00-2:30: [Members of US Pharmacopeia Expert Panel on HCP Analysis:](#)**

- Ned Mozier, Pfizer
- Svetlana Bergelson, Biogen Idec
- Denise Krawitz, Genentech
- Oliver Anderka, Novartis

**2:30-2:45: Afternoon Break**

### **2:45-4:15: [Members of European Pharmacopeia Expert Panel on HCP Analysis:](#)**

- Erika Friedl, PEI
- Joerg Engelbergs, PEI
- Michael Wiedmann, Roche-Penzberg
- Oliver Anderka, Novartis

**4:30-5:00: [Panel of all the experts–Audience Q&A](#)**

**5:00: Workshop Adjourns**

**Join us 5:30 for a hosted  
networking reception  
Hosted by: BioGenes**

# HCP Conference, Day 1, May 18, 2016

To view abstracts, click on the titles of the talks

## Session 1: HCP Immunoassay: Core Technologies

Session Chaired by: Thomas Waerner, Boehringer Ingelheim

9:00: [Conference Welcome](#)

[Proteomics Survey of CHO Cultures: Striking Similarities](#)

Denise Krawitz, Genentech

9:30: [Evaluation of a CHO Platform HCP ELISA](#)

Frieder Kroner, Novartis

10:00: [Case Study in HCP Assay Design: Impacts of Anti-HCP Antibody Purification & Assay Format](#)

Xiaohui Lu, Biogen Idec

*10:30-11:00 Morning Break*

11:00: [Lightning the Black Box of HCP Immunoassays—Alternative Immunization strategies in Combination with Innovative Characterizations Tools](#)

Olaf Stamm, Charles River Laboratories & Thomas Flad, Protagen Protein Services

12:00: [Identification of HCP in Purification Steps by Antibody Affinity Enrichment & LCMS/MS](#)

Eric Bishop, Cygnus Technologies

*12:30-1:30: Lunch*

## Session 2: Developing an Integrated Assessment using LC-MS/MS & Immunoassays

Session Chair: Michael Wiedmann, Roche-Penzberg

1:30: [Bridging the Gap: A Case Study Using Upstream Process Specific Assays to Monitor HCPs Identified by 2D-LC-MS](#)

Fengqiang Wang, Merck

2:00: [New Approaches for Analyzing HCP Coverage](#)

Stefanie Wohlrab, Roche-Penzberg

2:30: [HCP Analysis of a small drug-protein in process sample by Combining Platform Immunoassays and Mass Spectrometry](#)

David Chimento, Rockland Immunochemicals & Ejvind Mortz, Alphalyse

*3:00-3:30: Afternoon Break*

3:30: [Polysorbate Degradation by Phospholipase A2](#)

Lihua Huang, Eli Lilly

4:00: [HCP Case Studies for Blood Products—European Regulatory Views](#)

Erika Friedl, Paul Ehrlich Institute

## Day 2, May 19, 2016

## Session 1: Proteomics Approaches to HCP Analysis: Core Technologies

Session Chair: Chris Yu, Genentech

9:00: [Update on the New Chinese Hamster Reference Genome -2016](#)

Kelvin Lee, University of Delaware

9:30: [A Mass Spectrometric Library for HCP Quantification, Identification & Clearance](#)

Chris Yu, Genentech

10:00: [Identification & Quantification of HCPs by Mass Spectrometry](#)

Daniel Chelsky, Caprion Proteomics

*10:30-11:00: Morning Break*

11:00: [Single-digit ppm Level Identification of Host Cell Protein Contaminants using a Simple One-Hour Data-Independent LC/MS Acquisition Method and CHO Spectral library](#)

Eric Johansen, Stemcentrx

11:30: [In-Depth, Quantitative Host Cell Protein Fingerprinting of Adenovirus-Based Vaccines by Mass Spectrometry](#)

Annemiek Verwilligen, Janssen Infectious Diseases

## Session 2: Putting It All Together: Integrated Quality Strategy for HCPs using Available Assay Technologies

Session Chair: Fengqiang Wang, Merck

12:00: [Comparison of Host Cell Protein Profiles Between & Innovator & a Biosimilar Monoclonal Antibody](#)

Catalin Doneanu, Waters Corporation

*12:30-1:30: Lunch*

1:30: [Quality Aspects of Host Cell Protein Assays](#)

Thomas Waerner, Boehringer Ingelheim

2:00: [Establishing a Consistent, Phase Appropriate Approach to Integrating ELISA & LC-MS/MS Data During Product Development](#)

Susan Flor, Genentech



# HCP Conference Day 2, May 19, 2016

To view abstracts, click on the titles of the talks

2:30: [Practical Application of Orthogonal HCP Testing: How to Interpret & Use the Data](#)

Ned Mozier, Pfizer

3:30: *Conference Adjourns*

## Posters Titles:

[Identification and Quantification of mAb Host Cell Protein Impurities Down to 1 ppm: An Inter-Laboratory LC/MS Study.](#)

Scott Berger, Waters Corporation

[Antibody HCP Coverage Assessment: How to Calculate It?](#)

Zhong-Hua Gao, ZymoGenetics, Inc.

[Post Approval Process Changes: How Closely Do the HCPs Have to Match?](#)

Feny Gunawan, Roche-Genentech

[Small HCPs in a 12 kDa Protein Drug Analyzed by gelC MS/MS](#)

Rikke Raaen Lund, Alphalyse A/S

[Development of a Sensitive ELISA Platform Assay to Quantify Host Cell Protein](#)

Guojie Mao, Lonza Biologics plc

[Host Cell Proteins: The Hidden Side of Biosimilarity Assessment](#)

Kazutoshi Mihara, JCR Pharmaceuticals Co., Ltd.

[Improved Identification of Host Cell Proteins in a Protein Biopharmaceutical by LC-MS/MS with the ProteoMiner Enrichment Kit](#)

Harriet Mörtstedt, Swedish Orphan Biovitrum (Sobi)

[Comparison of Host Cell Proteins Profiles Between an Innovator and a Biosimilar Monoclonal Antibody](#)

Milla Neffling, Sciex

[Evaluating the Need for a Process Specific Host Cell Protein \(HCP\) Assay in Escherichia coli \(E. coli\) Expressed Recombinant Proteins](#)

Chandrima Palit, ZymoGenetics

[Image analysis used to minimize inter-user and inter-lab variation of results from measuring HCP-antibody coverage by comparing features between 2D gel and 2D western blots](#)

Kelly Parkin, Total Lab

[Generation and Characterization of E.Coli HCP Reagents of a Platform Immunoassay](#)

Romain Pizzato, Sanofi Pasteur

[Proteomics-Based LC-MS Approach For Assessing Host Cell Protein Impurities in a Complex Biological Product](#)

Pavlo Pristatsky, MSD

[Insights on the Identification of Host Cell Proteins by Nano-LC-MS/MS Bottom-Up Mass Spectrometry](#)

Ileana Rodríguez León, NovoNordisk

[Mass Spectrometry as a Powerful Tool for Host Cell Protein Analysis](#)

Anke Schnabel, Protagen

[Development of a Specific Host Cell Protein Assay for the Plant-Based Expression System Physcomitrella patens](#)

Stefan Sommerschuh, BioGenes

[Comparison of Five New Commercial Kits Specific for CHO-HCP Developed for the Gyrolab™ Platform](#)

Ann-Charlott Steffen, Gyros Protein Technologie

## Comments from last year's workshop:

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

Open dialogues, very honest, totally worthwhile.

Harold T., Merz Pharmaceuticals

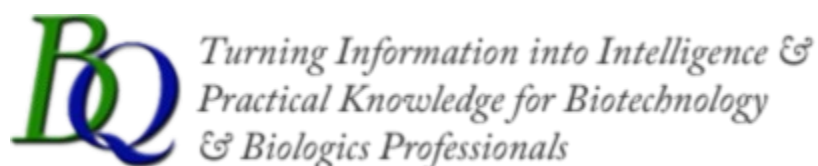
Very high quality of information in a very "familiar" atmosphere. One of the most useful workshops I ever visited.

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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\*Poster abstract must be submitted at the time of registration to receive discount.

## BEBPA: Who are we? What do we aim to accomplish?

The Biopharmaceutical Emerging Best Practices Association (BEBPA) is a not-for-profit association, founded in 2008, managed by and for the benefit of the biopharmaceutical scientific community. BEBPA provides an open forum for the presentation and discussion of scientific issues and problems encountered in the biopharmaceutical community.

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