

# Host Cell Protein Conference

May 14-16, 2018

[Valamar Dubrovnik President Hotel](#)

Dubrovnik, Croatia



## Pre-Conference Workshops, May 14, 2018 (8:30AM-5:00PM)

**Opening Keynote Address: Lipoprotein Lipase is a Difficult to Remove HCP: Studies from the 2018 Reference Genome**  
Kelvin Lee, Gore Professor of Chemical and Biomolecular Engineering University of Delaware

### Track 1: AM Workshops:

**Beginning Mass Spectrophotometry Analysis of HCPs**  
**Instructor:** Dr. Kevin Van Cott, Professor, University of Nebraska

### PM Workshops:

**Advanced Mass Spectrophotometry Analysis of HCPs**  
**Instructor:** Dr. Martha Staples, Principal Scientist, Genzyme

### Track 2: AM Workshops:

**HCP Risk Assessment**  
**Instructors:** BioPhorum Operations Group and Christina de Zafra, Principal Scientist, Amgen

### PM Workshops:

**HCP Specification Setting**  
**Instructor:** Ned Mozier, Sr. Director, Pfizer

## Day 1, May 15, 2018

8:15 Welcome to the Conference

### Session 1: Health Authority Considerations

*Session Chair: Christina de Zafra, Amgen*

**8:30 Assessing Immunogenicity Risk in Biotherapeutic Products and Process Development**  
Valarie Quarmby, Genentech

**9:00 European Pharmacopoea HCP Chapter**  
Gwenaël Cirefice, EDQM-Council of Europe

**9:30 Regulatory Aspects and the Pitfalls Regarding HCP Analysis and Documentation**  
Erika Friedl, Paul Erlich Institute

*10:00-10:30 Morning Break*

### Session 2: Generation of High Quality Anti-HCP Antibodies

*Session Chair:*

**10:30 Comparison of Common Approaches to Generation of Anti-HCP Antibody Reagents**  
Murty Chengalvala, Covance

**11:00 Generation of High Coverage Anti-HCP Polyclonal Antibodies: Is Coverage of HCPs Impacted by Animals?**  
Christina Seisenbeger, Roche

### Session 3: Anti-HCP Antibody Characterization

*Session Chair: Feny Gunawan*

**11:30 Protein-centric ELISA Reagent Coverage Evaluation by Affinity Purification Mass Spectrometry**  
Scott Henry, Seattle Genetics

*12:00-1:30: Lunch*

**1:30 HCP Antibody Purification from CHO K1SV Antisera for Broad HCP Coverage from BMSCHO Cell Line**  
Lei Zhang, Bristol-Myers Squibb

**2:00 It's all about the Quality of the Material, Developing Optimal HCP Immunoassay Critical Reagents**  
Jessica Campbell, Pfizer

### Session 4: HCPs for Non-Antibody Products

*Session Chair:*

**2:30 The challenges of developing HCPs methods for vaccines - risk based approach to HCP monitoring**  
Lee Smith, GreyRigge Associates, Ltd

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

**3:30 Applying Platform Knowledge and Risk Assessment tools to define HCP strategy for a Gene Therapy program**  
Carl Co, Biogen

### Session 5: Process Development Perspectives on HCP

*Session Chair:*

**4:00 Host Cell Protein Clearance in Downstream Purification Processes: Lessons Learned and Future Considerations**  
Jayme Franklin, Genentech

**4:30 Host Cell Protein Considerations for Cell Culture Process Development**

*Speaker To Be Determined*

**5:00 HCP Biological activity impact on product quality/stability (protein or polysorbate)**  
*Speaker To Be Determined*

**5:30: Conference Adjourns**

## Day 2, May 16, 2018

### Session 6: Reagent and Assay Lifecycle Management

*Session Chair:*

**9:00 Challenges and Lessons Learned in Implementing an In-House CHO Platform HCP Assay for Process Characterization**  
Fengqiang Wang, Merck Sharp & Dohme

**9:30 Replacement of HCP Assay for a Marketed Product**  
Stanislav Mandelc, Sandoz/Novartis

**10:00 Same but Different: A Case Study of HCP Comparability for an In-Licensed Project**  
Feny Gunawan, Genentech

*10:30-11:00 Morning Break*

**11:00 Design of Experiment (DOE) Based Approach for Defining Critical Parameters in Host Cell Protein Analytical Method Development and Validation**  
Joachim Diertenberger, Boehringer Ingelheim

### Session 7: Mass Spectrometry as an Orthogonal Method

*Session Chair: Martha Staples, Pfizer*

**11:30 HCP Profiling and Lipase Monitoring for DNA Derived Biopharmaceuticals by LC/MS/MS**  
Lihua Huang, Eli Lilly

*12:00-1:30 Lunch*

**1:30 Making LC-MS for HCP Reliable: Challenges from Sample Preparation to Data Analysis**  
Nicolas Lebesgue, Novartis

**2:00 Mass Spectrometry Brightening the HCP ELISA Results Black Box**  
Séverine Clavier, Sanofi R & D

### Session 8: Cutting Edge MS Technology for ID of HCPs

**2:30 Looking for a Needle in a Haystack: Characterization and Quantification of the Host Cell Proteome in Drug Substances by a Novel 2D LC- MSe Approach**  
Benedetta Lombardi, Merck

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

**3:30 Characterization, Optimization and Application of an LC-MS based Workflow for HCP Identification, Quantification and Control**  
Michael Schrim, Caprion

**4:00 Absolute Quantification of Host Cell Protein by SWATH LC-MS/MS towards Method Validation and Batch Release Testing**  
Thomas Kofoed, Alphalyse

**4:30: Conference Adjourns**