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Live Online Training

Speakers

Dr Jörg Engelbergs
Paul-Ehrlich-Institut,
German Federal Agency for
Vaccines and Biomedicines

Dr Thomas Flad
Protagene

Dr Erika Friedl
Paul-Ehrlich-Institut,
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Dr Marlen Kochte
IDT

Dr Florian Semmelmann
Roche

Dr Olaf Stamm
Charles River Laboratories

Host Cell Proteins

Current Trends and Requirements

Live Online Training on 18 April 2024

Highlights

- General Regulatory Requirements
- Blood Product Specific Requirements
- Traditional and new Tools to Address the HCP Challenge
- Controlling Host Cell Impurities in Biopharmaceuticals

Objectives

In this Live Online Training, on the one hand, you will be familiarized with the current regulatory requirements for various product groups, and on the other hand, experts from authorities, laboratories and industry will give you an insight into the current state of science and technology and an insight into methods and strategies.

Background

The fact that pharmaceutical products must be free of impurities has long been undisputed. Particulate impurities have hit the headlines several times in recent years.

But with the increasing number of biopharmaceutical products, including those based on recombinant proteins, the importance of protein-based impurities has also increased. As a rule, host organisms ranging from yeast to E.coli and CHO (Chinese Hamster Ovary) cell lines serve as producers of the recombinant proteins.

From these host cells, own proteins can appear as impurities of the active substance or the drug. These are grouped together as HCPs.

Host cell proteins (HCPs) are an inevitable impurity of biopharmaceuticals, regardless of whether they are produced by recombinant fermentation or extracted from natural sources. Even after multiple sophisticated purification steps, HCPs remain or copurify with product. Host Cell Proteins represent a heterogeneous variety of different proteins that need to be quantified in the drug substance and in intermediates from the downstream purification process. The risk for adverse effects, such as immunogenic reaction, does not necessarily correlate with the amount of certain host cell proteins, and even small traces of certain HCPs can be highly immunogenic.

The heterogeneity of the HCPs requires a thorough control regime and sophisticated assays for detection and quantitation in various samples matrices. Historically, immunoassays using polyclonal antibodies have been used for process development, validation, and release testing. However, with the advance in Mass Spectrometry, new orthogonal tools for identification and quantitation became available which help to gain a deep understanding of the HCP composition at various stages of the purification process and in the drug substance.

Target Audience

The course is intended for all persons from

- pharmaceutical manufacturers
- active ingredient producers
- regulatory and registration authorities
- contract laboratories
- research institutions

who deal with the problem of HCPs.

Programme

General Regulatory-Scientific Requirements for HCP Assessment and Specifities for Monoclonal Antibodies

- Safety considerations for HCP
- Process capacity for HCP removal
- HCP control strategy during clinical development
- Aspects for assay development: Characterisation of coverage rate and expectations on process specific assays

A Holistic View on Traditional and New Tools to Address the HCP Challenge

- Assays concepts: Generic-Platform-Project Specific
- Optimized strategies for generation of multi-analyte antibodies

Blood Product Specific Regulatory Requirements with HCP Case Studies

- Assay suitability (Process-specific assays versus vs generic assays)
- Setting appropriate specifications
- Life cycle management of HCP assays
- Problematic HCPs (identification and removal)

HCP Assessment in Vaccine Products

- Challenges of contract manufacturing of vaccines: Facing a broad spectrum of HCPs from different production cell lines and diverse matrix effects from different production processes
- Development and pre-validation of a platform DF-1 HCP-ELISA for MVA vector-based vaccinesH

Controlling Host Cell Impurities in Biopharmaceuticals

- Characterization strategy for HCP
- Limitations of common immunoassays
- Orthogonal methods

The Increasing Role of Mass Spectrometry (MS) within HCP Control Strategies

- MS for support of USP and DSP optimization
- Specificity coverage analysis by IAC-MS
- Summary and outlook

Speakers

Dr Jörg Engelbergs
Paul-Ehrlich-Institut, German Federal Agency for Vaccines and Biomedicines, Scientific-Regulatory Assessor for Quality, Non-Clinic and IVD/CDx

Dr Engelbergs is responsible at the Paul-Ehrlich-Institut for CMC and non-clinical assessments in clinical development and Marketing Authorization Applications / Follow-On procedures for immunoglobulins and Biotechs, with focus on monoclonal antibody based therapeutics including Biosimilars. His further tasks are national / EMA scientific advice procedures and national / global (USA/Asia) GMP inspections for Biotechs. On the European level Jörg is member of the EMA Methodology Working Party (MWP), member of the EMA CDx Expert Group and member of the EDQM P4Bio and EDQM Host Cell Protein working groups.

Dr Thomas Flad
Protagene, Director Business Development and Senior Director of Solutions & Innovation

Thomas Flad is pharmacist by training with a PhD in biochemistry. He is a protein analytical expert and author of numerous peer-reviewed articles. In 2004 he co-founded PANATecs GmbH as a protein analytical service company, where he served as CSO and Qualified Person for the first 4 years and then moved into Business Development for supporting Big Pharma and Biotech customers with analytical services for approval of biopharmaceuticals and vaccines until 2014. Since 2014 he is Director of Business Development at ProtaGene with responsibility for Pharma and Biotech customers in the D/A/CH region. With more than 18 years experiences in the biotech industry, Thomas has profound knowledge in design and optimization of analytical CMC concepts for development and approval of biopharmaceuticals.

Dr Erika Friedl
Paul-Ehrlich-Institut, German Federal Agency for Vaccines and Biomedicines, Quality Assessor

Erika Friedl is currently working as quality assessor (pharmaceutical quality/CMC) at the Paul-Ehrlich-Institute (PEI) in Langen, Germany. As quality expert in the European authorization process, she is responsible for the evaluation of blood products covering plasma-derived and recombinant proteins. In addition, she is involved as expert in national and international GMP inspections. Erika is a member of the Host Cell Protein Working Party at the EDQM (European Directorate for the Quality of Medicines & HealthCare, Strasbourg, France). Erika received her Ph.D. in biochemistry from the Albert-Ludwig University of Freiburg, Germany. During her career she worked in the fields of virology and transcription factors. As research associate, Erika joined the Department of Biochemistry at the Howard Hughes Medical Institute (UMDNJ, USA).

Dr Marlen Kochte
IDT, Expert Analytical Development

Marlen Kochte is currently working at IDT Biologika GmbH (IDT) as Expert in Analytical Development. In this role she is responsible for development/ validation/ transfer of biochemistry assays such as ELISA and Western Blot for titer quantification, impurities (HCPs, Benzonase, SAN HQ, BSA, HSA) and identity (raw material testing). She received her Ph.D. in biology from Georg-August-Universität Göttingen and started her professional career as scientific associate at IDT.

Dr Florian Semmelmann
Roche, Group Lead

Florian Semmelmann is a group lead at Roche Diagnostics GmbH in Penzberg, Germany. His team develops analytical tests to quantify process-related impurities in biopharmaceuticals. He studied biochemistry at the University of Regensburg in Germany and at the University of Colorado at Boulder in the USA.

Dr Olaf Stamm
Charles River Laboratories, Technical Business Development Director

Dr Stamm holds a doctoral degree in molecular parasitology and a master degree in drug regulatory affairs from the University of Bonn, Germany. He joined Charles River in 2003 and became responsible for the business development activities in Europe and Asia. Prior to joining Charles River he worked for Eurofins Scientific running their microbiological GMP testing laboratories in Switzerland. While being for many years the global subject matter specialist for impurity testing, most recently Dr Stamm has focused his work on analytical/regulatory consulting for Charles River Biologics Services in Asia and Europe.

Moderator
Clemens Mundo, Concept Heidelberg

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Host Cell Proteins
Live Online Training on 18 April 2024

Title, first name, surname

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Date of the Live Online Training

Thursday, 18 April 2024, 13.00 – 18.00 h CEST

Technical Requirements

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Fees (per delegate, plus VAT)

ECA Members € 690
APIC Members € 740
Non-ECA Members € 790
EU GMP Inspectorates € 395
The fee is payable in advance after receipt of invoice.

Registration

By e-mail message or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

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Conference Language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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