Jointly organised by

ECA Academy | BioPhorum | APIC

Speakers


Alexander Bartes
Roche Diagnostics


Dr Leendert J. van der Bos
Consultant for GlycoTherapeutics BV


Dr Kerstin Brack
Charles River Laboratories


Dr Anthea Darius
Microcoat Biotechnologie


Dr Samuel Dorey
Sartorius Stedim Biotech


Dr Rainer Gnibl
GMP Inspector


Georg Göstl
Takeda, QP


Jan Oliver Karo
PEI, German Federal Agency for Vaccines and Biomedicines


Dr Edwin Kellenbach
BioChem Oss B.V.


Isabelle Lequeux
BioPhorum


Dr Minkyung Kim
USP


Johannes Oberdörfer
Rapid Micro Biosystems


Dr Fabien Rousset
Sartorius Stedim Biotech


Andrew D. Schaefer
Eurofins BioPharma Product Testing

Raw Materials, Excipients, and APIs Used for Biological Medicinal Products

21/22 November 2023, Neuss/Düsseldorf, Germany

Control and Management of Raw Materials, APIs and Excipients

Highlights

- Pharmacopoeial Requirements
- QbD Approaches – for Registration and more
- Critical Materials in Cell- and Gene Therapies
- Quality and Regulatory Aspects of Plasma-Derived Products – a QP's Perspective
- Developing a bio-equivalent Heparin, decoupled from the Food Chain
- GMP Inspectors Experiences and Expectations
- Microbiological Safety - Regulators' Aspects and Authority Expectations
- Microbiological Control of Biological Materials – Mycoplasma, Bacteria and Endotoxins
- Endotoxin and Pyrogen Testing

Objective

This European Joint Conference is dedicated to quality and regulatory aspects of raw materials, excipients and APIs used for biological medicinal products. The following topics will be addressed

- Biological Raw Materials in Pharmacopoeias
- GMP requirements for raw materials – Guidances
- Supplier Relationships and Qualification
- Quality Control aspects of Biological Raw Materials
- Risk management and control of Biological Raw Materials, components and excipients
- Raw Materials for ATMPs

Background

Raw materials (RM), excipients and other products used in the manufacture of biological medicinal products must be well understood in terms of their role in the manufacturing process. Especially in a GMP-regulated environment, these raw materials, components and excipients require thorough control with regard to their consistent quality. Therefore, all critical quality attributes should be known and appropriate risk mitigation and control strategies should be established. Since there is currently less written guidance on risk-based management of biological raw materials, European Pharmaceutical Enterprises, EBE, has prepared a concept paper entitled "Management and Control of Raw Materials Used in the Manufacture of Biological Medicinal Products." But other approaches can also be helpful - a look at Annex 1 for products that need to be sterile or have a low bioburden claim. Or the QbD approaches for consistent quality of products.

Target Audience

This conference will be of significant value to

- Laboratory managers
- Quality control managers
- Analytical scientists
- Senior laboratory staff
- QA Units
- Qualified Persons (QPs)
- R&D

from biopharmaceutical companies, ATMP developers and manufacturers as well as vaccine producers.

This conference also addresses employees of contract labs being involved in development of methods, control testing and quality assurance as well as staff from regulatory affairs departments.

Programme

ECA/BioPhorum - Introduction and Organisational of the Joint Conference

Raw Material Management with United States Pharmacopeial Standards for Cell Therapy

Dr Minkyung Kim, APAC

- Regulatory Framework of raw materials and advanced therapies
- Risk-based qualification programs for raw materials
- USP raw material standards

QbD Approach to Registration of Raw Materials

Isabelle Lequeux, BioPhorum

- The BioPhorum approach to the registration of raw materials will be presented
- The approach is based on Quality by Design principles, and especially a mature approach to define quality for raw materials, including the use of risk assessment
- The approach not only allows future flexibility of sourcing of raw materials but also regulatory submissions of higher quality

This presentation is an introduction to the next three BioPhorum presentations.

Protein A Resin Addendum - Direct Application of QbD Approach for Registration of Material Changes to Enable Innovation and Process Efficiency

Fabien Rousset, Sartorius

- The presentation will summarize the in-depth risk assessment performed by Protein A resin subject matter experts (supplier and end-users in the biomanufacturing industry)
- The systematic approach of the risk assessment allows the definition of the critical material attributes of the Protein A resins and of the controls that need to be in place should manufacturers take the opportunity to increase process efficiency by using more performing resins
- A proposal is also put forward for regulatory notification of the change, for rapid implementation

Application of QbD Approach to Define Requirements for Changing Sterilization Method for Single-Use Systems from Gamma to X-Ray

Dr Samuel Dorey, Sartorius Stedim Biotech

- The presentation will summarize the in-depth risk assessment performed by single use system, plastic and radiation experts (suppliers and end-users)
- The systematic approach of the risk-assessment allowed for the definition of the critical material attributes of the drug substance holding containers and of the controls that need to be in place for the manufacturers to accept X-ray sterilized containers

The main body of controls will come from the suppliers' validation and regulatory package and as such the recommendations can also be used by suppliers to ensure adequacy of their assessment of the change
- A proposal is also put forward for global regulatory notification, based on initial feedback from FDA and EMA

Establishing a Unified Approach for Critical Materials in Cell and Gene Therapy

Andrew D. Schaefer, Eurofins BioPharma Product Testing

- The presentation summarizes the in-depth work performed to identify critical quality attributes and proposed standard release testing for recombinant endonuclease and polymer-based transfection reagents
- These materials are both used ubiquitously in cell and gene therapy, there is a lack of defined release test criteria throughout the pharmacopeial and regulatory landscape. Without a common test standard there is lack of consistency across suppliers, risk in the supply chain and potential can slow down drug development
- This forum of industry professionals set out to propose those release criteria based on the critical material attributes and work carried out using the QbD model.
- The team have generated a unified core set of criteria and standard test methods. A common testing standard would have multiple benefits including consistency across suppliers, protection of supplier intellectual property (IP), and facilitation of drug development

Quality and Regulatory Aspects of Biological Extraction Products

Dr Edwin Kellenbach, Biochemi Oss B.V.

- Quality considerations for biological extraction products (APIs)
- Naturally sourced products heparin and hCG
- Key differences between extracted products and biotech
- Pros and cons of current (draft) guidance for extracted products
- Consequences for industry

Inspector's Requirements on Biological (Raw) Materials

Dr Rainer Gnibl, GMP/EMA Inspector Government of Upper Bavaria

- Focus: ATMPs & biotech products
- Requirements on suppliers
- Receipt & incoming goods testing
- Bank systems
- Traceability

Developing a Bio-equivalent Heparin, Decoupled from the Food Chain: Nice to Have or Must Have?

Dr Leendert J. van den Bos, Consultant for GlycoTherapeutics BV

- Recent progress made in obtaining bioengineered heparin
- Comparing these compounds with the heparins currently on the market
- Could these bioengineered heparins serve as a replacement bio-equivalent to the existing products?
- What is the trend with other therapeutics from animal origin?

Quality and Regulatory Aspects of Plasma-Derived Products – a QP's Perspective

Georg Göstl, Takeda

- Regulatory background
- Limitations of starting materials
- Specific Issues during manufacturing
- Certification by the Qualified Person
- Potential Issues when using plasma-derived products as excipient

Microbiological Safety - Regulators Aspects and Authority Expectations

Jan-Oliver Karo, PEI, German Federal Agency for Vaccines and Biomedicines

Viral Contamination Risk Control Strategies for Biological Raw Materials used in Biomanufacturing

Dr Kerstin Brack, Charles River Laboratories

- Regulatory aspects in viral safety of biological raw materials used in the manufacturing process of biologics
- Viral risk identification and mitigation strategies
- Considerations for viral safety of biological raw materials used in ATMP production

Rapid Microbiological Control of Raw Materials with an Automated, Non-destructive Rapid Microbial Detection System

Johannes Oberdörfer, RMB

- Introduction to the Growth Direct System – hardware and methodology
- Raw material and excipient testing – range of application
- Case studies and real-world samples – results, evaluations and feasibilities

Endotoxin Detection in Raw Materials

Anthea Darius, Microcoat Biotechnology

- Testing typical raw materials of drug product formulations
- Hot spike and sample hold time experiments
- Mitigation of low endotoxin recovery

Mycoplasma Real-Time PCR: Generic Method Validation of T-Cell Culture

Alexander Bartes, Roche

Alexander Bartes, Roche Diagnostics, Microbiological QC

Alexander Bartes studied chemical engineering with emphasis on biotechnology and genetic engineering at the University of Applied Science Aachen/Jülich, Germany. After completion of his master thesis at Roche Bioscience, Palo Alto, CA, USA, he joined Roche Diagnostics, Penzberg in 2002. From 2009 to 2014 he was Manager R&D. He was responsible for the development of qPCR/NAT based assays and Kits for Roche Applied Science Custom Biotech. Currently, he works at Roche in the Microbiology QC department.

Dr Leendert J. van der Bos, Consultant for GlycoTherapeutics BV

Dr van der Bos obtained his MSc and PhD degree in bioorganic chemistry from Leiden University. He joined Organon BioSciences as a Scientist in 2007 and worked subsequently for Schering-Plough, Merck Sharp & Dohme and Aspen Pharmacare mostly in the field of Process Research & Development. Leendert holds an Executive MBA from Nyenrode University.

Dr Kerstin Brack, Charles River Laboratories, Scientific Director Global Biosafety

Dr Kerstin Brack works as a Scientific Director at Charles River Laboratories Germany GmbH since 2018 and is a subject matter expert for biosafety testing of biologicals. She holds a diploma in Biology from the University of Bremen, Germany, where she subsequently also earned her PhD in Virology. In 2001, Kerstin joined NewLab BioQuality AG (now Charles River Laboratories Germany GmbH) as a Study Director in the Virology Department. Between 2004 and 2018 Kerstin headed the departments for biosafety testing and bioassay services at Charles River Laboratories Germany.

Dr Anthea Darius, Microcoat Biotechnologie, Project Leader

Anthea studied at the Technical University Munich and became following Doctoral Student in Molecular Virology at the Institute of Medical Virology and Epidemiology, UKT. After two years as scientist at the TUM, she joined Microcoat in 2022 as Project Leader Endotoxin Services.

Dr Samuel Dorey, Sartorius Stedim, Senior Scientist

Samuel studied in Lyon und Muhouse. He joined Sartorius in 2008 as scientist. After several years in different positions /pProject Leader, Scientis II and Senior Scientist, he became Principal Scientist Materials & Irradiationsin 2022.

Dr Rainer Gnibl, Government of Upper Bavaria, Germany, GMP Inspector for EMA and local Government

Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government of Upper Bavaria and the EMA and performs GMP inspections worldwide.

Georg Göstl, Takeda, QP

Georg Göstl studied Chemistry in Vienna and is now working in pharmaceutical industry since more than 36 years, thereof more than 26 years as a QP. He is Chair of the Austrian QP Association aqpa and member of the EQPA Board of Directors. In Austria, he is also a member of Blood Commission at the MoH.

Jan Oliver Karo, Paul-Ehrlich-Institute, German Federal Agency for Vaccines and Biomedicines

Dr Edwin Kellenbach, BioChem Oss B.V., Principal Scientist

Edwin Kellenbach obtained his PhD in biophysical chemistry on multidimensional NMR of protein-DNA interaction in 1991 with Prof. Robert Kaptein at Utrecht University. He has over 30 years' experience in the pharmaceutical industry in analytics, quality, registration, and product development of biological molecules. He is a member of expert group 6 (Biologicals) of the European Pharmacopoeia, the expert panel on Complex Biologics and Vaccines of the United States Pharmacopoeia (USP) and the USP heparin expert subcommittee. He has (co)authored over 40 papers and book chapters in peer reviewed journals on protein and peptide NMR, analytical (bio)chemistry, heparin, and (bio)process development.

Isabelle Lequeux, BioPhorum, Director at ILEQ

Isabell studied Pharmacy at University of Montpellier. After 21 years in different positions at GSK, she joined BioPhorum in 2018. Her current position is Regulatory Lead.

Dr Minkyung Kim, USP, Scientific Affairs Manager at US Pharmacopeia

Dr Minkyung Kim, Pharm.D., MBA, M.Sc., is currently serving as the Scientific Affairs Manager at USP, APAC. With licenses as a registered pharmacist in both the United States and South Korea. In her position, Kim assumes primary responsibility for overseeing the field of monoclonal antibodies and advanced therapies, commonly referred to as Cell and Gene Therapy. She has taken charge of numerous internal and external working groups, as well as cross-functional teams.

Johannes Oberdörfer, Rapid Micro Biosystems, Field Application Scientist

Johannes studied at the University for Applied Sciences in Bingen. He joined Boehringer in 2005 as Biological Technician. After positions as Expert Analytical Scientist, responsible for Potency assays and Head of Sample Management he became Lead Scientist responsible for Rapid Microbiology Methods. After leaving Boehringer, he joined Rapid Micro Biosystems as Field Application Scientist.

Dr Fabien Rousset, Sartorius Stedim Biotech, Principal Expert Purification

Fabien has a PhD in polymer chemistry. After graduation, he worked at companies such as Pall, Novasep and Daicel in Dereich R&D and product management and has experience in mixed-mode resins, chrome membranes, columns and systems for DSP, chromatography and filtration and innovative purification solutions for recombinant proteins and gene therapies Today, Fabien is working at Sartorius in downstream and chromatography.

Andrew D. Schaefer, Eurofins, BioPharma Product Testing

Andrew Schaefer oversees Raw and Ancillary Material services at Eurofins BioPharma Product Testing. Mr Schaefer and his team initiated some of the very first raw material testing strategies for successful US commercialization efforts of chimeric antigen receptor T-cell therapies. He holds a Bachelor of Science in Biology, Master of Business Administration with a concentration in Analytics, and Certifications in Regulatory Affairs. Mr Schaefer contributes frequently to publications and works within the BioPhorum and other standard setting organizations. His laboratory actively publishes research in areas of cell culture applications, most notably in-vivo cytokine and growth factor stability.

About BioPhorum

BioPhorum's mission is to create environments where the global biopharmaceutical and device industry can collaborate and accelerate its rate of progress, for the benefit of all.
Since its inception in 2004, BioPhorum has become the open and trusted environment where senior leaders of the biopharmaceutical industry come together to openly share and discuss the emerging trends and challenges facing their industry.

Growing from an end-user group in 2008, BioPhorum now comprises over 135 manufacturers and suppliers deploying their top 6,000 leaders and subject matter experts to work in nine focused Phorums, articulating the industry's technology roadmap, defining the supply partner practices of the future, and developing and adopting best practices in drug substance, fill finish, process development and manufacturing IT. In each of these Phorums, BioPhorum facilitators bring leaders together to create future visions, mobilize teams of experts on the opportunities, create partnerships that enable change, and provide the quickest route to implementation, so that the industry shares, learns, and builds the best solutions together.

About APIC

APIC is one of CEFIC's Sector Groups, comprising producers of active pharmaceutical ingredients (APIs) and intermediates in Europe. For this reason, APIC considers itself to be a very important stakeholder in new EU Regulations and Guidelines related to APIs and intermediates. Our 64 members are located all over Europe and include three national associations: AFAQUIM (Spain), PHARMACHEMICAL IRELAND (Ireland) and SICOS (France).

APIC's key objectives are:

- To promote the use of compliant APIs in medicinal products to ensure patient safety
- To represent the interests of European based companies producing APIs globally by being recognized experts who advance and influence the global GMP and Regulatory environment.

APIC has played and continues to play an important role in improving the regulatory environment for the API manufacturing industry, increasing patient safety and benefiting society as a whole.

APIC's membership consists of companies from different pharmaceutical industry sectors, all involved in the manufacture of APIs. This provides an ideal basis for developing and communicating a balanced, holistic view on API-related regulations and guidelines. APIC's focus is on worldwide Quality, Good Manufacturing Practice (GMP) and Regulatory matters relating to APIs and Intermediates. Through the years APIC has developed into a high-profile industry association with an excellent, worldwide reputation.

About the ECA Academy

The ECA Academy is the educational organisation supported by the ECA Foundation (please see www.eca-foundation.org for more detailed information). It develops and organises a wealth of international education courses, conferences (also as part of a GMP Certification Programme) and webinars around GMP and regulatory compliance, picking up emerging GMP challenges and currently discussed subjects. While courses and webinars are designed to provide continuous education for GMP professionals in production, quality control, quality assurance etc, European conferences are organised as discussion forums on new trends and developments.

The Academy is supported by the ECA Foundation Advisory Board. This Board acts as conceptual sponsor in the development of new courses and conferences and ensures best quality and participant satisfaction by evaluating all events. As the Foundation does not employ own staff all services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg, a leading professional European training and information services provider in the pharmaceutical industry environment (please see www.concept-heidelberg.com for further information).

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Reservation Form (Please complete in full)

Raw Materials, Excipients and APIs Used for Biological Medicinal Products
21/22 November 2023, Neuss/Düsseldorf, Germany

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
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- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks prior to the conference 100 %.

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In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

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Date
Tuesday, 21 November 2023, 09.00 – 18.00 h
(Registration and coffee 08.30 -09.00 h)
Wednesday, 22 November 2023, 09.00 – 18.00 h

Venue
Crowne Plaza Düsseldorf/Neuss
Rheinallee 1
41460 Neuss, Germany
Phone +49 (0) 2131 77 00
Email emailus.neu02@gchhotelgroup.com

Fees (per delegate, plus VAT)
ECA Members € 1,590
APIC Members € 1,590
BioPhorum Members € 1,590
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice and includes dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation
Concept Heidelberg has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Presentations / Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

Organisation and Contact
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