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ebe european biopharmaceutical enterprises

APIC active pharmaceutical ingredients committee

An **ECA**, **EBE** and **APIC** Joint Conference

Biological Raw Materials, Excipients and APIs

Quality, Safety and Control

20-21 November 2018, Düsseldorf/Neuss, Germany

HIGHLIGHTS:

- Building knowledge about raw materials
- Biological raw materials – regulatory perspective
- Raw and starting materials in the ATMP arena
- USP Pharmacopeial Monograph Criteria for Raw Material Specifications
- Management of raw materials for biologicals – the EBE concept paper
- Quality and regulatory aspects of biological extraction products
- Virus risk minimisation strategies
- Testing of Raw Materials for Herbal Medicines
- Risk management and control for raw materials, components and excipients
- ECA's new Guidance "Analytical Procedure Lifecycle Management"

SPEAKERS


DR CORNELIA BODINET
Schaper & Brümmer, Germany


MARIEKE VAN DALEN
Aspen Oss, The Netherlands


DR MARKUS FIDO
VelaLabs, Austria


SERGIO FRACCHIA
Novartis, Switzerland


DR ANNICK GERVAIS
UCB, Belgium


DR RALF KLEIN
ViruSure, Austria


DR GERD JILGE
Boehringer Ingelheim, Germany

DR INGRID MECKLENBRÄUKER
Novartis Pharma Stein, Switzerland


DR CHRISTOPH MÜCK
Austrian Agency for Health and Food Safety (AGES)


JENNIFER PURDIE
Eli Lilly, USA


DR JOHANNES REICH
MicroCoat Biotechnologie, Germany


DR DON SINGER
United States Pharmacopoeia/ GSK


CHRISTINE WEISS
Labor LS, Germany

This conference is recognised for the ECA GMP Certification Programme „Certified API Production Manager". Please find details at www.gmp-certification.eu

Biological Raw Materials, Excipients and APIS

20 – 21 November 2018, Düsseldorf/Neuss, Germany

Objectives

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

- Biological Raw Materials in Pharmacopoeias
- GMP requirements for raw materials – Guidances
- The EBE Concept paper on management of raw materials for biologicals
- Quality Control aspects of Biological Raw Materials
- Risk management and control of Biological Raw Materials, components and excipients
- Regulatory aspects, change management and life cycle approach for Biological Raw Materials

In this conference the new EBE Concept paper on management of raw materials for biologicals will be introduced and discussed.

Background

Raw materials (RM) used in the manufacture of biological medicinal products need to be well understood with respect to their role in the manufacturing process. In particular in a GMP regulated environment these raw materials, components as well as excipients require a thorough control regarding consistent quality. Therefore all critical quality attributes should be known and appropriate risk mitigation and control strategies should be established. As there are currently no written industry guidelines available dedicated to a risk-based biological raw materials management approach the European Pharmaceutical Enterprises, EBE, has developed a concept paper entitled "Management and Control of Raw Materials Used in the Manufacture of Biological Medicinal Products" in which the principles of such a risk based approach is outlined.

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). 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

Overview of new materials and excipients – dedicated for material income

- Overview of new materials and excipients
- Material income control & product specific or method-related
- Everything parts with raw material – defined use for manufacturing and quality control
- Selected methods for raw material release (case study)

Dr Markus Fido, VelaLabs, Austria

Special materials in special products – biological excipients/raw materials in biopharmaceuticals

- Overview
- Active substance and excipients combinations
- Stability
- Regulatory framework

Dr Christoph Mück, AGES, Austria

Raw and starting materials in the ATMP arena: differences and similarities with biologicals

- Definition of ATMPs and major differences between ATMPs and Biologicals
- Starting and raw material: definitions, differences and regulatory landscape
- Impact of raw and starting materials on ATMP process manufacture and final product quality attributes
- Example of starting materials and implications in process development, manufacturing and filing
- Raw materials: differences and similarities between ATMPs and biologicals
- Human derived materials: a special reagent used in ATMP production

Sergio Fracchia, Novartis, Switzerland

Are Pharmacopeial Monograph Criteria Sufficient for Raw Material Specifications?

- Microbiological criteria for many raw materials are not globally harmonized
- Scientists use pharmacopeial criteria as a rule or they customize criteria. There are risks and benefits to using pharmacopoeial criteria for specifications
- A practical and appropriate approach to raw material microbiological specifications will be discussed

Dr Don Singer, USP, USA

EBE Concept paper on management of raw materials for biologicals

- Effective management and control of raw materials – minimum requirements from a quality regulatory and business perspective
- The EBE Concept paper – purpose, structure and content
- Background information related to raw materials regulatory requirements and industry challenges
- Key principles to consider in setting up a risk-based RM management approach and control strategy
- Examples

Dr Annick Gervais, UCB, Belgium

Programme

Quality and regulatory aspects of biological extraction products
- 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

Marieke van Dalen, Aspen Oss, The Netherlands

Importance of a Quality Relationship with a Raw Material Supplier – Industrial Point of View
- Robust medicinal products for patients depend on a robust supply chain
- Microbiological quality of raw materials require control for assurance in the supply chain
- Different origins of raw materials lead to different risk management approaches
- Suppliers must have control to ensure quality and safety attributes are met
- Alignment of supplier - customer expectations leads the way to quality

Dr Don Singer, GSK, USA

Virus risk minimisation strategies for biopharmaceutical aw materials
- Basic strategies for understanding and controlling virus risk
- Historical incidents of contamination in biopharmaceutical products
- Lessons learned in how best to control the risk

Dr Ralf Klein, ViruSure, Austria

Interactive Discussion:
Organizational cultures and strategies for microbiological control of raw materials
Don Singer, GSK/USP

Testing of Raw Materials for Herbal Medicines
- Requirements for the pharmaceutical quality of herbal medicinal products and raw materials of plant origin
- Natural microflora of plants and medicinal herbal drugs
- EP acceptance criteria for the microbiological quality (EP 5.1.8, 5.1.4)
- Testing procedures (EP 2.6.31)
- Antimicrobial pre-treatment of herbal raw materials

Dr Cornelia Bodinet, Schaper & Brümmer, Germany

Detection of pyrogenic contaminations in raw materials
- Methods for endotoxin and pyrogen detection in raw materials
- Test interference during raw material testing
- Low Endotoxin Recovery (LER) and the importance of raw material testing

Dr Johannes Reich, MicroCoat Biotechnology, Germany

Testing of Raw Materials - Experiences of a Contract Lab
- Actual tendencies in testing of raw materials
- Reasons for suitability and routine testing
- Water - a special kind of raw material

Christina Weiß, Labor LS, Germany

How to mitigate and control risks related to raw materials, components and excipients – case studies
- Varying risks to patient safety, depending on their use in the process and the nature of the component
- Residual concentrations of raw materials in the final drug product - particular concern with respect to patient safety
- A phase appropriate control strategy - development and update during process development
- Implementation of risk assessments and subsequent control strategies for residual raw materials for new bioproducts.

Jennifer Purdie, Eli Lilly, USA

Reduced Testing of Raw Materials and Excipients
- Microbiological Acceptance Criteria
- Classification
- Microbiological Characteristics
- Test Frequency
- OOE limits
- Examples

Dr Ingrid Mecklenbräuker, Novartis, Switzerland

ECA's new Guidance "Analytical Procedure Lifecycle Management"
Dr Gerd Jilge, Boehringer Ingelheim, Germany

SPEAKERS

DR CORNELIA BODINET | *Schaper & Brümmer, Germany, Head of Division "Pharmaceutical Laboratories"*

Cornelia studied Biology with focus on Microbiology at University of Saarbrücken and University Greifswald, Germany. Since 1986, she is at Schaper & Brümmer. Today, she is head of Division "Pharmaceutical Laboratories" and a member of the management board.

MARIEKE VAN DALEN | *Aspen Oss B.V., The Netherlands Global regulatory specialist*

Marieke is the global regulatory specialist in the regulatory group dedicated to APIs, with almost 30 years of experience in the regulatory field. She is a board member of APIC, the European API Industry organization, and she participates in the Japan task force, Emerging markets task force and the Quality metrics task force. She frequently represents APIC in meetings and conferences organized by EMA, EDQM, ICH etc.

DR MARKUS FIDO | *VelaLabs, Austria*

Markus Fido is CEO and Founder of Vela Laboratories, were he is responsible for Finance & Controlling, Regulatory Affairs & Quality Operations. Before that he was Head Quality Control at Igeneon / Aphton Biopharma AG where he was in charge for all QC aspects of pre-clinical and clinical projects such as stability studies, specifications, method validation, and product release. Prior he was working as a Group Leader of Immunology and Product Development at Biomin GmbH, Head Biochemical Control at Baxter AG and Head Quality Operations at Octapharma GmbH. His focus is GMP/GCLP concerns during the development of Biopharmaceuticals, Biosimilars and Biologics. He holds a Ph.D. in Biochemistry and Molecular Microbiology from the Technical University in Graz (Austria).

SERGIO FRACCHIA | *Novartis, Switzerland, Reg CMC Ass Dir CGTU*

Sergio presently works as Associate Director RegCMC – Cell and Gene Therapy at Novartis. He is presently RegCMC representative for the development of several gene therapy and gene editing investigational medicinal products at different stage of development.

DR ANNICK GERVAIS | *UCB Pharma, Belgium, Director of Physico-Chemical Method Development*

Annick is Chemical engineer by education and Doctor from University Louis Pasteur (Strasbourg, France). She is currently Director of Physico-Chemical Method Development in Analytical Sciences for Biologicals in UCB Pharma (Braine L'Alleud, Belgium) dealing with development, validation, transfer of methods and process support from early phase to life cycle management for therapeutic proteins and monoclonal antibodies in the field of immunology. She is also representing UCB in European Biopharmaceutical Enterprises (EBE) biomanufacturing working group (part of EFPIA).

DR RALF KLEIN | *ViruSure, Austria, Business Development Management*

Prior to his position at ViruSure he has worked at several other CRO´s (BioReliance, Invitrogen, NewLab BioQuality and Charles River Laboratories). At BioReliance he was a Study Director for virus validation studies for about 4 years before moving into the role of a key account manager for biosafety testing services. His subsequent positions at other CRO's has been in business development / key account management.

DR GERD JILGE | *Boehringer Ingelheim, Germany, Member of the ECA QC Group*

In 1991 Dr Gerd Jilge joined Boehringer Ingelheim working in product development where he was responsible for method development and validation for the application of analytical procedures. In 2000 Gerd took a position in Drug Regulatory Affairs of Boehringer Ingelheim with the focus on CMC documentation for the submission of new and registered drug products. Since July 2007 he is working in Quality Control on topics like method transfer as well as method optimization and validation for active drug substances. In 2014 Gerd became a member of the EDQM expert group 11.

DR INGRID MECKLENBRÄUKER | *Novartis Pharma Stein, Switzerland, QC Lab Coordinator*

Ingrid Mecklenbräuker studied biology at the University of Vienna with focus on microbiology and genetics and earned her PhD in genetics at the University of Cologne. After postdoctoral studies at the Rockefeller University in New York, she worked as a scientist at the Albert-Ludwigs-University Freiburg and co-founded in 2007 a start-up company for development of novel antibiotics against multidrug-resistant pathogens. In 2011 she joined Eurofins | GeneScan GmbH where she was involved in building up the microbiological division and validation of new molecular detection methods for pathogenic microorganisms in food. In 2013 she joined Novartis Pharma Stein AG as QC Lab Coordinator (Non-sterile Drug Products).

DR CHRISTOPH MÜCK | *Austrian Agency for Health and Food Safety (AGES), Quality Assesor Biological Drug Products*

Christoph studied pharmaceutical engineering and held an M.SC in Biomedical Engineering. Before he joined the Austrian Agency for Health and Food Safety, he worked 6 years in pharmaceutical companies with responsibilities in Process Validation and Quality by Design projects.for gene therapy and recombinant products.

JENNIFER PURDIE | *Eli Lilly, USA, Consultant Engineer*

Jennifer studied Chemical Engineering and Chemistry at the Universities of Notre Dame and Indianapolis. After working as Process Engineer at National Starch and Chemical, she joined Eli Lilly in 2001 as QA Representative. Since 2006 she is Associate Senior Consultant Engineer.

DR JOHANNES REICH | *MicroCoat Biotechnologie, Germany, General Manager*

Johannes holds a PhD from the University Regensburg. He focused his research on the aggregation and interaction behaviour of lipopolysaccharides as well as the related activity in limulus based detection systems. In 2016, Johannes joined Microcoat Biotechnology GmbH and has recently been appointed General Manager. Johannes Reich also received a degree in Business administration from University of Applied Science in Regensburg, Germany. While pursuing his degree, he worked as Product Manager for the department "Drugs of Abuse" at Profos AG.

DR DON SINGER | *United States Pharmacopoeia/ GSK, Biopharmaceutical GMP Ops*

Don Singer is a GSK Senior Fellow, an American Society for Quality Fellow and Manager, Biopharmaceutical GMP Ops at GSK. Don has been a member of the USP Microbiology Committee of Experts since 2000, and is currently Vice-Chair of the committee. He is a Certified Specialist Microbiologist (NRCM) and Certified Pharmaceutical GMP Professional (ASQ), and has been a Malcolm Baldrige National Quality Award Examiner. Don's career spans over 35 years of research, quality control, quality assurance experience in the pharmaceutical, cosmetic, and food industries. He is currently an adjunct instructor in the Biopharmaceutical Quality program at University of Maryland Baltimore County.

CHRISTINE WEISS | *Labor LS, Germany, Head of Quality Control*

Christine Weiß studied nutritional sciences and home economics at the Technical University of Munich. In 2006 she joined Labor LS where she worked first as head of department and some years later as division manager for microbial testing of non-sterile products. In 2018 she became head of quality control for the division of non-sterile product testing.

ABOUT EBE

EBE is the voice of biopharma in Europe, bringing together innovators and developers of biopharmaceuticals of all sizes (small, mid-size and large).
EBEs mission, as the only European industry association fully dedicated to healthcare biotech, is to be the source of expertise on emerging science and biopharma innovation in Europe.

EBEs current work topics include bio-manufacturing, bio-therapeutics, advanced therapies, personalised medicines including novel & combination therapies, allergen immunotherapy and medicines based on or working through the microbiome. A key focus of EBE is to work on funding and innovation models for innovative companies and small and medium-sized enterprises (SMEs). EBEs goal is to improve the funding options available in Europe to ensure that innovative SMEs in research-intensive areas like biopharmaceuticals find the right conditions in Europe to develop into successful businesses and bring new job opportunities to the European economy.
EBE creates added value for its members by developing clear policy positions, access to expertise, to regulators and legislators, and through representing the interests of innovative developers of biopharmaceuticals.
EBE provides services to its members through knowledge sharing, networking, access to content, regulatory know-how and science & market intelligence.
EBE, being a specialised group of EFPIA, our members also profit from access to the Innovative Medicines Initiative (IMI), the largest public-private-partnership dedicated to the development of innovative medicines, and to EFPIA work topics.

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 pharmaceutical and chemical companies producing APIs and intermediates in Europe by being recognized experts who advance and influence the global GMP and Regulatory Environment.APIC is very active in communicating and monitoring developments of the active pharmaceutical ingredients industry as well as in defending the APIC views and positions on proposed legislation, regulations and Guidelines.

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 highprofile 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).

SOCIAL EVENT

On 20 November you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
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e-mail:
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Internet:
www.gmp-compliance.org

Date
Tuesday, 20 November 2018,
09.00 – 18.00 h
(Registration and coffee
08.30 – 09.00 h)
Wednesday, 21 November 2018,
08.30 – 15.30 h

Venue
Crowne Plaza Düsseldorf/Neuss
Rheinallee 1
41460 Neuss, Germany
Phone +49 (0) 2131 77 00
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Fees (per delegate plus VAT)
ECA Members € 1,690
APIC Members € 1,690
EBE Members € 1690
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved a limited numger 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.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG
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D-69007 Heidelberg, Germany
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Conference language
The official conference language will be English.

For questions regarding content please contact:
Dr Gerhard Becker (Operations Director) at +49-62 21/84 44 65, or per e-mail at becker@concept-heidelberg.de.
or
Mr Axel Schroeder (Operations Director) at +49-62 21/84 44 10, or per e-mail at schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Mr Ronny Strohwald (Organisation Manager) at +49-62 21/84 44 51, or per e-mail at strohwald@concept-heidelberg.de.

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Reservation Form (Please complete in full)

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- An ECA, EBE and APIC Joint Conference -
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