ECA Academy
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GMP Certification Programme
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Speakers


Dr jur Bita Bakhschai
Scheller & Kollegen


Dr Matthias Braun
Austrian Agency for Health and Food Safety (AGES)


Xenia Dimont
Local Government of Upper Bavaria


Dr Sophie Fröhlich
Takeda Wien


Dr Lucia Gnauer
Takeda


Cornelia Haas
VTU Engineering


Dr Manuel Hafner
Loba Biotech


Dr Björn Hegemann
CSL Behring


Dr med habil Stephan Kießig
PreviPharma Consulting


Dr Ralf Knels
Eurocode International Blood Labelling e.V.


Roman Rolka
Takeda


Michael Schiffer
CSL Behring


Prof Dr Stefan Wittke
University of applied Sciences Bremerhaven

Blood, Blood Products, and Plasma

Quality, Safety, SoHO and recent Developments

14/15 May 2024 | Berlin, Germany

Highlights

- Impact of SoHO
- Innovations and Developments in the Field of Blood and Plasma
- Inspection from a GMP Inspector's Perspective
- Contamination Control Strategy
- Virus and TSE Safety

Objective

During this conference, speakers from authorities, industry, sciences and donation services provide you with information about the current developments and revisions of the regulatory requirements, e.g. for mass spectrometry, Annex 1 and blood labeling. Furthermore, important topics such as inspections from the perspective of a GMP inspector, stability study management and virus safety will be considered. You will benefit from experts presenting their practical experiences and knowledge in the field of quality and safety of blood, blood products and plasma.

Other information provided during this event includes developments in plasma protein research, automation in a process lab, asset management and much more.

Background

In July 2022, the European Commission adopted the proposal for a Regulation on standards of quality and safety of substances of human origin intended for human application. The Council agreed on its negotiating mandate in October 2023. Negotiations with the European Parliament began in November 2023 and conclude with provisional agreement since Dec 2023. With the repeal of the Blood Directive (2002/98/EC) and the Tissues and Cells Directive (2004/23/EC), the Regulation finalizes the revision of the regulatory framework for blood, tissues and cells in the light of new scientific, technical and societal developments. It aims to prioritize and ensure donor safety, patient safety, security of supply and the development of innovative medical procedures in Europe.

Furthermore, the EU GMP Guideline, Annex 1 „Manufacture of sterile medicinal products“ also came into effect on 25 August 2023.

But what impact will these two new regulations have on donation centres and on companies that manufacture blood and plasma products in Europe? A harmonized regulation is essential for patient safety as well as the quality of the products, but new regulations often raise many questions and should definitely be clarified before inspection by the authorities.

Take the opportunity to exchange experiences with experts at this event and also talk about new developments, e.g. in analytics, production, products and existing issues and problems, e.g. inspections, blood labeling and more.

Target Audience

This conference is designed for persons from

- Donation services/Blood services
- QA Staff
- National and international Authorities
- Plasma Fractionation
- Control Laboratories

who are involved in regulatory affairs, quality assurance, quality control and manufacturing of blood, blood products or plasma.

Programme

How the Verdict of the CJEU relating to MSM has been implemented in German Law - *Bita Bakhschai*

- Consequences of the Judgment of the CJEU (Court of Justice of the European Union) of 29 April 2015 (C-528/13)
- Does the fact that a man has had or has sexual relations with another man (MSM - men having sex with men) constitute “sexual behaviour”?
- German Transfusion Act (“Transfusionsgesetz”) in the version of May 2023
- German “Guideline Hemotherapy” of the Federal Chamber of Physicians

Short Overview of the “Proposal for a Regulation on Substances of Human Origin” - *Bita Bakhschai*

This new proposal, inter alia,

- supports the continued provision of SoHO therapies,
- ensures high safety and quality standards,
- improves harmonisation across member states, facilitating cross-border exchange of SoHO and improving patient access to the therapies they need,
- creates conditions for safe, effective and accessible innovation,
- improves crisis preparedness and resilience to safeguard access to therapies.

Current regulatory Challenges in the Field of Blood and Plasma Products - *Dr Matthias Braun*

- Evaluation of epidemiological data on blood transmissible infections:
  - current guideline and current practical approaches
  - future perspectives and next steps
- SoHO: impact of the novel regulation and next steps

Trends in Innovation and Development in PDMPs *Dr Stephan Kießig*

- Current status of plasma sourcing outside EU and USD
- Plasma testing
- Current trends in the product development and indications
- Fractionation market
- Current fractionation
- Trends outside EU / US
- New equipment

A Glimpse into the Future of Biopharmaceutical Manufacturing - *Dr Lucia Gnauer*

- Trends in biopharma / Industry 4.0
- Some examples of PAT
- Sustainability

Recent Developments in Plasma Protein Research at CSL - *Dr Björn Hegemann*

- CSL: a plasma-based biotech
- Nebulised IgG in respiratory disease
- Heme- and Hemoglobin scavengers

Possibilities for Automation in a Process Lab
Roman Rolka

- Overview Takeda Process Labs
- Digitalisation & automation
- KPIs as a tool for decision-making
- Challenges & opportunities

Inspections of Blood Establishments by Authorities
Xenia Dimont

- Current legal framework
- Inspection procedure
- Challenges and outlook

Why is a unique Identification of Substances from Human Origin important? - *Dr Ralf Knels*

- Unique, ISO conform coding of blood, tissue, cells and other substances of human origin
- Eurocode IBLS is a non-profit organisation managed by medical professionals in the field
- Eurocode coding system is compatible with EU tissue coding system and ISBT 128 managed by ICCBBA in the field of tissues and cells

Asset Management in the Pharmaceutical Industry
Dr Manuel Hafner

- What is asset management, and why might you need it?
- Available technologies and hurdles in relation to frozen materials (Plasma/Intermediates)
  - why QR/Barcodes are bad
- Sample Use Cases

Annex 1 Contamination Control Strategy - *Cornelia Haas*

- New GMP Annex 1 requires contamination control strategy
- Contamination control strategy shall be holistic approach covering facility, raw materials and process

Stability Study Management – unifying the World under different Conditions - *Dr Sophie Fröhlich*

- A product is a product is a product: stability-related challenges and requirements from East to West
- Cost-benefit ration und regulatory requirements – limitations for increasing study effectiveness by predictive analysis
- Reducing tests increasing data analysis capabilities - time efficiency in the bottleneck for submissions

Mass Spectrometry and its Opportunities in Drug Development: an old Hat or the Future?
Prof Dr Stefan Wittke

- LC-MS/MS in stability testing of drugs
- LC-MS/MS and the detection of impurities in pharmaceutical products
- LC-MS/MS and its opportunities to investigate isoforms of blood proteins (immunoglobulins, coagulation factors, plasminogen)
- LC-MS/MS for the optimization of production conditions

Defending against the Unseen: Mastering Virus and TSE Safety through holistic Safety Concepts and Contamination Control Strategies - *Michael Schiffer*

- Design of a state-of-the-art plasma product pathogen safety profile
- CCS: Consideration of the new EU GMP Annex I for the pathogen safety of PDMPs
- Intra- and inter-batch segregation concepts

Speakers

Dr. jur. Bita Bakhschai, Scheller & Kollegen
Attorney at law

Dr Bakhschai studied law at the University of Bayreuth and Erlangen-Nuremberg. She has been admitted to the bar since 2002 and has been a certified specialist lawyer attorney for medical law since 2006. Her focus is on German and European law for blood and plasma products, cell therapeutics and biotechnology.

Dr Matthias Braun, Austrian Agency for Health and Food Safety GmbH (AGES)
Quality Assessor for Biologics

Dr Matthias Braun studied biotechnology and holds a doctorate in protein technology. Before joining AGES, he worked at the University of Vienna and as a laboratory manager in a medical diagnostic blood laboratory. Since 2022, he is a quality assessor for biologics at Austrian Agency for Health and Food Safety GmbH (AGES) in Vienna.

Xenia Dimont, Local Government of Upper Bavaria
GMP/GDP Inspector

Ms Xenia Dimont works as a GMP/GDP inspector for the government of Upper Bavaria. Ms Dimont gained her professional experience in various pharmacies before moving to the Government of Upper Bavaria (ROB) in Munich in 2011. Ms Dimont's activities include carrying out official inspections of active substance and medicinal product manufacturers in accordance with Section 64 AMG in Germany and in third countries. Since 2020, she has been Head of the Blood Division in the Pharmacy Department of the Government of Upper Bavaria and is a member of the official state committee Expert Group 06 „Blood / Blood Products".

Speakers

Dr Sophie Fröhlich, Takeda Wien

Head of Product Stability PDT & Hematology

Sophie Fröhlich studied technical chemistry at the Vienna University of Technology and Executive Business Administration and Management at California Lutheran University. After her PhD in Vienna, she worked as a Senior Scientist at Boehringer Ingelheim from 2014-2018. After her time at Nabriva as Associate Director Pharmaceutical Analysis & Quality Control and AOP Orphan Pharmaceuticals as Senior CMC Lead, she joined Takeda in 2022 as Head of PDT & Hematology Product Stability.

Dr Lucia Gnauer, Takeda

Head of PDT Process Development

Lucia Gnauer was working in ARC Seibersdorf, AIT in Austria and gained experience in analytics prior joining Baxter in 2007, which later became Baxalta, Shire, and Takeda. Throughout her tenure, Lucia has held various roles in Plasma Product Development and Manufacturing Science in key areas, showcasing her versatility and expertise. In 2019, Lucia made her way to plasma-derived therapies R&D, taking over the role of Head of PDT Process Development within Pharm Sci. In this role, she is responsible for driving the development of innovative processes to enhance pharmaceutical manufacturing.

Cornelia Haas, VTU Engineering

Manufacturing Science & Technology Expert

Cornelia Haas was working on USP process development of perfusion systems at the University of Natural Resources and Life Sciences in Vienna prior to joining the manufacturing science and technology (MS&T) team of VTU Engineering in 2017. In the last years she has worked on the topic of microbial and particulate contamination control strategies for several multinational companies. She wrote and supported the establishment of these procedures in the areas of biopharmaceutical drug substance and drug product manufacture.

Dr Manuel Hafner, Loba Biotech GmbH

Head of Production Biotech

Dr Manuel Hafner worked in various positions at Siemens Healthineers, Roche Diagnostics, Jungbunzlauer, Takeda and handle medical GmbH. He has now 10 years of experience in pharmaceutical and diagnostic research and development, production, supply chain management, automation design, marketing, product management, quality and operational excellence. He currently works at Loba Biotech GmbH as Head of Production Biotech and is responsible among others for Installation and Management of the cell culture Production Facility.

Dr Björn Hegemann, CSL Behring

R&D, Lead Plasma Protein Research

Trained in Biochemistry at the University of Potsdam, followed by a PhD in cell biology and proteomics at the Institute of Molecular Pathology (IMP), Vienna, and the University of Vienna. Postdoctoral work at the ETH Zürich, Switzerland. Joined CSL Research Bern in 2016 to lead process development and early research projects and later to build and lead the Joint R&D mass spectrometry team. Leading Plasma Protein Research since 2022 to drive CSL's early research activities for novel plasma-based therapeutics.

Speakers

Dr med. habil Stephan Kießig, PreviPharma Consulting

R&D

From 1992 to 2001 Stephan Kießig was Head of R&D Diagnostics at Immuno GmbH. At the same time, he assumed responsibility as head of control, head of production and later as senior physician for many plasma centres. From 2001 to 2005, he established the blood and plasma donation centres in different german cities as Medical Director of the DGH (German Society for Human Plasma). 2005 to 2008 CSO (Chief Science Officer) of LipoNova AG. 2008 - 2013 at Haema AG, senior medical officer and expert for North Rhine-Westphalia. Then CEO, GF, expert person at Ruhrplasma in Bochum. Currently CMO and QP at VCC Medical Germany and R&D at Previpharma.

Dr Ralf Knels

Eurocode International Blood Labelling e.V.

Dr Knels worked since 1996 in several positions in transfusion medicine at University Jena and the German Red Cross Blood Donor Service North-East. He was the Chairperson of Eurocode International Blood Labeling System for 8 years and is currently Board Member of the organization. From 2013 till 2019 he was the CEO of a private medical lab in Dresden. As Medical Director of HAEMA (2020 – 2023) he was actually responsible for coordinating the work of 10 Head Physicians for 41 Blood Donation Centers. Since the starting of 2024 he is working as a medical director for CSL Plasma.

Roman Rolka, Takeda

Head of Process Labs & Qualification

Roman Rolka began his career at the Isovolta Group as a laboratory technician. In 2008, he moved to Baxter (later Shire) and was promoted to QC Lab Head Chromatography due to his expertise in this field. He joined Takeda in 2016 and is currently Head of Process Labs & Qualification. He provides technical and functional leadership for the departments within Manufacturing Sciences and is partner for the global wet lab network and first point of contact for Vienna regarding process labs and process qualification.

Michael Schiffer, CSL Behring

R&D, Head of Global Pathogen Safety Support CH

Michael Schiffer worked at Novartis from 2013 to 2020 in various functions in the area of fill & finish of commercial and clinical biopharmaceuticals and their launch. After his start in microbiological quality assurance and then working as a process expert in manufacturing, he headed a quality control laboratory for chemical-physical release and stability testing. Since 2020 within Research and Development at CSL Behring in the Global Pathogen Safety department, he provides global support to general matters related to Pathogen Safety and leads the scientific support team for Switzerland.

Prof Dr Stefan Wittke, University of applied Sciences Bremerhaven

Head of Laboratory for Biotechnology

Prof Dr Stefan Wittke completed his chemistry studies at the University of Göttingen and his doctorate at the University of Paderborn. Following his time at Mosaiques diagnostics GmbH and LipoNova AG, he has been a professor at the University of Bremerhaven since 2008. As Head of Laboratory for (marine) Biotechnology and member of the §64 working group “mass spectrometry for Protein Analysis to Detect Food Fraud and Food Allergens” of the Federal Office of Consumer Protection and Food Safety (BVL), his work focus includes protein analysis, mass spectrometry and blood proteins (PLG, IG, CF).

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GERMANY

Reservation Form (Please complete in full)

Blood, Blood Products and Plasma, 14/15 May 2024, Berlin, 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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German law shall apply. Court of jurisdiction is Heidelberg.

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Date
Tuesday, 14 May 2024, 08.30 – 16.30 h
(Registration and coffee 08.00 – 08.30 h)
Wednesday, 15 May 2024, 08.30 – 15.00 h

Venue
DoubleTree by Hilton Berlin Ku´Damm
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone: +49(0) 30 2127 0
Email: info@doubletreeberlinkudamm.com

Fees (per delegate, plus VAT)
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
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 conference. 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.

Conference language
The official conference language will be English.

Social Event

In the evening of the first conference day, 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.

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