Blood, Blood Products, and Plasma
Quality, Safety and GMP Aspects

SPEAKERS

FROM AUTHORITIES:

DR DRAGOSLAV DOMANOVIC
European Center for Disease Control

DR MICHA NÜBLING
World Health Organisation/ Paul-Ehrlich Institut, Germany

EVA LINDBERG
Swedish Medical Products Agency

DR KARMIN SAADAT
AGES, Austria

DR FRANK SIELAFF
Local GMP Inspectorate Darmstadt, Germany

FROM SCIENCE AND INDUSTRY:

SVENJA BARCKHAUSEN
Biotest

DR NORBERT BECKER
KABS

DR STEPHAN KIESSIG
VCC Medical

DR WOLFGANG SCHUMACHER
SPC

MICHAEL SZKUTTA
Octapharma

DR STEPHAN WALSEMANN
KEDPLASMA

AHARON WEINSTEIN
OrSense

17-18 April 2018, Vienna, Austria

Conference Highlights

- Epidemiological Data – Evaluation and Interpretation
- Residual Risk Calculation
- Donor Safety and Acceptance
- Quality Requirements – from GMP to GDP
Objectives
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 epidemiology, PMF and product quality. Furthermore, the developments in microbial safety – requirements and methods – will be introduced, e.g., residual risks of transmission of viral diseases. 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 course includes Donor Vigilance, quality requirements of plasma fractionators and preparative plasmapheresis issues.

Background
During the next years, blood donation services, plasma establishments and the plasma industry expect an increasing need of plasma for fractionation. Due to patient blood management and the decreasing recovered plasma this problem can be solved only by extension of preparative plasmapheresis and increased procurement of source plasma in Europe and worldwide. Especially new indications of blood products – e.g., the use of IVIG in immunologic disorders – will cause a growth of plasma derived medicinal products. Against this background, the number of donations must be increased to ensure the patient centred care as well as the supply of the industry. The amount of imported plasma for fractionation between the European countries as well as from USA will also increase. The necessary base for a comprehensive and sufficient maintenance in the EU countries is a consistent and standardised level of quality and safety of blood and plasma donations.

Based on the regulations of the European Union, e.g.
- the “Plasma Master File”, 2003/63/EC
- the European Pharmacopoeia or
- the EDQM “Guide to the preparation, use and quality assurance of blood components”

integrative procedures for all countries are essential. Donor screening, microbial testing, donation practises and later on storage, distribution and look back systems should be on the same level in all member states.

Additionally, new guidelines and guideline drafts related to microbiological safety issues – like those related to HEV transmission or to classic GMP issues like process validation – have an impact on the field of blood and plasma products.

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

Moderators
Dr Stephan T. Kiessig, Axel H. Schroeder

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.
Mosquitoes as nuisance and vector species in Europe
- Spread of exotic species like Aedes albopictus and in the view of climate change
- Chikungunya and dengue fever are occurring on the European continent
- Disease risk and control options

Current infectious threats to the blood safety in EU
- Characteristics of donor derived infections
- Epidemiology of transfusion-transmitted infection
- Reported infections among blood donors in the last years in the EU
- Reported transfusion transmitted infections in the last years in the EU

Evaluation of Epidemiological Data
- Evaluation
- Analysis
- Benchmarking
- Comparing epidemiological data
- Setting of acceptance limits

Plasma Quality vs. Volume
- Extracorporeal volumes during plasmapheresis procedures
- Compartments of interest during plasmapheresis
- Metabolism of proteins, especially IgG
- Impact of donation volumes and donation frequencies on the plasma quality and the donor safety

Hyperimmunization in Europe?
- Hyperimmune products at the EU market
- Hyperimmunization of plasma donors vs. selection of donors
- Impact of the analytical assays
- A list of wishes

WHO Guideline Residual Risk Calculation
- Virus safety of blood components and of plasma products
- Differential contribution of screening assay categories
- Virus epidemiology of first time and repeat donors
- Adjustment factors

Donor Safety – View from Plasma Source
- Donation volumes
- Donation frequencies
- Lessons learned from studies for intensified plasmapheresis

Non-invasive Methods for Evaluation of Donor Acceptance
- Principles of non-invasive measurements
- Pre- and post-analytical errors with different methods
- Experience with regulation
- Pitfalls of the Hemoglobin measurement

EMA Plasma Master File certification procedure
- Plasma master File (PMF) procedure
- PMF data requirements
- Data requirements for epidemiological data, monitoring change, alert limits

Quality Expectations – Inspectors View
- Quality requirements
- Industrial standards and their relevance
- Inspections and inspection procedure

Quality Aspects on Contract Manufacturing
- Applicable regulations
- Expectations and requirements from an authority point of view
- Realization phase and role as "consultant"
- Practical hints

Data Integrity – Impacting Blood Products?!
- QMS/PQS sections to be adjusted for Data Integrity
- Critical steps in the collection and manufacturing processes
- New “Critical Data” definition in the EU GPG (valid Feb. 2018)
- DI assessment of computer systems
Interfaces in Plasma product manufacturing – Experience of an Inspector

- Involved actors from plasma donation to distribution of finished product
- GMP requirements for the involved parties
- Deficiencies recently identified in GMP inspections

GDP relating to Transport and Storage of Plasma for Fractionation

- GDP basics and the impact for plasma
- Peculiarities of transportation
- Peculiarities of storage

Speakers

Svenja Barckhausen, Biotest AG, Senior Director, Plasma Alliance Operations and Protein Procurement
Svenja holds a degree as Industrial Manager approved by the chamber of commerce of Frankfurt am Main and studied business administration in Mainz. She worked at the Hoechst AG/Sanofi – Aventis until 2008. From 2008-2009 she joined Sabinsa Europe. Currently she is Senior Director, Plasma Alliance Operations and Protein Procurement Representative with power of attorney at Biotest AG.

Norbert Becker, German Mosquito Control Association (KABS) and European Mosquito Control Association (EMCA)
Norbert Becker is the Scientific Director of the German Mosquito Control Association (KABS) since 1981 and Executive Director of the European Mosquito Control Association (EMCA) since 2000. He is teaching seminars in medical entomology and ecology at the University of Heidelberg. He was member of the Steering Committee (SC) for Biology and Control of Vectors (BCV) of the World Health Organization (WHO/TDR) in Geneva from 1989-1994 and was involved in consultation as a member of the SC for BCV, WHO/TDR in Asia, Africa and South America. Since 2015 member of the Federal Expert Committee on “Mosquitoes as vectors of human diseases” in Germany.

Dragoslav Domanovic, MD, PhD, transfusion medicine specialist, ECDC Sweden
Working experiences gained at the National Institute for transfusion medicine Ljubljana, Slovenia as a head of the national blood bank and the cord blood bank. Also has practical experiences in the collection, processing, and storage of peripheral blood stem cells, isolation of CD34+ cells, production of platelet gel and storage of amniotic membranes. Currently at the position of a Senior Expert Vigilance and Traceability of Substances of Human Origin at the European Centre for Disease.

Dr Stephan Kiessig, VCC Medical Deutschland GmbH, Germany
He studied human medicine at the University Leipzig and Berlin, he is a specialist in immunology. From 1981 – 92 he was at the AIDS Test group Charité Berlin, 1992 - 2002 in R&D of IMMUNO (later Baxter) as medical head for several plasma centres and European marketing manager hyperimmunes. From 2002 – 05 he was director quality management of DGH and 2005 – 08 CSO at LipoNova developing a tumour vaccine. After positions as medical head and QP at Haema for 5 years and CEO at Ruhr-Plasma. He joined VCC in 2017.

Eva M. Lindberg, Medical Products Agency, Sweden
Eva Lindberg studied Pharmacy at the University of Uppsala and hold a M.Sc. She is Pharmaceutical assessor at the Medical Products Agency in Sweden, working with quality assessment of biologics and normative work within this field with a focus on blood derived products and PMF. Furthermore, Eva is co-chair of the EMA PMF group which is a subgroup to the CHMP Biologics working party (BWP).

PD Dr Micha Nübling, WHO, Geneva, Switzerland
Micha studied biology at the University of Freiburg, graduated 1990 and got his Habilitation in Medical Virology in 2004 from the University of Frankfurt / Main. In 1990 he joined the Paul-Ehrlich Institut, the German Federal Agency for Vaccines and Biomedicines. He was Deputy Head of Virology Division until 2014. Since 2015 he is at the WHO Headquarter, Geneva, Switzerland, as Head of the Blood Products and Related Biologicals group.

Dr Karmin Saadat, GMP Inspector, AGES, Austria
Karmin Saadat studied Pharmacy at the University of Vienna and became a Quality Manager by training. Currently he is GMP/PMF Inspector focusing in Blood Establishments and laboratories. He is Chairman PIC/S expert circle on Quality Risk Management.

Dr Wolfgang Schumacher, formerly F. Hoffmann-La Roche Ltd., Switzerland
Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he headed different positions. In 2001 he joined F. Hoffmann-La Roche, Basle, where he was Head of the Quality Computer Systems department. He is a member of the ECA Advisory Board.

Dr Frank Sielaff, Local GMP Inspectorate Darmstadt, Hessen, Germany
Frank Sielaff is a pharmacist. Before joining the GMP-inspectorate in Darmstadt he worked several years in the pharmaceutical industry in the field of Quality Control and as Qualified Person. To his duties in the GMP inspectorate belongs the inspection of drug manufacturers, laboratories and blood and plasma establishments in Germany and outside of the EU.
**Speakers cont’d**

Michael Szkutta, Head Corporate Quality Management Plasma, Octapharma Pharmazeutika Produktions GmbH, Vienna, Austria

Head of corporate Quality Management Plasma and responsible for the life cycle of Octapharma’s world-wide plasma supply from a quality perspective. Over the last 10 years I have held different positions in the Pharmaceutical Industry: Division Supplier Quality Management, Quality Manager Pharmaceutical Production, Quality Manager for pre-clinical Test Sites, internal and external Auditor and Head of Training Management.

Dr Stephan Walsemann, Managing Director KEDPLASMA GmbH, Munich, Germany

Stephan Walsemann studied IT at the Technical University in Brunswick, and medicine at the Georg August University in Goettingen, where he received his degree and PhD in medicine. After residency in pharmacology and toxicology and internal medicine, Dr Walsemann joined pharmaceutical industry for a decade holding managerial and executive positions in sales and marketing in Germany, Austria and Switzerland. The following 6 years, he worked at the Bavarian Red Cross Transfusion Service in Munich as Director of the Finished Goods Division, being responsible for therapeutic products as well as products for industry. In 2009 Dr Walsemann joined KEDPLASMA GmbH as managing director. In 2013, Dr Walsemann was elected as Chairman of the European Plasma Alliance (EPA) of PPTA.

Aharon Weinstein, Vice President Research Haematology, OrSense, Israel

Mr Weinstein has over two decades of experience in research and algorithm development in physics and biophysics. Previously, he served as Senior Scientist at Netmor, Ltd. Prior to that he was a research assistant in the Materials and Interfaces department at the Weizmann Institute of Science. Mr Weinstein holds a B.Sc. in Physics and Mathematics from the Hebrew University of Jerusalem and an M.Sc. in Physics from the Weizmann Institute.

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We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – otherwise the booking platform window will not open.
Date
Tuesday 17 April 2018, 09.00 – 17.30 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 18 April 2018, 09.00 – 16.00 h

Venue
Radisson Blu Park Royal Palace Hotel Vienna
(former Austria Trend Hotel)
Schlossallee 8
1140 Vienna, Austria
Phone  +43/1/89110 0
Fax  +43/1/891 109 090
park.royal.palace@austria-trend.at

Fees (per delegate plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice
and includes conference documentation, dinner on the first day,
lunch on all days and all refreshments. VAT is reclaimable.

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

Accommodation
CONCEPT HEIDELBERG CONCEPT 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.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the
organisation of this event.
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
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.:
Ms Nicole Bach (Organisation Manager) at
+49-62 21/84 44 22, or per e-mail at
bach@concept-heidelberg.de.