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# 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



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# Bood, Blood Products, and Plasma

17-18 April 2018, Vienna, Austria

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## 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.

- Directive 2002/98/EC “Setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC”,
- 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

## Programme

### **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 Biologics 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 Octapharmas worldwide 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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On the Internet at [www.gmp-compliance.org](http://www.gmp-compliance.org) you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to [info@gmp-compliance.org](mailto:info@gmp-compliance.org) or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

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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.

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Germany



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

### 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](http://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  
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### 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.

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

17-18 April 2018, Vienna, Austria

Mr  Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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