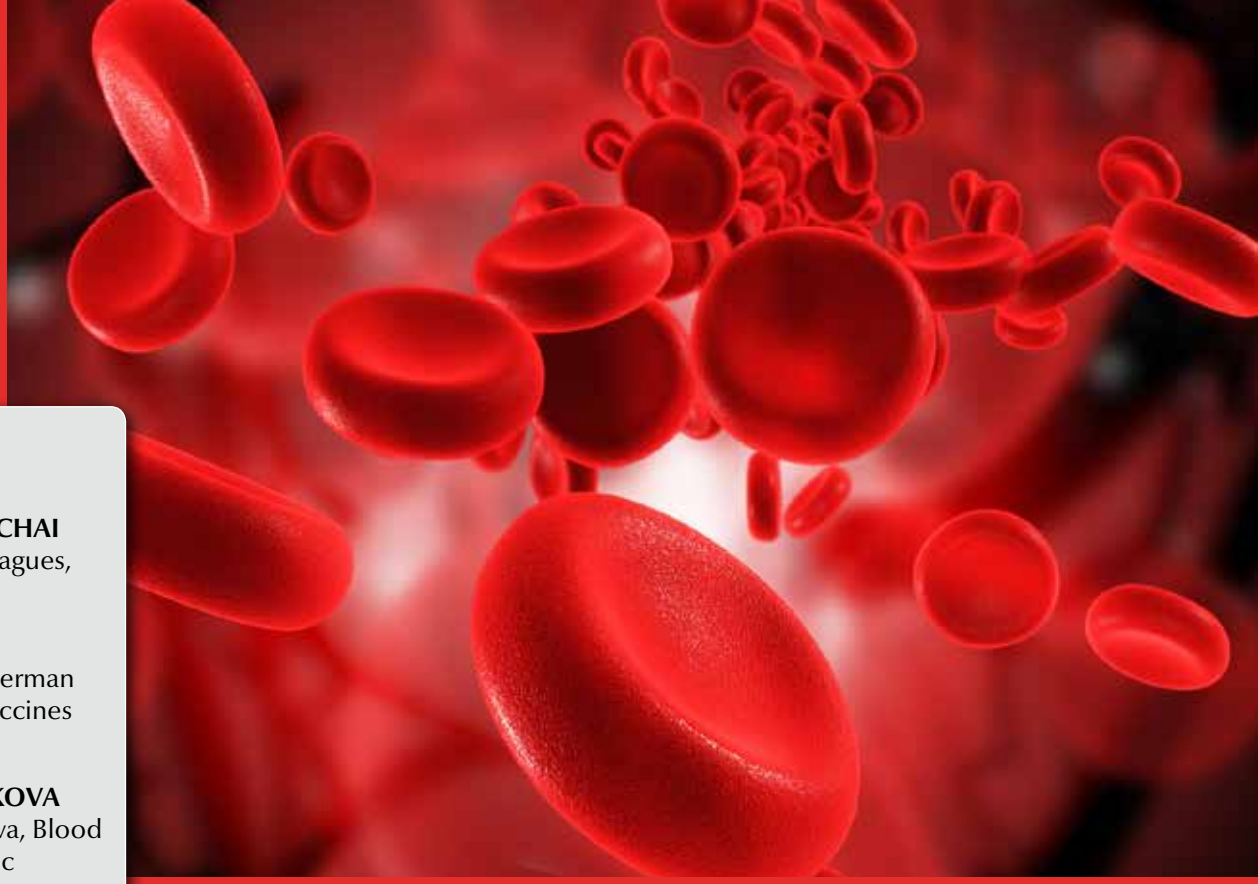
ECA ACADEMY



**SPEAKERS**

**DR. IUR. BITA BAKHSCHAI**
Boltz, Scheller & Colleagues, Law Office, Germany

**DR SALLY BAYLIS**
Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines

**DR ZUZANA CERMAKOVA**
Faculty Hospital Ostrava, Blood Center, Czech Republic

**DR DRAGOSLAV DOMANOVIC**
European Centre for Disease Prevention and Control (ECDC), Sweden

**DR BARBARA GLANTSCHNIG**
Baxter AG, Austria

**DR CHRISTINE GÜNTHER**
Apceth, Germany

**DR STEPHAN KIESSIG**
Ruhrplasma, Germany

**DR MANUELA LEITNER**
AGES, Austria

**PROF AXEL SELTSAM**
German Red Cross Blood Donation Centre, Springe

**PROF HELMI STORCH**
Haemo Consult, Germany

**PROF ERWIN STRASSER**
University Hospital Erlangen, Germany

# Blood, Blood Components, and Plasma

## QUALITY AND SAFETY

### 15 – 16 April 2015, Heidelberg, Germany

**HIGHLIGHTS:**

- Epidemiological challenges for blood and tissues in Europe
- Case Study: Blood Transfusion in Czech Republic - Transition and Adaptation to EU standards
- Regulatory Developments
- Plasmapheresis – Current Challenges
- Plasma provider, fractionator, regulator – current challenges and proposed solutions
- Microbial Safety – e.g. HEV

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

# Bood, Blood Components, and Plasma

15 – 16 April 2015, Heidelberg, Germany

## 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 virus safety or for process validation. You will also find out more about the strategies to accomplish the goal of a European standard. Furthermore, the developments in microbial safety – requirements and methods – will be introduced. 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 Plasma Vigilance, quality requirements of plasma fractionators and therapeutic and preparative plasmapheresis issues.

## Background

During the next years, blood donation services, plasma establishments and the plasma industry expect an increasing need of Source Plasma and following of donations in Europe and worldwide. Especially new applications of blood and plasma products – e.g. the use of IVIG for Alzheimers disease – can cause a rapid progression. 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 blood and plasma 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",
- the European Pharamcopoeia 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 people from

- Donation services
- Authorities
- Plasma Fractionation
- Control Laboratories

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

## Moderators

Prof. Helmi Storch
Axel H. Schroeder

## Social Event

On 15 April 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**

## Epidemiological challenges for blood and tissues in Europe

- Emerging and re-merging infections
- Donor derived infections
- Surveillance system for infections transmitted through substances of human origin (SoHO)
- Epidemiological data of some infectious diseases transmissible through SoHO

*Dr Dragoslav Domanovic,, European Centre for Disease Prevention and Control (ECDC)*

## European legal framework

- Regulations, Directives, Guidelines
- Import of blood into the European Union
- Blood donation, deferral and discrimination of MSM

*Dr. iur. Bita Bakhschai, Boltz, Scheller & Colleagues*

## Guideline on process validation in the manufacture of biotechnology derived active substances and data to be provided in the regulatory submission (EMA/CHMP/BWP/187338/2014).

- Introduction
- Process validation
- Points to consider in process validation

*Dr Manuela Leitner, AGES*

## Blood Transfusion Service in CZ Republic- transition and adaption to EU standards

- Organization and production of CZ blood transfusion service, changes during last 25 years
- Cumberstones of transition from glass bottles / whole blood to standards common in EU countries
- Implementation of quality
- Harmonization with EU legislation
- CZ self-sufficiency in blood components and plasma products: coexistence of hospital based BTS and independent plasma-collecting centers
- CZ contribution to EU plasma pool

*Dr Zuzana Cermakova, Faculty Hospital Ostrava, Blood Center*

## The German Qualified Person Assocation: Activities in the Field of Blood, Tissue and Cell-based Products

## From blood and tissue to ATMP manufacturing: current challenges

- Quality of starting material
- Standardization of donation procedures
- Specific consideration of autologous and allogeneic sourcing,

*Dr Christine Günther, Apceth*

## Production and Usage of Blood and Blood Products in Germany

- Regulatory Background for Data collection
- Blood Donation
- Preparation and Consumption of Erythrocyte- and, Thrombocyte Concentrates
- Production of Plasma for Fractionation
- Preparation and Consumption of Plasma Proteins,

*Stephan Kiessig, Ruhrplasma*

## Regulatory Requirements on Stability Testing of Plasma Products

- Guidance documents
- Authorities Expectation
- Classical Issues

*Manuela Leitner, AGES*

## Plasma provider, fractionator, regulator – current challenges and proposed solutions

- How do Changes at the plasma provider affect the fractionator?
- Hurdles in the current Plasma Master File regulation: is there room for a more pragmatic approach?
- Considerations on current donor deferral criteria and Look Back requirements for e.g. Tattoos, Piercings

*Barbara Glantschnig, Baxter AG, Vienna*

### Plasma for fractionation in Europe- ways to get it

- European Pharmakopoe
- Different qualities
- Concept of EU-self sufficiency
- Close or far to the EU-goals
- Steps to improve the situation

*Prof Helmi Storch, Haemo Consult*

### Preparative apheresis and use of plasma products – regulative aspects and common tasks

- Donor selection and regulatory aspects
- Quality aspects of apheresis plasma
- Therapeutic use of fresh frozen plasma (FFP) and plasma products

*Prof Erwin Strasser, Universitätsklinikum Erlangen*

### Donor vigilance in plasmapheresis

- Physiology of blood donation and plasmapheresis
- Regulatory requirements for donor vigilance
- Established vigilance systems
- Comparison of unexpected events in blood and plasma donations

*Dr Stephan Kiessig, Ruhrplasma*

### Hepatitis E virus in blood and plasma donations – implications for fractionated products

- Review of the EMA Workshop on Viral safety of plasma-derived medicinal products with respect to hepatitis E virus (HEV) including
  - Detection of HEV in blood/plasma donations
  - Epidemiology of HEV in donors
  - The clinical consequences of HEV infection
  - Virus reduction strategies for plasma products

*Sally Baylis, PEI*

### Pathogen reduction treatment for non-fractionated blood products

- Emerging pathogens,
- Pathogen reduction technologies,
- Clinical efficacy of pathogen-reduced blood components,
- Outlook

*Prof Axel Seltsam, German Red Cross Blood Donation Centre, Springe*

## Speakers

**Dr Dragoslav Domanovic, European Centre for Disease Prevention and Control (ECDC), Sweden**
Dragoslav Domanovic is a specialist in transfusion medicine. He has experiences as head of blood bank, head of cord blood bank and in collection, processing and storage of peripheral blood stem cells at National institute for transfusion medicine Ljubljana, Slovenia. Currently he is Senior Expert Vigilance and Traceability of Tissues and Cells of Human Origin at the European Centre for Disease Prevention and Control, Stockholm, Sweden.

**Dr iur Bita Bakhschai, Boltz, Scheller & Colleagues, Law Office, Germany**
She has studied law at the Universities of Bayreuth and Erlangen-Nürnberg and has further acquired the degree "Wirtschaftsjurist (Univ. Bayreuth)" (commercial law specialist). She is admitted as Lawyer since 2002 and is specialist solicitor for medical law since 2006. She concentrates on German and European pharmaceutical law, law regulating blood and blood components, tissues and cells and biotec law. She has released numerous publications in these fields and is member of the editorial board of the journal "Transfusion Medicine and Hemotherapy".

**Dr Sally Baylis, Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines**
Dr Sally Baylis has worked in academic research at the University of Oxford and in research and development in the pharmaceutical industry. She has been working at the Paul-Ehrlich-Institut since January 2008, prior to that she worked at NIBSC for 10 years. At the PEI she is involved in assessment of the virus and TSE safety of plasma derivatives, advanced therapy medicinal products, and a range of recombinant products and vaccines for clinical trials and marketing authorization. Her research work involves different aspects of virus contamination of biologicals; detection (assay development, standardization) and investigation of virus inactivation/removal.

## Speakers

**Assoc. Prof Zuzana Cermakova, MD, PhD, Medical Faculty, University of Ostrava**
Zuzana Cermakova studied at Medical Faculty, University of Olomouc. After her PhD graduation she became associate professor at the Medical Faculty, University of Brno. She had Short term attachments at the AKH Wien, Dept.of Blood Banking and Tissue Typing, the European School of Transfusion Medicine and the Mayo Clinic, Division of Transfusion Medicine, Rochester, Minnesota, USA. Today she is head of Faculty Hospital Ostrava, Blood Center.

**Barbara Glantschnig, Director QA Plasma Sourcing Europe, Baxter AG, Vienna, Austria**
Barbara Glantschnig studied Biology at the University of Vienna.1993 - 2011 she had different positions of growing responsibility in Plasma Sourcing and Quality Assurance, and since 1998 in management positions at Octapharma Pharmaceuticals. 2011 she joined Baxter and is currently Director QA Plasma Sourcing Europe, Kontrolllaborleiter & Qualified Person. She represents Baxter in various Industry organizations and task forces (PPTA, Pharmig, Austrian Blood Council)

**Dr Stephan Kiessig, Ruhr-Plasma-Center, Bochum, Germany**
He studied human medicines at the University Leipzig and Berlin, he is a specialist 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 centers, European marketing manager hyperimmunes, 2002 - 05 director quality management of DGH, 2005 – 08 CSO at LipoNova developing a tumor vaccine, 2008 – 13 medical head and QP at Haema, since 2013 at Ruhr-Plasma.

**Dr Manuela Leitner, AGES – Austrian Agency for Health and Food Safety**
She studied Veterinary Medicine at the University of Veterinary Medicine Vienna. From 1999 to 2002 she was Scientific assistant at that university. 2002 she joined Wyeth Whitehall Export GmbH as drug safety officer and 2004 CoaChrom Diagnostics, Since 2006 she is employed at the AGES. Her current position is Quality Assessor for plasma derived Medicinal Products and Plasma Master File. Since 2008 she is an EMA expert.

**Prof Dr med Axel Seltsam, German Red Cross Blood Donation Centre, Springe**
Axel Seltsam studied at the Friedrich-Alexander-University Erlangen. 1996-1998 he worked at the Clinical Center Fuerth. 1998 he joined as Resident the Department of Hematology, Oncology and Blood Bank, Humboldt-University Berlin. Additionally, he was from 2001-2003 Research Group Leader at the Institute for Transfusion Medicine of the Hanover Medical School. 2003 he became Professor at the Institute for Transfusion Medicine, Hanover Medical School. Currently, he is leading the production and R&D departments of the German Red Cross Blood Services NSTOB in Springe. His current research focus is on blood safety, particularly on pathogen inactivation of blood components.

**Prof. Dr. Helmi Storch, Haemo Consult, Trusetal**
He studied human medicines at the University Leipzig and is a specialist in transfusion medicines. From 1988 – 1994 he was the medicinal head of the institute for transfusion medicine Suhl. 1994 – 2005 he was employed in leading positions at Immuno AG and Baxter Healthcare. Since 2006 he works as free consultant. He worked in several working groups like ARGE Plasmapherese, AK Blood and the subgroup for Look Back.

**Prof Dr Erwin Strasser, Transfusionsmedizinische und Hämostaseologische Abteilung, Universitätsklinikum Erlangen**
He studied Human Medicine at the University Munich (LMU) 1982-1988, was trained in Oncology between 1989 and 1992 and until 1996 in Immunology. In 1996 he joined to the University Leipzig and received his medical education in cardiac surgery. In 1997 started his specialization in Transfusion Medicine at the Institute of Transfusion Medicine University Jena and received 1998 the responsibility for the production process of blood products. In 1999 he started his scientific career at the University of Erlangen. Since 2010 he is Associate Medical Director of the Transfusion and Haemostaseology Department at the University Hospital Erlangen and Head of the coagulation laboratory. Main topics of interest are cellular apheresis (since 2010 Head of the section preparative and therapeutic apheresis of the German Transfusion and Immunohematology Society DGTI), cellular immunotherapy, as well as haemostaseology. He is author, reviewer and editor of many scientific papers.

## Heidelberg – Optimal Accessibility via Frankfurt

Airport Shuttle Service: Airport shuttle services bring you promptly and reliably from the airport to your hotel.
Info: www.hls-online.de or www.ics-logistik.de.
Train: You can get on the train at the Airport Station. A train leaves up to three times per hour and it usually takes less than one hour to get to Heidelberg.

## Easy Registration

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

**Reservation Form:**
**+ 49 6221 84 44 34**

**e-mail:**
**info@concept-heidelberg.de**

**Internet:**
**www.gmp-compliance.org**

### Date
Wednesday, 15 April 2015, 09.30 - 17.30 h
(Registration and coffee 09.00 – 09.30 h)
Thursday, 16 April 2015, 08.30 – 16.00 h

### Venue
Crowne Plaza Heidelberg
Kurfürstenanlage 1
69115 Heidelberg, Germany
Phone +49 (0)6221 – 9170
Fax+49 (0)6221 – 21 00 7

### Fees (per delegate plus VAT)
ECA Members: € 1.590
APIC Members: € 1.690
EU GMP Inspectorates: € 895
Non-ECA Members: € 1.790
Academic Rate € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on two 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.

---

If the bill-to-address deviates from the specification to the right, please fill out here:

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Reservation Form (Please complete in full) +49 6221 84 44 34

## Blood, Blood Components, and Plasma – Quality and Safety
15-16 April 2015, Heidelberg, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

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

Street / P.O. Box

City Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

**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.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.

If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
**Terms of payment:** Payable without deductions within 10 days after receipt of invoice.
**Important:** This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
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).

**Privacy Policy:** By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.