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

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
**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

- the “Plasma Master File”,
- the European Pharamcopoeia or
- the EDQM “Guide to the preparation, use and quality assurance of blood components”

integriative 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 Bakhshchai, 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 Association: 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 Bakschai, 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 – 06 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 Plasmapheres, 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

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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.
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 Inspectors: € 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 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

E-mail (Please fill in)

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