ECA
European Compliance Academy

Blood, Blood Products, and Plasma

QUALITY AND SAFETY

9 – 10 April 2013, Vienna, Austria

HIGHLIGHTS:

- European Guidelines
- Regulatory Inspections
- Plasma Master File
- Microbial Safety
- Industrial Supplier Audits
- Donor Epidemiology and MSM
- Batch Release

SPEAKERS

PATRICK BAYER
AGES

DR JOHANNES BLÜMEL
Paul-Ehrlich-Institute

GEORG GÖSTL
Baxter

DR MARGARETE HEIDEN
Paul-Ehrlich-Institute

SABINE HEINZ-STEMPEL
Paul-Ehrlich-Institute

DR ULRIKE HEISSENBERGER
AGES

DR MARTINA JOSEPH
AGES

CHRISTOPH KEFEDER
AGES

DR KNUD-PETER KRAUSE
Haema Blood Donation Service

DR MANUELA LEITNER
AGES

DR RUTH OFFERGELD
Robert Koch Institute

PROF. KURT ROTH
GFE

KARL-HEINZ SCHNEIDER
CSL Behring

DR ALEXANDRA SEIFNER
AGES

PROF. HELMI STORCH
Haemo Consult

MICHAEL SZKUTTA
Octapharma

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

Bood, Blood Products, and Plasma

9-10 April 2013, Vienna, Austria

Objectives

During this conference, speakers from European authorities, industry, sciences and donation service provide you information about the current developments of the regulatory requirements, strategies to accomplish the goal of a European standard. Furthermore, the developments on microbial safety – requirements and methods – will be introduced. With their presentations, these experts will present their practical experiences and knowledge in the field of quality and safety of blood, blood products and plasma.

Information is also given on the contribution of the manufacturing process of plasma-derived medicinal products with respect to viral safety and reduction of thrombosis generating agents.

For plasma derived final products, Directive 2001/83/EC requires an official control authority batch release. This aspect is as well matter of discussion at this conference.

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 donation 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. Necessary base for a comprehensive and sufficient maintenance in the countries of the European Union 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" or the "Guide to the preparation, use and quality assurance of blood components" of the EDQM, 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 the member states.

Target Audience

This conference is designed for persons 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 9 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

Module 1 Microbial Safety and Inspections

Marketing authorisation of blood products – a challenge despite well established procedures
DR MARGARETE HEIDEN

Virus and TSE issues on plasma products and blood components
- West Nile Virus and Usutu Virus
- Hepatitis E Virus
- Current state on TSE

DR JOHANNES BLÜMEL,

Impact of NAT on infection safety of Blood and Blood Products
- Current status of NAT – Possibilities and Borders
- Automation of NAT

PROF WILLI KURT ROTH

Donor epidemiology, donor risk factors and their impact on product safety.
- HIV, HCV and HBV infections in different donor populations
- Sexual risk behavior and deferral periods
- Adherence to donor selection criteria

DR RUTH OFFERGELD

Blood and plasma donation in Europe unified in a concept of the future
- The German landscape in blood and plasma donation
- Stakeholder with different specialization
- Combined production of plasma for fractionation and blood products for direct clinical use in modern plasmaapheresis center

DR KNUD-PETER KRAUSE

Module 2 Plasma Master File

EMA-certified plasma for fractionation – the PMF procedure
- What does "plasma master file (PMF)" mean and what is the benefit of the centralized PMF procedure?
- The centralized PMF procedure from the assessor's point of view – content, workflow, responsibilities, outcome

DR MARTINA JOSEPH

Batch Release for Blood plasma
- Legal Background for Batch Release of Blood Plasma
- Relevant Guidelines for Validation of Analytical Methods
- A Practical Example (Full Validation of a Nucleic Acid Amplification Technique)

CHRISTOPH KEFEDER

Supplier Audits of donation centres
- Regulatory justification
- Audit performance
- Supplier audits – Benefits?

MICHAEL SZKUTTA

Module 3 Plasma derived Medicinal Products

The new Guideline on plasma-derived medicinal products
- What is new?
- The guideline from the perspective of a regulator

DR ULRIKE HEISSENBERGER

Parenterals/Injectables – Leachables
- Background and Risk Concern
- Regulatory Agencies Expectations
- CSL Behring GmbH : E&L Approach
- Case Study, Example

KARL-HEINZ SCHNEIDER

Plasma for Fractionation (PfF) in Europe
- The concept of self sufficiency
- Different types of PfF
- Main contributor in Europe
- The role of plasmapheresis
- Outlook for PfF sourced Europe

PROF HELMI STORCH

Module 3 Plasma derived Medicinal Products (cont'd)

Industrial Quality Requirements on Plasma for Fractionation
- Regulatory Background
- GMP Quality Requirements
- Specific Aspects in Plasma Fractionation

GEORG GÖSTL

Inspections in connection with Plasma for Fractionation – Regulatory Background and Experiences
- Regulatory Background
- Current developments - What's new?
- Inspections in connection with the PMF-Procedure

SABINE HEINZ-STEMPEL, PAUL-EHRLICH-INSTITUT

Official Control Authority Batch Release in a Nutshell
- Legal Basis of OCABR
- The Austrian Official Medicines Control Laboratory (OMCL)
- Role of the European Directorate for the Quality of Medicines (EDQM)

PATRICK BAYER

Module 4 Specific Topic Immunoglobulins and TEEs

EP Monographs on Immunoglobulins regarding Thrombosis Generating Agents
- Update of EP monographs on immunoglobulins - new versions of EP monographs 0918 and 0338
- Process steps relevant to thrombogenic agents

DR MANUELA LEITNER

Comparison of Immunoglobulins
- Analytical methods for the assessment of thrombogenic agents in immunoglobulins
- Assessment of immunoglobulin concentrates from the Austrian market on thrombogenic activity

DR ALEXANDRA SEIFNER

Speakers

Patrick Bayer, AGES – Austrian Agency for Health and Food Safety
Patrick Bayer studied Chemistry at the University of Applied Sciences in Idstein/Germany. 2003 he started his career as a validation coordinator, later as head of laboratory in an international pharmaceutical company (Vienna). In 2008 he changed to AGES and his current position as the head of the department for biological chemical analysis at the Austrian OMCL. In this position he is responsible for batch release of medicinal products derived from human plasma within the framework of OCABR in both analytical and legal aspects.

Dr Johannes Blümel, Paul-Ehrlich-Institute, Federal Agency Vaccines and Biomedicines Germany
Johannes started his career in the field of research on virus diagnostics at the University of Bonn. Since 1998 he has been working for the Paul-Ehrlich-Institute, the German Federal Agency Vaccines and Biomedicines. At present Johannes is heading the section of viral safety. His main areas of responsibility are risk evaluation of medicinal products (blood products, biopharmaceuticals) and applied research. Johannes is also an assessor for the evaluation of the reduction of TSE risk at EDQM.

Georg Göstl, Baxter AG, Austria
Georg started his professional experience in 1987 at Immuno AG in different roles of rising responsibilities within the Quality Control and Quality Assurance teams. In 1997 Immuno AG was merged with Baxter.Since 1997 he is as Qualified Person responsible for the release of the plasma products at Baxter in Vienna. He is a member of the commission for blood of the Austrian Ministry of Health.

Dr Margarete Heiden, Head of Section Transfusion Medicine, Paul-Ehrlich-Institut Germany
In her current position as Head of Section Transfusion Medicine, she is responsible for marketing authorisation of blood components, licensing of stem cells, installation DHR. She represented the PEI in several international groups and organisations e.g. CD-P-TS at European Council, DG Sanco bei EC, BEST research group, BRN at WHO.

Sabine Heinz-Stempel – Head of Section Inspections of Biological Medicinal Products Paul-Ehrlich-Institut Germany
She studied pharmacy and started her professional career in the pharmaceutical industry in 1995. Since 2001 she is an inspector, first for the Federal Institute for Drugs and Medical Devices (BfArM) where she was also Head of the PAT-Team, then for the Paul-Ehrlich-Insitut. In her current position she is responsible for inspections in connection with Plasma for Fractionation both in Germany and the USA as well as for Pharmacovigilance- and GCP-Inspections. She is also involved in the PMF-assessment.

Dr Ulrike Heißenberger, AGES – Austrian Agency for Health and Food Safety
She studied Veterinary Medicines at the Institute for Microbiology of the Veterinary University of Vienna. From 1999 to 2005 she was the responsible person for batch release of plasma products and vaccines at the national competent authority BIFA. Since 2006 she is Leader of the Group for Human Plasma Derived Products and Vaccines at the AGES.

Speakers

Dr Martina Joseph, AGES – Austrian Agency for Health and Food Safety
She started her quality assessor's career at the Federal Institute for Medicines, Since then she has gained wide experiences in the quality assessment of plasma-derived medicinal products as well as the centralized PMF (plasma master file) procedure and became Senior Expert in 2011. She is EMA Expert, PMF Contact Point as well as member of the European Medicines Agency's CHMP Plasma Master File Drafting Group since several years.

Christoph Kefeder, AGES – Austrian Agency for Health and Food Safety
He studied Medical and Pharmaceutical Biotechnology at the University of Applied Sciences in Krems. He started his career in the field of validation and method development at the Austrian Agency for Health and Food Safety OMCL in the department for biological analyses dealing with blood plasma and vaccines. Since 2012 after some common validation and method development projects he became deputy head of the department of biochemical analyses dealing with SD plasma, coagulation factors and sealants.

Dr Knud-Peter Krause, Haema Blood Donation Service, Chief Medical Officer
Graduated in Pécs, Hungary, Dr Krause started in 1988 at the Charité Hospital Humboldt University Berlin Department of Transfusion Medicine his career. From 1992-1994 he was there the head of the research department focusing on cryopreservation. In 1996 he took part in the foundation of Haema and became the CMO of this blood donation service. He is member of the German Advisory Board "Arbeitskreis Blut" a group of specialists advising the German Ministry of Health in topics related to blood and blood transfusion.

Dr Manuela Leitner, AGES – Austrian Agency for Health and Food Safety
From 1991 to 1999 Manuela studied at the University of Veterinary Medicine Vienna. From 1999 to 2002 she was Scientific assistant at that institute. 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.

Dr Ruth Offergeld, Robert-Koch-Institut, Berlin
She began her career as a clinical physician and obtained a board certification for transfusion medicine. Since 2002 she works at the department for infectious disease epidemiology at the Robert Koch Institute and is responsible for the blood donor surveillance. She conducts research in the areas of donor selection and blood safety and serves as an expert in national and international groups. She is the managing director of the National Advisory Committee "Blood" and a member of the epidemiology group of the EMA.

Prof Dr Willi Kurt Roth, GFE Blut mbH, Frankfurt
He studied in Munich and worked after his graduation at the Max-Planck-Institute for Biochemistry, Martinsried, the LMU Munich and Johann-Wolfgang-Goethe-University, Frankfurt. Since 1996 he is Professor at Johann-Wolfgang-Goethe-University, Frankfurt. 1996 to 2005 he was the head of the section for donor screening at the transfusion centre of the Red Cross Frankfurt. 2006 he became CEO of the GFE Blood mbH, a company for Development and distribution of diagnostics in the field of blood donation. He is a member of several expert groups e.g. AABB, ISBT, DGTI and Dechema.

Karl_Heinz Schneider, CSL Behring Pharma
K.-H. Schneider spent more than 18 years in Regulatory Affairs and was involved in the global licensure of biological products with primary focus on U.S. Product and Establishment License Applications. Since late 2005 he works in the Validation Department and deals with the validation of aseptic and non-aseptic processes and primarily working on E | L activities. During the past four years he has been involved in the creation and implementation of a practical approach for E | L testing of product-contacting plastic derived materials comprising in-process materials and drug product elastomeric stoppers.

Dr Alexandra Seifner, PhD, AGES – Austrian Agency for Health and Food Safety
Alexandra studied Chemistry at the University of Vienna and graduated 2009. 2009 she joined the AGES as Deputy Head Biological Chemical Analyses and since 20012 she is Biopharmaceutical Consultant there.

Prof. Dr Helmi Storch, Haemo Consult, Trusetal
He studied human medicines at the University Leipzig and is a specialist in transfusion medicines. From 1988 to 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.

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

Easy Registration

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Date
Tuesday, 09 April 2013, 09.00 h – 17.30 h
(Registration and coffee 8.30 h – 09.00 h)
Wednesday, 10 April 2013, 8.30 h – 16.00 h

Venue
RENAISSANCE WIEN HOTEL
Linke Wienzeile – Ullmannstrasse 71
1150 Vienna, Austria
Phone +43 1 89102 - 0
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Fees
ECA Members: € 1.590,- per delegate + VAT.
APIC Members: € 1.690,- per delegate + VAT
EU GMP Inspectorates: € 895,- per delegate + VAT.
Non-ECA Members: € 1.790,- per delegate + VAT.
Academic Rate EUR 895.- per delegate plus VAT
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 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
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Blood, Blood Products and Plasma – Quality and Safety
9 – 10 April 2013, Vienna, Austria

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- until 2 weeks prior to the conference 10 %,
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