ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

Speakers

Dr. med. habil. Stephan T. Kiessig
Previpharma

Dr jur. Bita Bakhschai
Scheller & Kollegen

Elke Weitershaus
Government of Saxony-Anhalt

Blood and Plasma – Audits and Inspections

03/04 November 2021 | Berlin, Germany

Highlights

- Regulatory Requirements in Europe and More
- Blood and Plasma-based Starting Materials and Drug Products
- Donor Documentation and Data Protection in the Light of the General EU Data Protection Regulation
- PMF - Plasma Master File
- Structure of the Quality Management
- Inspections
  - Preparation of Audits and Inspections
  - Procedure of Audits
  - Follow-up of Audits and Inspections

From regulatory background to preparation and final performance

Objective

This seminar will familiarize you with existing regulatory requirements for blood, blood products, plasma and blood products and will give you an overview of the latest changes. In addition, representatives from authorities, establishments, industry and consultants will show you which requirements are placed on you and your quality management system during an audit or inspection and how you should prepare and follow- up an audit or inspection.

Background

As a manufacturer or supplier of medicinal products or their starting materials, blood and plasma donation establishments as well as stem cell facilities are subject to drug approval and/or drug supervision. This means that the current rules and regulations regarding the collection, storage, transportation and processing of blood and plasma products should be familiar. In addition to the current legislation some national requirements (e.g. the German Guideline on haemotherapy), the Guideline on Plasma-derived Medicinal Products, or the guidelines of the medical associations in the member states should be taken into account. Especially for establishments and responsible persons located in the medical field, the pharmaceutical legal requirements and documentation requirements often present a new challenge.

Target Audience

This course is aimed at employees from blood and plasma suppliers, such as blood donor establishments, transfusion centres, fractionators etc. It is aimed at the same way to blood and plasma processing companies such as pharmaceutical manufacturer. Especially employees in manufacturing, quality assurance, quality control and analytics will benefit from this course.

Social Event

In the evening of the first course 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

Responsible Persons for the Manufacture and Placing on the Market of Blood Products

- Manufacturer, Head of Production, Head of Quality Control, Qualified Person, Head of LQS/LQA
- Pharmaceutical entrepreneur, step-by-step plan officer, information officer
- Personal responsibility, delegation of tasks

What are Audits and what are Inspections and what is the Legal Basis?

- EC Blood Directives and other international Guidelines
- The Guideline on Plasma-derived Medicinal Products
- Manufacture of medicinal products from blood or plasma - Annex 14
- How do the different pieces of legislation interlock?

Starting Materials and Drug Products

- Raw material / Production / Quality control
- Virus inactivation/virus reduction
- Risk assessment for viral transmission and TSE

Drug Products from Plasma Fractionator

- Supplier qualification and management
- Quality assurance for fractionation & processing of blood products
- Storage and transport of blood products

Contractual Agreements with Supplier of Plasma

- Key regulatory points for a contract between plasma fractionator and plasma centers/donation establishments.

Plasma Master File

- Plasma qualities
- Acceptance of blood and plasma establishments

Donor Documentation and Data Protection in Blood Establishments in the Light of the General Data Protection Regulation

- EU General Protection Regulation,
- Donor documentation and archiving

Product Quality Review – PQR

- Regulations for a PQR
- Content of an PQR
  - Deviation and CAPA Management
  - Quality measurers in blood and plasma establishments
- Licensed and non-licensed products

Quality Management - Organisation and Relevant Persons

- Quality assurance during extraction & application
- Inclusion and evaluation of donors and donations
- Role of physicians
- Production, storage and transport of blood products
- Transfusion commissioner, responsible person for transfusion, quality officer

The Forthcoming Inspection: Preparation and Planning Phases

- Inspection by the authorities
  - How to prepare for an inspection
  - How to answer on inspection reports
- Supplier audits – qualification of contracted partners

The Procedure of Audits and Inspections Part 1: The Point of View of the Blood Establishment

- The donors' path through the centre
- Ways of the product
- Waste
- Deliveries

The Procedure of Audits and Inspections Part 2: Inspectors' Point of View

- Inspection focus for blood and plasma facilities
- Responsibilities and powers of inspectors
- Frequent errors and defects

The Follow-up of Audits and Inspections Part 1: Inspector's Point of View

- The official inspection report
- Category of deficiencies and their significance
- Opinion on the inspection report (action plan)

The Follow-up of Audits and Inspections Part 2: The Point of View of the Blood Establishment

- Findings
- CAPA
- Responsibility of the persons involved (expert person, head of production, head of QK, QM, auditor, administrative assistance)

Speakers

Dr. med. habil. Stephan T. Kiessig
Previpharma, R&D

From 1992 to 2001 Head of R&D Diagnostics at Immuno GmbH. At the same time, he assumed responsibility for pharmaceutical law in this area as well as in the plasma area as head of control, head of production and later as senior physician for the plasma centres in Mannheim, Heidelberg, Aachen, Karlsruhe and Saarbrücken. From 2001 to 2005, he established the blood and plasma donation centres in Koblenz, Dessau, Krefeld and Dresden as Medical Director of the DGH (German Society for Human Plasma). 2005 to 2008 CSO (Chief Science Officer) of LipoNova AG. 2008 - 2013 at Haema AG, senior medical officer and expert for North Rhine-Westphalia. Then CEO, GF, expert person at Ruhrplasma in Bochum. Currently CMO and QP at VCC Medical Germany and R&D at Previpharma.

Dr jur. Bita Bakhschai
Scheller & Kollegen, Attorney

Dr Bakhschai studied law at the University of Bayreuth and Erlangen-Nuremberg. She has been admitted to the bar since 2002 and has been a certified specialist lawyer attorney for medical law since 2006. Her focus is on German and European law for blood and plasma products, cell therapeutics and biotechnology. She is a member of the editorial board of the journal Transfusionsmedizin und Hämotherapie (Transfusion Medicine and Hemotherapy).

Elke Weitershaus
Government of Saxony-Anhalt, GMP Inspector

In the authority in Halle (Saale) she is responsible for medicinal products. This includes inspection of Blood, Plasma and Stem Cells Facilities, pharmaceutical manufacturers, distribution channels and pharmacies. She is also a member of the ZLG Expert Group 06 (blood and blood products). This group deals with all issues arising from the implementation of the legal basis with regard to the donation, processing, storage and testing of blood and blood products.

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Blood and Plasma – Audits and Inspections, 03/04 November 2021, Berlin, Germany

Title, first name, surname

Department Company

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

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:
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German law shall apply. Court of jurisdiction is Heidelberg.

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.

Date

Wednesday, 03 November 2021, 09.30 – 18.00 h
(Registration and coffee 09.00 – 09.30 h)
Thursday, 04 November 2021, 08.30 – 15.30 h

Venue

Hotel Bristol Berlin
Kurfürstendamm 27
10719 Berlin, Germany
Phone +49(0)30 8843 40
Email reservations@bristolberlin.com

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 both days and all refreshments. VAT is reclaimable.

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.

Registration

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

Conference language

The official conference language will be English.

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training....“ This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

Organisation and Contact

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

For questions regarding content please contact:
Mr Axel H. Schroeder (Operations Director) at
+49(0)62 21/84 44 10, or at
schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Nicole Bach (Organisation Manager) at
+49(0)62 21/84 44 22, or at
bach@concept-heidelberg.de.