



Speakers



Dr. med. habil. Stephan T. Kiessig
Previpharma



Dr. jur. Bitu Bakhschai
Scheller & Kollegen



Elke Weitershaus
Government of Saxony-Anhalt

Blood and Plasma – Audits and Inspections



Live Online Training on 03/04 November 2021



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 Live Online Training 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 Live Online Training 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.

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 for Blood 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

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.

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. Bitra 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.

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

Reservation Form (Please complete in full)



Blood and Plasma – Audits and Inspections, Live Online Training on 03/04 November 2021

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)

CONCEPT HEIDELBERG

P.O. Box 101764

Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg

GERMANY

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 %
 - Cancellation until 1 week prior to the conference 50 %
 - Cancellation 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 HEIDELBERG will 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 can-

cellation 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).

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 of the Live Online Training

Wednesday, 03 November 2021,

09.00 – 18.00 h CET

Thursday, 04 November 2021,

09.00 – 17.00 h CET

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,590

APIC Members € 1,690

Non-ECA Members € 1,790

EU GMP Inspectorates € 895

The fee is payable in advance after receipt of invoice.

Registration

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

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at <https://www.gmp-compliance.org/on-demand-online-training/recorded-online-training-webinars>. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

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 organisation please contact:

Ms Nicole Bach (Organisation Manager) at

+49(0)62 21/84 44 22, or at

bach@concept-heidelberg.de.