ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

Speakers

Dr jur. Bita Bakhschai
Scheller & Kollegen

Dr med. habil. Stephan T. Kiessig
PreviPharma Consulting

Eva Lindberg
Swedish Medical Products Agency

Elke Weitershaus
State Administration Office of Saxony-Anhalt

Blood, Plasma and Stem Cells – Audits and Inspections

Live Online Training on 05/06 November 2024

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.

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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.

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

EMA Plasma Master File (PMF) Certification Procedure and PMF Dossier Requirements

- PMF procedure
- Guideline on the Scientific Data Requirements for a Plasma Master File
- Inspection and audit requirements for PMF certification

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

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.

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 QC, QM, auditor, administrative assistance)

Speakers

Dr jur. Bita Bakhschai
Scheller & Kollegen, Attorney at law

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).

Dr med. habil. Stephan T. Kiessig
PreviPharma Consulting, 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.

Eva Lindberg
Swedish Medical Products Agency, Assessor

Eva Lindberg studied Pharmacy at the University of Uppsala and holds a M.Sc. She is pharmaceutical assessor at the Medical Products Agency in Sweden, working with quality assessment of biologics and normative work within this field with a focus on blood derived products and PMF. Furthermore, Eva is chair of the EMA PMF group which is a subgroup to the CHMP Biologics working party (BWP).

Elke Weitershaus
State Administration Office 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:

_____

_____

_____

_____

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, Plasma and Stem Cells – Audits and Inspections, Live Online Training on 05/06 November 2024

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:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks 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).
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

Tuesday, 05 November 2024,
08.30 – 17.30 h CET
Wednesday, 06 November 2024,
09.00 – 17.00 h CET

Technical Requirements

We use WebEx for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
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.

You cannot attend the live event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

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 Clemens Mundo (Operations Director) at
+49(0)62 21/84 44 42, or at
mundo@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.