EuBIS Academy
European Blood Inspection System
Initiated under the Public Health Programme of the EC
Directorate General SANCO - GA No. 2006202

EuBIS#Virtual

Quality management and inspection of blood establishments
- EuBIS Seminar and Training Workshop –

'From good practices to best practices' in blood and blood components referring to GPG and GMP

EuBIS#Virtual 8th – 9th of September 2021

**Organised by the Paul-Ehrlich-Institute (PEI)
and the EuBIS Academy in cooperation with the
African Society of Blood Transfusion (AfSBT)**

AfSBT
AFRICA SOCIETY FOR BLOOD TRANSFUSION
Societe Africaine De Transfusion Sanguine
Africa Sociedade Para Tranfusao De Sangue

Paul-Ehrlich-Institut

GHP Programme

Regulatory Capacity Strengthening in Africa funded by the Global Health Protection Program (GHPP)
Seminar and training workshop of the African Society for Blood Transfusion (AfSBT)
In cooperation with the Paul-Ehrlich-Institute (PEI and the EuBIS Academy)

EuBIS Seminar and training workshop – 'From good to best practice' referring to Good Manufacturing Practice (GMP) and Good Practice Guidelines (GPG) of blood and blood components

The seminar and training workshop is organised by the AfSBT and the PEI funded by the GHPP and will build on previous EuBIS training courses with the scope to train on the impact of Good Manufacturing Practice (GMP) and Good Practice Guidelines (GPG) regulations for blood and blood components and on standards for regulatory inspection of transfusion services / blood establishments that are internationally highly recognised and standards to develop best practice and to ensure safety and effectivity of blood and blood components used for the treatment of patients.

The **Virtual Seminar** will comprises Lectures and Case work plus Quizes (Pollings) and intends to prepare the participants to understand principles of GMP / GPG including aspects of quality management as referenced in the EuBIS guide based on cases covering several aspects of quality management system such as:

- EuBIS guide covering all critical steps for an quality management system
  with cross-references to PIC/S, EU Directives, GP guidelines and GMP guidelines

Special focus will be on the following topics:

- General principles of quality management systems and inspections
- Regulations and regulatory frame-work
- **R**isk assessment.
  linked topics as below will be outlined.
- Requirements for buildings, premises and storage facilities
- Validation and Qualification, staff training and evaluation
- Inspection / Internal Audit
- Change Control / Management

The training and seminar are performed to support Regulatory Capacity Strengthening in Africa funded by the Global Health Protection Program (GHPP).

Training course language**: English**

Distant Learning Material:
Please find Information for preparing for the training (EuBIS Training Guide and GMP/GPG related guidelines and documents): www.eubis-europe.eu

Training course participants:

- Qualified as inspectors by a National Regulatory Authority (NRA)
- Individuals working in a blood establishment in the area of quality management.

Participants will receive a certificate of participation.

Registration for the EuBIS#Virtual seminar:

Training course participants are requested to **register via the BloodTrain GHP (PEI**). Please write an e-mail to BloodTrain@PEI.DE referring in the e-mail header to**: EuBIS#Virtual Workshop**

Publication notice:

EuBIS inspection manual and guide

The training is performed based on the EuBIS manual and EuBIS Guide developed under the Public Health Programme co-funded by the European Commission, Health and Consumer Protection Directorate General, Public Health and Risk Assessment Directorate, DG Sanco Grant Agreement No. 2006202. (2003-2008)

The manual and guide comprise common standards and criteria for the inspection of blood establishments and have been developed based on the European blood legislation and cross referenced to GMP, EDQM, PIC/S standards and the GP guidelines referred to in Directive 2016/1214.

Further information on this manual including updated versions is available from the project Website of **EUBIS (European blood inspection system)** (www.EUBIS-europe.eu).

Supported by the European Blood Alliance (EBA)

The
EuBIS Inspection Standards and Criteria
EuBIS Inspection Training Guide
Educational Material

are the **final versions developed by the EuBIS Project (Copyright ®).**

CATIE facilitator manual

For the educational material of this course parts of the exercises have been based on the CATIE Facilitator manual developed by the CATIE consortium under the contract No. 2011/S 167-27519 of the Executive Agency for Health and Consumers (EAHC) and the Directorate General Sanco (GD Sanco).

Disclaimer:

The content of the manual, guide or the educational material does not necessarily reflect the views of the European Commission. Neither the Commission nor any person acting on its behalf can be held responsible for any use that may be made of the information in this report.

Neither the EuBIS Academy members nor the European Commission assume any responsibility for the use that may be made of the information in the manual and training material.

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Virtual – Programme 8.-9. September 2021 - Overview

Agenda

Wednesday, 8th of Sept. 21	**Day 1**	Chairs
Time	**Title**	Speaker
13:00–16:15	**Overview on GMP/GPG**	
	Common regulatory requirements and quality standards (*EuBIS manual and guide*) and updated cross-references to GMP/GP guidelines	Jens Reinhardt (PEI) Christian Seidl (EuBIS) Simonetta Pupella (EuBIS) Alex Aquilina (EuBIS) Fewzi Teskrat (EuBIS) Margarida Amil (EuBIS) Jose Manuel Cardenas (EuBIS)
	The GP Guidelines (Directive 2016/1214): Essential elements of quality management for blood establisments	
	Good practice for blood components and source plasma for fractionation with reference to the EuBIS manual and guide *(GMP and GP guidelines)*	
	Q&A (Quiz)	
Thursday, 9th of Sept. 21	**Day 2**	Chairs
Time	**Title**	Speaker
13:00 -15:30	**Risk identification**	
	General requirements for risk identification and analysis	Christian Seidl (EuBIS) Alex Aquilina (EuBIS) Fewzi Teskrat (EuBIS) Margarida Amil (EuBIS) Simonetta Pupella (EuBIS) Jose Manuel Cardenas (EuBIS)
	Non-Compliances – Classification and risk analysis Case Study – Labelling	
	Q&A - Summary and Conclusions	

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Organiser

The Paul-Ehrlich-Institute (Germany)
Dr. Jens Reinhardt
Division of Haematology and Transfusion Medicine
GHPP BloodTrain
Paul-Ehrlich-Institut
Federal Institute for Vaccines and Biomedicines
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The EuBIS Academy (c/o GRCBDS, Germany)
Prof. Dr. Christian Seidl
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Vice Medical Director,
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In Cooperation with

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Dora Mbanya MD; PhD; FRCPath
Head, Haematology & Transfusion Service Centre Hospitalier et Universitaire (CHU) Yde
Yaounde; Cameroon.
President, Africa Society for Blood Transfusion (AfSBT)

Organisers and Cooperating Partners

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Dr. Vincenzo de Angelis	Director Centro Nazionale Sangue CNS Istituto Superiore di Sanità (ISS), Rome	**Italy**
Dr. Fewzi Teskrat	Senior Expert Substance of Human Origin (SoHO) EuBIS Academy Expert on regulatory aspects for blood, tissue and cells Responsible Person Health-Mater Dei Hospital, Art Clinic	**Malta/France**
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Dr. Jose Manuel Cardenas Díaz de Espada	President of the SETS - Spanish Society of Blood Transfusion and Cellular Therapy Director (emeritus), Centro Vasco de Transfusion y Tejidos Humanos (CVTTH) EuBIS Academy Expert on regulatory aspects for blood and blood components, San Sebastian	**Spain**