

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*

12th – 14th of October 2022
Cape Town, South Africa

Organised by the Paul-Ehrlich-Institute (PEI)
and the EuBIS Academy in cooperation with the
African Society of Blood Transfusion (AfsBT)
and the Western Cape Blood Service (WCBS)



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) 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 – in particular the virtual EuBIS seminar and training, September 2021 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 seminar comprises lectures and group work in a face-to-face fashion 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
- Requirements for buildings, premises and storage facilities
- Validation and Qualification, staff training and evaluation
- Inspection / Internal Audit
- Change Control / Management and risk assessment

The training and seminar is 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 are offered an examination (optional) with a certificate of successful participation in the examination by EuBIS Academy / AfSBT.

The examination will be in English language.

Training places are limited: Selection of training participants and confirmation of participation will be on the basis on time of registration.

Registration

Registration:

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**

Front Picture: By Gary - The plains..., CC BY 2.0, <https://commons.wikimedia.org/w/index.php?curid=2612602>

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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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Organiser and Cooperating Partners

Organiser

The Paul-Ehrlich-Institute (Germany)

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Division of Haematology and Transfusion Medicine
GHPP BloodTrain
Paul-Ehrlich-Institut
Federal Institute for Vaccines and Biomedicines
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Coordination Office, c/o GRC Blood Transfusion Service
Institute of Transfusion Medicine and Immunohematology
Frankfurt am Main, Germany

In Cooperation with

The African Society African Society of Blood Transfusion (AfsBT)

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President, Africa Society for Blood Transfusion (AfsBT)

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Western Cape Blood Service - WCBS (South Africa)

Gregory Bellairs, CEO / Medical Director
Glynis Bowie, Quality Assurance Manager
Head Office: Pinelands



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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
Dr. Alex Aquilina	Director National Blood Transfusion Service Malta, La Mangia EuBIS Academy Expert on regulatory aspects for blood and blood components	Malta
Dr. Margarida Amil	Responsible Person (emeritus) Hospital Blood Bank and Transfusion Medicine, Hospital St António, Centro Hospitalar do Porto EuBIS Academy Expert on regulatory aspects for blood and blood components, Porto	Portugal
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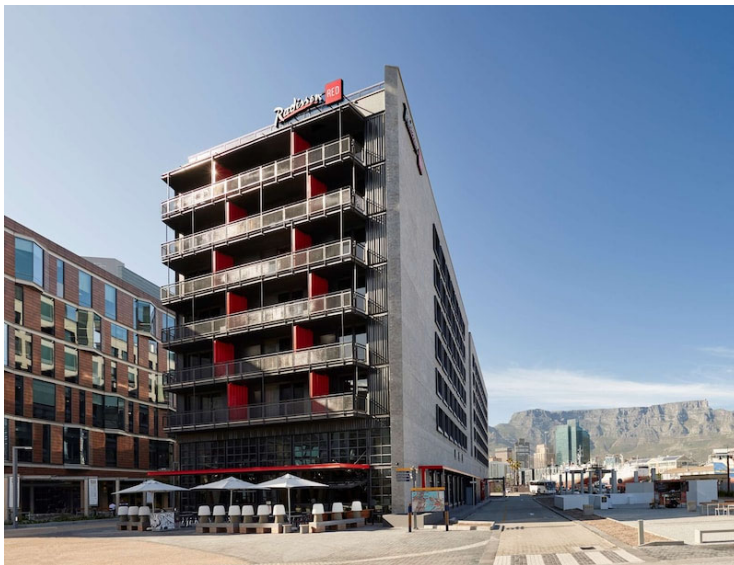


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Meeting Hotel:

Radisson Red Capetown V&A Waterfront

Silo 6, Silo Square, V&A Waterfront,
Cape Town, 8001, South Africa



Training Location – Western Cape Blood Service

