

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



24th – 26th of June 2020, Cape Town, South Africa

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





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 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

<u>Training course participants:</u>

- 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:

Training course participants are requested to register via the

African Society for Blood Transfusion

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