

**EuBIS#Virtual** 

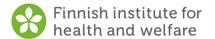
# Quality management and inspection of blood establishments - EuBIS Seminar and Training Workshop –



Organised by the EuBIS Academy in cooperation with the EU funded Support to Ukraine for Developing a Modern Public Health System coordinated by the GFA in consortium with the Finnish Institute for health and welfare







## 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

Organised by the EuBIS Academy in cooperation with Ukrainian Ministry For Health and GFA Consulting with the scope to train on inspection system, 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 in Ukraine .

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

- EuBIS guide covering all critical steps for and Inspection and quality management system with cross-references to PIC/S, EU Directives, GP guidelines and GMP guidelines
- Special focus will be on the following topics:
  - o General principles of quality management systems and inspections
  - o Regulations and regulatory frame-work
  - o Risk assessment.
  - o Qualification, staff training and evaluation
  - Inspection / Internal Audit

Training course language: English (with simultaneous translation into Ukraine)

#### **Training course participants:**

- In the process to be Qualified as inspectors by the Ukrainian National Regulatory Authority (NRA)
- Individuals working in a blood establishment in the area of Quality Management/Quality Control/ Administration.

Participants will receive a certificate of participation.

#### Registration for the EuBIS#Virtual seminar:

Training course participants are requested to **register via GFA - Project Office (Kyiv) Mohammed Farouk ABOUELFARAG, MD, MBA**e-mail: mohammed.abouelfarag@gfa-group.de

EU funded Support to Ukraine for Developing a Modern Public Health System

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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)** (<u>www.EUBIS-europe.eu</u>).

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.

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#### Support to Ukraine for Developing a Modern Public Health System

This project is funded by the European Union Implemented by GFA Consulting Group GmbH in consortium with the Finnish Institute for health and welfare

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#### The EuBIS Academy (c/o GRCBDS, Germany)

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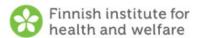
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