

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*

*“Strengthening the Blood Safety and Inspection System
in the Ukraine”*



EuBIS#Virtual 07th – 08th of March 2023

**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**



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:
 - General principles of quality management systems and inspections
 - Regulations and regulatory frame-work
 - Risk assessment.
 - 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

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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:

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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
Seminar and training workshop organised by the EuBIS Academy

Organiser

Support to Ukraine for Developing a Modern Public Health System

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in consortium with the Finnish Institute for health and welfare

Mohammed Farouk ABOUELFARAG, MD, MBA

Key Expert on Blood Safety
Project Office in Kyiv
Ukraine

The EuBIS Academy (c/o GRCBDS, Germany)

Prof. Dr. Christian Seidl

Coordination Office, c/o GRC Blood Transfusion Service
Vice Medical Director,
Institute of Transfusion Medicine and Immunohematology
Frankfurt am Main
Germany

Dr. Fewzi Teskrat

Senior Expert Substance of Human Origin (SoHO)
EuBIS Academy Expert on regulatory aspects for blood, tissue and cells
EuBIS International Councilor
France



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health and welfare

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Organisers and Cooperating Partners

Mohammed Farouk ABOUELFARAG, MD, MBA	Key Expert on Blood Safety Support to Ukraine for Developing a Modern Public Health System - Project is funded by the European Union Implemented by GFA Consulting Group GmbH in consortium with the Finnish Institute for health and welfare Project Office in Kyiv, Ukraine	Ukraine
Dr. Fewzi Teskrat	Senior Expert Substance of Human Origin (SoHO) EuBIS Academy Expert on regulatory aspects for blood, tissue and cells EuBIS International Councilor	France
Prof. Dr. Christian Seidl	EuBIS Academy Coordinator Vice Medical Director German Red Cross Blood Donation Service (GRCBDS) , Institute of Transfusion Medicine and Immunohematology, Frankfurt/Main	Germany
Dr. Simonetta Pupella	Director Medical Affairs & Blood Inspection System – CNS Istituto Superiore di Sanità (ISS), Rome <i>EuBIS Academy Expert on regulatory aspects for blood and blood components</i>	Italy
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
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