



XXXIst International Congress of the ISBT
BERLIN, GERMANY, JUNE 26 - JULY 1, 2010



EuBIS Seminar and Training

Standards and Criteria for the Inspection of Blood Establishments



*From 'good to best' practice
implementing
quality management requirements to safeguard
the 'vein' to 'vein' process*

organised by the EUBIS Project in cooperation with the ISBT Academy





EuBIS Seminar and Training, ISBT congress, Sunday 27th of June

Welcome Address

Dear colleagues and friends,

the EuBIS objective is 'to ensure that patients who receive blood transfusion in the European Union are given safe blood'.

This goal is specifically supported by the development of criteria and standards for the inspection of blood establishments based on the EU blood legislation. These are summarised in a manual designed to assist

- blood establishments in need to optimise their quality system and self-inspection process related to the EU blood directive.*
- blood establishments to prepare for regulatory inspections by competent authorities and*
- competent authorities, which wish to use the manual as a reference for the implementation process of the European blood legislation related to regulatory inspections.*

The manual is accompanied by a training guide and educational material to assist the inspection process.

The Project is co-funded by the European Commission under the framework of its Public Health Programme addressing the quality and safety of blood.

EuBIS is coordinated by the German Red Cross Blood Donation Service with the participation of 25 collaborating partners from 19 Member States, cooperative working partnerships with five organisations and three projects, and is supported by the European Blood Alliance.

The EuBIS seminar and training during the ISBT congress is organised in cooperation with the ISBT Academy.

On behalf of all Project participants and collaborating partners, we would be happy to welcome you to this 1st International EuBIS course in Berlin.

Prof. Dr. Dr. h.c. Erhard Seifried

Prof. Dr. Christian Seidl



PROGRAMME (EuBIS), Sunday the 27th of June,

9:00-12:00 **Session I – Quality management and Regulatory inspections EuBIS Manual and Training Guide**

9:00 Opening and Welcome
Prof. Dr. Erhard Seifried, president ISBT and EuBIS project leader

Chair: Prof. Dr. Erhard Seifried, Prof. Dr. Christian Seidl

9:10 The EUBIS standards and criteria for the inspection of blood establishments
Introduction and overview of the EuBIS manual and training guide
Prof. Dr. Christian Seidl, EuBIS project coordinator, Germany

9:40 EuBIS Manual - Preparing for regulatory inspections
Mark Nightingale, WP-Leader, NHSBT, United Kingdom

10:10 Coffee break

Chair: Prof. Dr. Rainer Seitz, Dr. Jeroen deWit

10:30 EuBIS manual - Regulatory inspection scheme
Dr. Margarethe Heiden, Paul-Ehrlich Institute, Germany

11:00 The EUSTITE Guidelines for the inspection of tissue and cell facilities
SOHO V&S project (new EU project: Vigilance and Surveillance of Substances of Human Origin)
Dr. Deirdre Fehily, CNT, Italy

11:30 Training exercises and tools – Preparing for Regulatory Inspections
EuBIS educational material - Overview
Dr. Jan Peter Jansen van Galen, WP-Leader, Sanquin, The Netherlands

12:00 Lunch break (served in the meeting room)

12:30-15:30 **Session II – Training requirements for good practice**

Chair: Prof. Dr. Giuliano Grazzini, Dr. Alan Slopecki

12:30 The EU Blood and Tissue directive requirements
Dr. Brita Kaltenbrunner-Bernitz, PhD, European Commission
Directorate-General for Health and Consumers, DG Sanco, Belgium

12:50 WHO activities in training and education
Dr. Neelam Dhingra, Coordinator, Blood Transfusion Safety, WHO Headquarters,
Switzerland

13:10 The ISBT perspective on good practice in blood establishments
Dr. Silvano Wendel, president elect ISBT, Brazil

13:30 Coffee break



PROGRAMME – continued (EuBIS), Sunday the 27th of June

Chair: Prof. Dr. Christian Seidl, Dr. Fewzi Teskrat

13:45

EuBIS educational material - Manual Part C Training exercise for good practice in blood establishments

- Donor management and collection
- Manufacturing and component production
- Testing and release

Boudewijn Hinloopen, BSc. BEd, Sanquin, The Netherlands
Dr. Alex Aquilina, MBTS, Malta
Jan Ceulemans, BBTS, Belgium

- Corrective and preventative actions
Dr. Fewzi Teskrat, Afsapps, France

14:30

Training on national levels based on EuBIS educational material

- Dr. Klara Baroti-Toth, HBTS, Budapest, Hungary
- Prim. MUDr. Zuzana Cermakova, FNSPO, Ostrava, Czech Republic
- Prof. Dr. Giuliano Grazzini, CNS, Rom, Italy

15:20

Concluding remarks and training course announcement
Prof. Dr. Christian Seidl and Prof. Dr. Giuliano Grazzini

15:30

End of EuBIS seminar and training

18:00

ISBT congress - Opening Ceremony

Welcome addresses

Opening Performances (Concert and Ballet)

19:30

Welcome reception (until 22:00)

Trade Hall and Exhibition Area, ICC



EuBIS Seminar and Training

Standards and criteria for the Inspection of blood establishments

General Information

Date: Sunday, the 27th of June 2010
Time: 9:00 – 15:30 (registration open from 8:00 am)

Meeting venue: ICC Berlin, Room 42

Messedamm 22
14055 Berlin
Germany
<http://www.icc-berlin.de>

Registration:

The following registration fee apply :

free for all registered ISBT congress participant
registration:

A special reduced weekend (Saturday and Sunday) rate is available for registration to the ISBT Academy programme

100,- Euro only Saturday and Sunday (ISBT Academy)*

*includes

- Opening Ceremony
- Welcome Reception

For online registration please refer to: <http://www.isbt-web.org/berlin>





Sunday, the 27th of June – ISBT Programme Overview

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|---------|--|----------------------------|---|--------------------------|--|--|
| 08:30 ▶ | | ISBT Working Party on TTID | EUBIS Project Quality Management and Regulatory Inspections | ISBT Working Party on IT | ISBT Working Party on Donors and Donation | |
| 10:00 ▶ | Coffee break | | | | | |
| 10:30 ▶ | DGTI Fortbildungsveranstaltung für Transfusionsverantwortliche und -beauftragte* | ISBT Working Party on TTID | EUBIS Project Training Course | ISBT Working Party on IT | ISBT Working Party on Donors and Donation | Koch Metschnikow Forum** |
| 12:00 ▶ | Lunch break | | | | | |
| 12:30 ▶ | DGTI Fortbildungsveranstaltung für Transfusionsverantwortliche und -beauftragte* | ISBT Working Party on TTID | EUBIS Project Training Course | ISBT Working Party on IT | | Koch Metschnikow Forum** |
| 14:00 ▶ | DGTI Fortbildungsveranstaltung für Transfusionsverantwortliche und -beauftragte* | ISBT Working Party on TTID | EUBIS Project Training Course | ISBT Working Party on IT | S1 Pediatric transfusion medicine | |
| 15:30 ▶ | Tea break | | | | | |
| 16:00 ▶ | DGTI Fortbildungsveranstaltung für Transfusionsverantwortliche und -beauftragte* | Satellite Symposia | | | S2 German/French Joint Symposium (DGTI/SFTS) | ISBT Working Party on Platelet Immunobiology |
| 17:30 ▶ | Opening Ceremony | | | | | |
| 18:00 ▶ | Opening Trade Exhibition / Welcome Reception | | | | | |
| 19:30 ▶ | Opening Trade Exhibition / Welcome Reception | | | | | |
| 22:00 ▶ | Opening Trade Exhibition / Welcome Reception | | | | | |

* in German

** in German and Russian (Simultaneous Translation)

Session type/stream: ISBT Academy