



EuBIS Seminar and Training

Quality management and inspection criteria
for blood establishments

14th – 15th of April 2011, Rome, Italy



From 'good to best' practice

organised by the EuBIS Academy
in cooperation with Centro Nazionale Sangue (CNS)



2nd International Seminar and Training Course - Rome, 14th -15th of April 2011

Seminar and training scope:

Comprehensive overview of commonly used standards and criteria summarised in the EUBIS manual and training guide

Learn key elements of quality management

Advanced knowledge on how to use the cross-reference to commonly used international standards such as the

- GMP standards
- CoE/EDQM guide
- PIC/S standards.

Common practice and practical advice for the inspections of blood establishments covering the

- collection,
- processing,
- testing to
- storage and distribution of blood

Practical exercises to train your knowledge in

- Planning of inspections and defining critical points
- Risk based assessment and management of errors
- Observation and communication skills
- Classification of observations and errors

Finally the training course will be an excellent opportunity to meet experts in the fields, to discuss and to receive information and advice if required.

Language skills: English



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EuBIS Academy members – Training Session:

Dr. Alex Aquilina, MBTS, Malta
Jan Ceulemans, HBRC-V, Belgium
Boudewijn Hinloopen, Sanquin, The Netherlands
Dr. Helga Huber, PEI, Germany
Dr. Simonetta Pupella, CNS, Italy
Wiebke Siegel, WHO expert, Germany
Dr. Fewzi Teskrat, AFSAPPS, France

Organisers:

Prof. Dr. Christian Seidl, EuBIS academy office
Prof. Dr. Dr. h.c. Erhard Seifried, BSD-BH
Prof. Dr. Giuliano Grazzini, CNS
Dr. Andrea Aguzzi, CNS

Affiliates:

Dr. Alex Aquilina, EBA executive member

Meeting Venue:

Centro Nazionale Sangue (CNS)
Istituto Superiore di Sanita
Via Giano della Bella, 27
00162 Rome

Meeting language. English

Registration fee:

The following registration fee applies: 350,- Euro
Dinner on Thursday evening (optional) 45,- Euro

For registration please refer to:

EuBIS Coordination Office
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Course Information : www.eubis-europe.eu (registration forms)



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Thursday, the 14th of April 2011

9:00-12:00 Seminar I – Quality management and inspections EuBIS Manual and Training Guide

9:00 Opening and Welcome

Introduction of the participants 'Break the Ice'

9:30 Common regulatory requirements and quality standards
(EuBIS manuals)
Discussion (all participants)

10:45 Coffee break

11:00 Essential elements of quality management in blood establishments
(EuBIS training guide)
Discussion (all participants)

12:00-12:45 Lunch break (served in the meeting room)

12:45-18:30 Training Exercises Training exercises and tools – EuBIS educational material – Overview

13:00 -14:15 **Exercise 1 - Inspection design and donor collection**
1.1. Design an inspection
1.2 Donor collection activities

14:30 -16:30 **Exercise 2 - Donor eligibility and blood processing**
2.1 1st case study – Adverse event on blood processing
2.2 Quiz 1: donor eligibility
Quiz 2: Self-inspection and regulatory audit

16:00-18:30 **Exercise 3 – Classification of mistakes (Video exercises)**
3.1 Donor eligibility and blood collection
3.2 Blood processing

18:30-19:00 Summary and conclusion of learning points (Day 1)

20:00 **Dinner** for EuBIS course participants and Academy members



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Friday the 15th of April

9:00 - 10:00 Seminar II - Quality management and inspections EuBIS Manual and Training Guide

9:00-9:30 Quality assurance and specification of whole blood and blood components

9:30-10:00 Risk assessment and management of errors in blood establishments

Discussion (all participants)

10:30 - 11:00 coffee break

11:30 - 18:30 Training exercise

11:30-12:30 **Exercise 4 – Classification of mistakes**
4.1 Classification of mistakes using examples (2 groups)

12:30 – 13.30 lunch

13:30 - 15:00 **Exercise 5 – Blood testing** - role play (BE/CA)
Introduction and preparing (2 groups)
Role play
Debriefing and summary

15:00 - 17:00 **Exercise 6 – Quality assurance and Inspection report**
6.1 Quiz on quality assurance
6.2 Writing non-compliances / reports

17:00-17:30 Summary and conclusion of learning points (Day 2)

17:00 Concluding remarks and *EuBIS Training Certificates*