Common standards and criteria of the inspection of Blood Establishments as proposed by the EuBIS Guide

Prof. Dr. Christian Seidl

EuBIS
European Blood Inspection System
Co-funded by the EC – GA No. 2006202

Regulatory blood inspections: the European framework

Directorate-General for Health & Consumers

Legal base - EU action in health

The Treaty of the Functioning of the European Union – article 168 (former article 152 TEC)

- "A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities"

with kind permission from Brita Kaltenbrunner-Bernitz, DG Sanco, EC

Directorate-General for Health & Consumers

EU legislation – substances of human origin

- **Blood Directive** (2002/98/EC)
  - 3 Implementing Directives (2004/33/EC, 2005/61/EC, 2005/62/EC)
- **Tissues and Cells Directive** (2004/23/EC)
  - 2 Implementing Directives (2006/17/EC, 2006/86)
- **Directive on Organ Donation and Transplantation** (May 2010)
  (Directive 2010/53/EC)

with kind permission from Brita Kaltenbrunner-Bernitz, DG Sanco, EC

TITLE XIII – Public Health - *EU Treaty (Amsterdam)*

Article 152 (4)a and (5) (Article 168)

If a Member State classifies blood as a medicinal product as defined by the pharmaceutical legislation, then it must comply with the that legislation.

Directive 2001/83/EC – Article 1 (2)

Definition of a **medicinal product** :
‚Any substance or combination of substances presented for treating or preventing disease in human beings.‘

‚Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.‘

‚the European blood legislation requirements‘

Directive 2002/98/EC and its **technical annexes**.

Directive 2004/33/EC – Tech. Requirements

Directive 2005/61/EC – Traceability and SAR / SAE

Directive 2005/62/EC - Quality Management

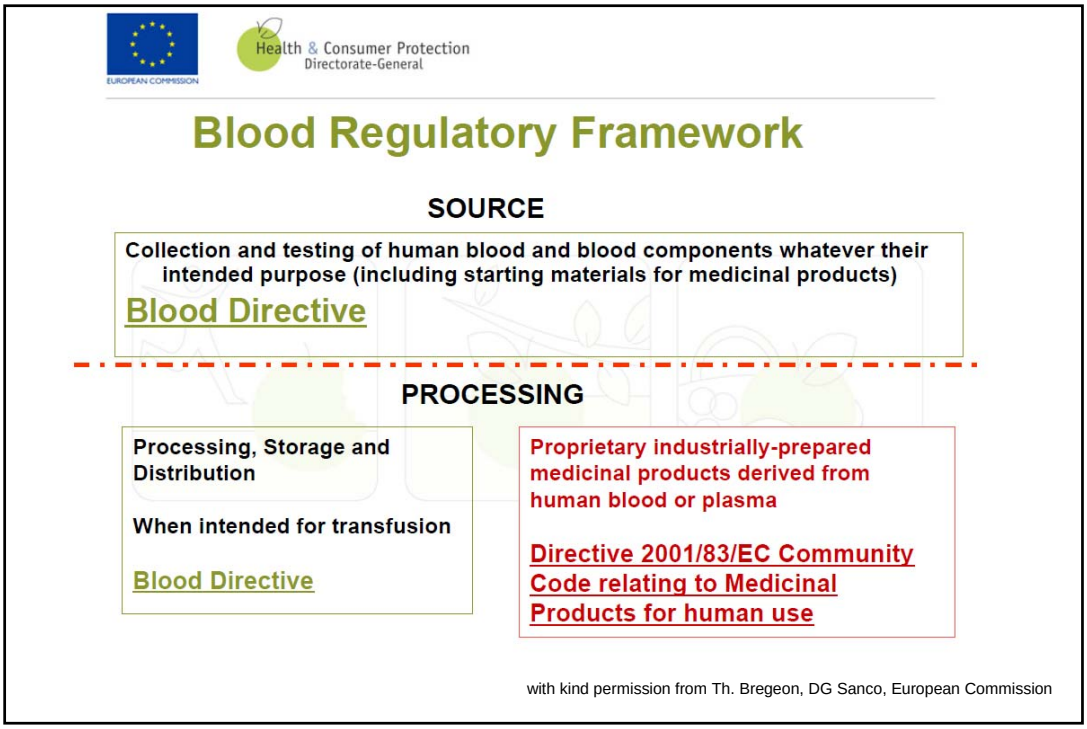
1.10.2005 EN Official Journal of the European Union L 256/41

COMMISSION DIRECTIVE 2005/62/EC
of 30 September 2005
implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments

Article 2 (2005/62/EC). Good practice (GP) guidelines shall be developed by the Commission, .. the Commission shall take fully into account the detailed principles and guidelines of good manufacturing practice (GMP), as referred to in Article 47 of Directive 2001/83/EC.

The Blood and blood components Legal Framework

- Supervision of blood and blood components collection, testing, processing, storage and distribution
- Designation, authorisation, accreditation or licensing of blood establishments
- Inspection and control measures
- Quality systems
- Traceability
- Notification of Serious Adverse Events and Reactions (SAE/SAR)



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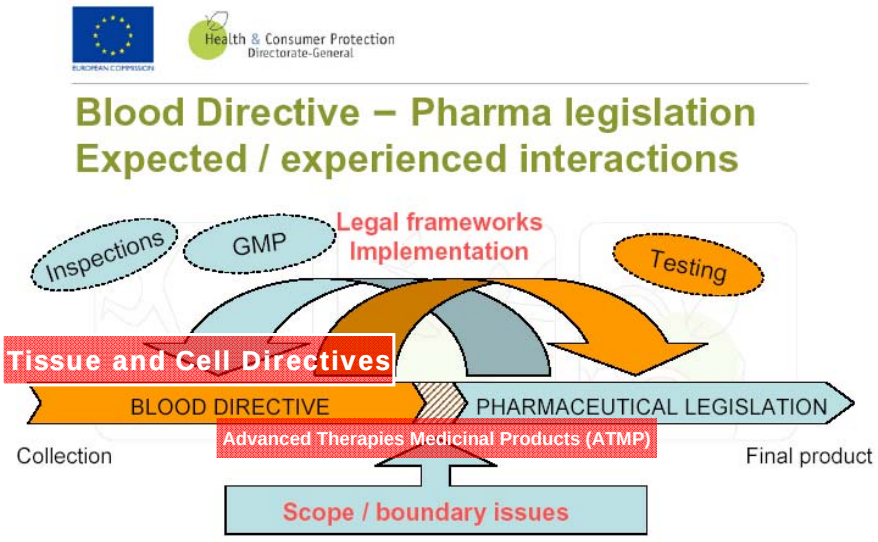


Directive 2002/98/EC
Directive 2004/23/EC

Directive 2001/83/EC

modified with kind permission from Th. Bregeon, European Commission 2008

Directive 2002/98/EC
Article 8 - Inspection and control measures

1. Member States shall ensure that the competent authority (CA) organise inspections and appropriate control measures (ICM).

2. The interval between two ICM shall not exceed two years.

3. Such ICM shall be carried out by officials representing the competent authority who must be empowered to:
(a) inspect blood establishments as well as facilities of any third parties on its own territory
(b) take samples for examination and analysis;
(c) examine any documents relating to the object of the inspection,

4. The CA shall organise ICM as appropriate in the event of any serious adverse event or reaction (SAE/SAR) or suspicion thereof

Health & Consumer Protection Directorate-General

PROJECTS FUNDED IN 2003-2006

Blood

- Standard operating procedures for collection and processing (2004)
- Standards for inspections (2006)
- Optimal use (2006)
- **Optimal Donor Management (2007)**

EU-Q-Blood-SOP
Methodology for standard operational procedures
Co-funded by the EC GA2004217

EuBIS
European Blood Inspection System
Co-funded by the EC – GA No. 2006202

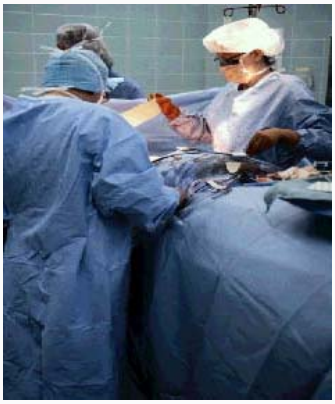
Optimal Blood Use Project
Promoting & sharing best practice across the EU

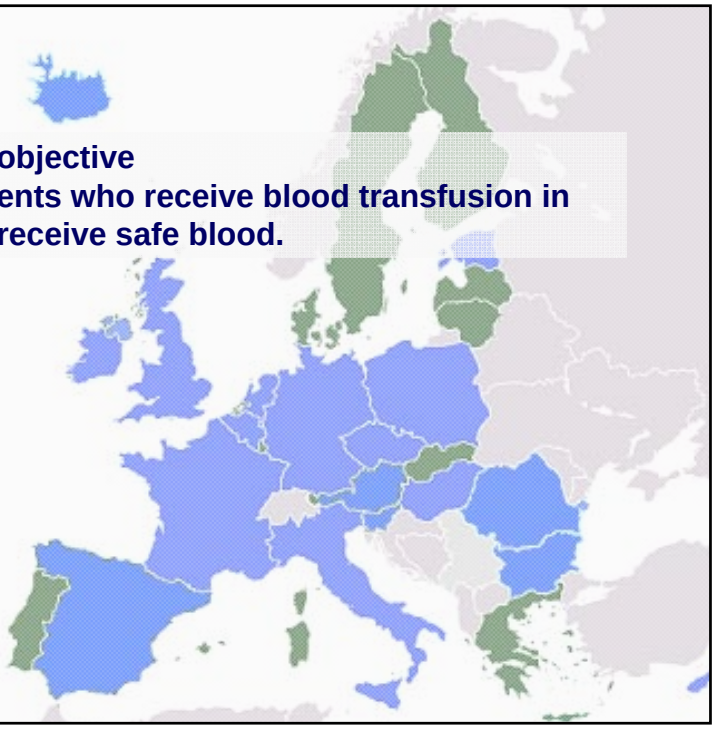
DOMAINE
Donor Management in Europe

Supported by
EBA European Blood Alliance

with kind permission from Th. Bregeon, European Commission 2008

The Projects overall objective is to ensure that patients who receive blood transfusion in the European Union receive safe blood.





Quality Management Standards and Regulatory Inspections

Directive 2005/62/EC Quality Management

Annex

1 General Principles

2 Personnel and Organisation

3 Premises

4 Equipment and Materials

5 Documentation

6 Blood collection, testing and processing

6.1 Donor eligibility

6.2 Collection of blood and blood components

6.3 Laboratory testing

6.4 Processing and validation

6.5 Labelling

6.6 Release of blood and blood components

7 Storage and distribution

8 Contract Management

9 Non-Conformance

9.1 Deviations

9.2 Complains

9.3 Recall

9.4 Corrective and preventive actions (CAPA)

10 Self-inspection, audits and improvements

EU-Q-Blood-SOP (**EQUAL**) **www.equal-blood.eu**

Manual describing a methodology based on good practice that

(1) **assists blood establishments to implement or expand their standard operating procedures (SOPs).**

(2) contributes to the understanding and management of quality processes in blood services.

(3) **assists blood establishments in preparing for the inspection of their services** related to the implementation of quality relevant elements required by the EU directive 2002/98/EC.

EU SOP - Master


EUBIS

EU-SOP | Standard Operating Procedure (SOP) | Page 1 of 4

Scope: Institution / Department (Name the department or unit issuing the SOP)

SOP:
Document-Code (e.g. EU-SOP)
Document-Version (e.g. Version 1.0)

Title: EUBIS SOP Master Document

Valid from: Effective date: Expiry date: A document control procedure must be established to guarantee a regular review of documents and to keep the history of documents (previous versions).

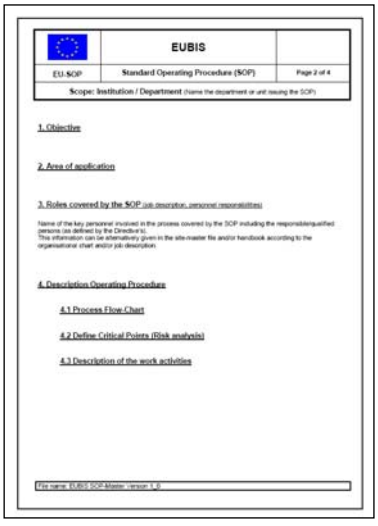
Replaces Version: Document-Code and Document-Version

Changes: - Please describe/list the relevant changes that have been made in comparison to the previous version of the document - Reasons for changes

Distributor: Original: Quality management office; Copy-Identification Number (Examples: 1, 2, 3 etc.); the use of electronic copies is optional

Written by: | Reviewed and authorised by:
Date: | Date:
Name of person(s): | Name of person(s)

File name: EUBIS SOP-Master Version 1.0


EUBIS

EU-SOP | Standard Operating Procedure (SOP) | Page 2 of 4

Scope: Institution / Department (Name the department or unit issuing the SOP)

1. Objective

2. Area of application

3. Roles covered by the SOP (job description, personnel responsibilities)

Name of the key personnel involved in the process covered by the SOP including the responsible/qualified persons (as defined by the Directive's). This information can be alternatively given in the site-master file and/or handbook according to the organisational chart and/or job description.

4. Description Operating Procedure

4.1 Process Flow Chart

4.2 Define Critical Points (Risk analysis)

4.3 Description of the work activities

File name: EUBIS SOP-Master Version 1.0

EQUAL – Blood Quality Project

EU-Q-Blood-SOP

Co-funded by the EC GA2004217

Requests for EU-Q-Blood-SOP Manual

e-book link and/or hardcopy

(October 2007 until September 2010) :

about 302 Institutions

- blood establishments,
- competent authorities
- pharmaceutical industry

from **48 countries** in Europe and World wide

Europe

Austria
Belgium
Bulgaria
Cyprus
Denmark
Finland
France
Germany
Greece
Island
Ireland
Italy
Latvia
Lithuania
Luxembourg
Poland
Portugal
Romania
Slovak Republic
Spain
United Kingdom
- England
- Scotland

Worldwide

Abu Dhabi
Afghanistan
Argentina
Brazil
Canada
Chile
China
Croatia
Egypt
Guatemala
Hong Kong
Israel
Indonesia
Korea
Nigeria
Japan
Morocco
Mexico
Montenegro
Palaestine
Pakistan
Peru
Philippines
Rep. of Macedonia
Russia
Switzerland
South Afrika
Turkey
Sri Lanka
USA

EU-Q-Blood-SOP Project, Project Grant Agreement no. 2004217

EuBIS

European Blood Inspection Project

Co-funded by the EC – GA No. 2006202

EuBIS - General Objectives

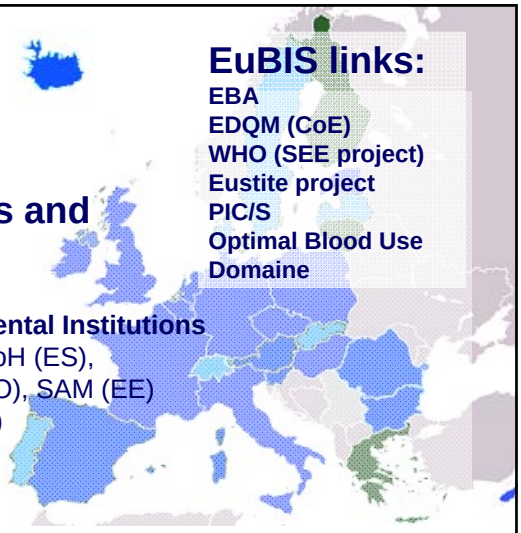
(1) define requirements for quality management systems of blood establishments based on the Directive 2005/62/EC.

(2) develop a manual covering pan European standards and criteria for the inspection of blood establishments based on GMP guidelines to assist national inspections in implementing the Directive 2002/98/EC and its technical annexes.

(3) develop a training programme for inspectors

EuBIS
European Blood Inspection System
Co-funded by the EC – GA No. 2006202

EuBIS Project: Working group participants and collaborating partners



EuBIS links:
EBA
EDQM (CoE)
WHO (SEE project)
Eustite project
PIC/S
Optimal Blood Use Domaine

Competent Authorities and Governmental Institutions
PEI (DE), RPDA (DE), IMB (IE), CVT/MoH (ES),
ISS (IT), MoH (CY), MoH (MT), MoH (RO), SAM (EE)
JAZM (SO), SUKL (CZ), AFSSAPS (FR)

Blood Establishments
GRC-BH (DE), Sanquin (NL), NHSBT (UK), EFS (FR), HNBTS (HU), RBS (AT), HBRK (BE), NBT (BG), FNSPO (CZ), BTS (IS), NBTS (IE), IBT (MT), IHBT (PL), FMP (RO), SBTS (SO), NEBS (EE),

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate C - Public Health and Risk Assessment
C6 - Health measures

Meeting of the Competent Authorities (CA) on blood and blood components (Art. 25 Dir. 2002/98/EC)

18 October 2007
9.30 – 17.00

Brussels, Centre Albert Borschette (CCAB), (Rue Froissart 36, 1040 Bruxelles)
Room: AB-3B

Evaluation Code: EuBIS-Survey-XX-XX EuBIS – Survey Questionnaire Page 1

EuBIS
European Blood Inspection System - Project

Survey-Questionnaire

Preamble:

This questionnaire is an activity of the EuBIS (European Blood Inspection System) Project undertaken in the framework of the EU Public Health Programme and co-funded by the European Commission.

Its aim is to collect information related to the inspection of blood establishments in the European Union which will be used as the basis for the establishment of commonly accepted criteria and standards among Member States (see Annex for Project details).

The questionnaire has been divided into six sections. Sections I - V are related to blood establishments - Processes covered; Member State establishments; Quality Systems; Inspections and audits; and Inspection process. Section VI covers Objectives and deliverables of the EuBIS project.

You are invited to complete this questionnaire and return it by 28 September 2007 to:

Postal Address:

EuBIS Project Management Team
Institut für Transfusionsmedizin und Immunhämatologie
DRK-Blutspendedienst Baden-Württemberg-Hessen gGmbH
JW Goethe Universitätsklinikum
Sandhofstrasse 1
D-60528 Frankfurt am Main
Germany

E-Mail: EuBIS@blutspende.de

Please note! Completed questionnaires will be evaluated by the Project team, who will maintain the questionnaire code in order to ensure data confidentiality.

For assistance in completing the questionnaire, please contact the Project Management Team by e-mail (above), by telephone or by fax (numbers below).

Project Management Team: Dr. Veronika Bittner
Dr. Thea Müller-Auller

Telephone number: +(49)-69-6782-118

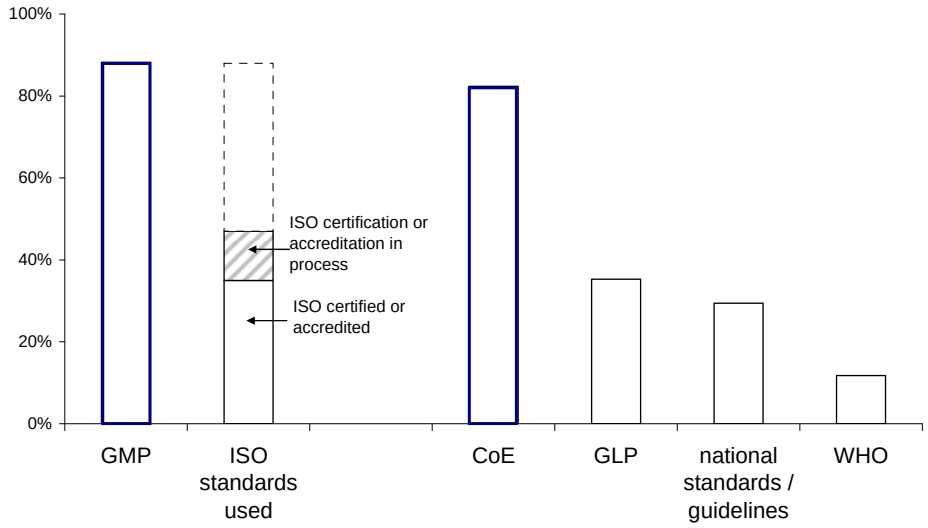
Fax-number: +(49)-69-6782-254

EU-Blood-Inspection Project co-funded by the European Commission, Health and Consumer Protection Directorate General, Public Health and Risk Assessment Directorate - Grant Agreement No 2006202

EuBIS Survey – Blood establishments activity profiles

Activity	%
Blood component preparation	
Cellular (Erythrocyte and / or Platelet concentrates	100
Fresh Frozen Plasma (whole blood)	94
Apheresis component preparation	
Apheresis Erythrocyte / Platelet concentrates	100
Apheresis Fresh Frozen Plasma	75
Related preparations	
Stem cells	75
Cord blood	31
Granulocytes	69
Lymphocytes	50
Source Plasma for Fractionation	75
Cryoprecipitate	56
Autologous blood components	88

Section I - Common standards used for quality systems of blood establishments



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EuBIS Working Groups

WG 1: Quality management system evaluation
WG 2: Donor recruitment and blood collection
WG 3: Processing and testing
WG 4: Blood component issuing, storage and logistics

Meeting of the Competent Authorities
18th October 2007

EDQM CD-P-TS, Strassbourg
29th / 30th October 2007

Ministry of Health, Madrid
13th / 14th of May 2008

Meeting of the Competent Authorities
27th / 28th of Januar 2009

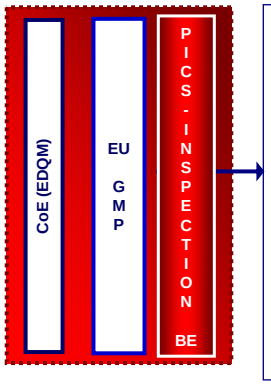
EuSTITE Project Meeting, Mestre, Italy
18th / 19th of Februar 2009

SEE Blood safety project meeting (WHO)
Ljubljana, Slovenia, 17-18 March, 2009

Meeting of the Competent Authorities
7th / 8th of December 2009

EuBIS Manual and Training (WP5)

Cross reference to ‚good practice' following the EU-Directives



European Commission

- 2002/98/EC
- 2005/62/EC Quality Management
- 2004/33/EC Technical Requir.
- 2005/61/EC – Haemovigilance

EUBIS - MANUAL

TRAINING - PROGRAM

Manual

EuBIS
European Blood Inspection Project
Co-funded by the EC – GA No. 2006202

The **EuBIS manual**(s) are designed
to be used as **tools** to advise

- **blood establishments that wish to optimise** their quality system and self-inspection process related to the requirements set by the EU blood directive

- **blood establishments to prepare** for regulatory inspections by competent authorities

- **if wished by competent authority, to be used as a reference** during the implementation process of the EU directive requirements

EuBIS
European Blood Inspection System
Co-funded by the EC – GA No. 2006202

Manual on common inspection standards and criteria

Chapters

3 EU LEGISLATIVE REQUIREMENTS FOR QUALITY SYSTEMS OF BLOOD ESTABLISHMENTS
4 COMMON STANDARDS AND CRITERIA FOR THE INSPECTION OF BLOOD ESTABLISHMENTS

5 SELF-INSPECTIONS OF BLOOD ESTABLISHMENTS

6 INSPECTIONS OF BLOOD ESTABLISHMENTS BY COMPETENT AUTHORITIES
7 CONDUCT OF INSPECTION
8 INSPECTION PROCEDURES – AFTER THE INSPECTION
9 EVALUATION OF THE INSPECTION SYSTEM

ANNEX I **MODIFIED SITE MASTER FILE FOR BLOOD ESTABLISHMENTS (SMF-BE)**

ANNEX II **EUBIS INSPECTION REPORT BY COMPETENT AUTHORITY**

ANNEX III DOCUMENTS CONSULTED IN MANUAL'S DEVELOPMENT
ANNEX IV ADDITIONAL REFERENCES
ANNEX V PROJECT PUBLICATIONS
ANNEX VI TERMINOLOGY (GLOSSARY)
ANNEX VII PARTICIPATING INSTITUTIONS AND COLLABORATING INSTITUTIONS AND INDIVIDUALS

EuBIS
European Blood Inspection System
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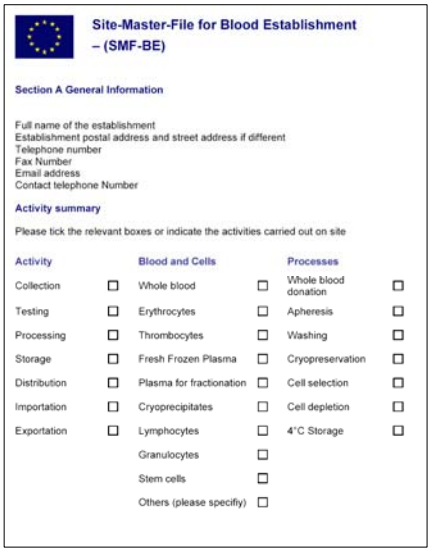
Regulatory Inspection by Competent Authority

ANNEX I
SITE MASTER FILE FOR BLOOD ESTABLISHMENTS (SMF-BE)

Section A - General
- Activity Profile and processes covered
- Blood components processed/manufactured

Section B Activity Details
Section C – Personnel
Section D – Facilities
Section E – Equipment
Section F – Documentation
Section G – Contracts
Sectino H – Haemovigilance
Section I – Complaints and product recall
Section J – Risk Management System
Section K – Quality System



Site-Master-File for Blood Establishment – (SMF-BE)

Section A General Information

Full name of the establishment
Establishment postal address and street address if different
Telephone number
Fax Number
Email address
Contact telephone Number

Activity summary

Please tick the relevant boxes or indicate the activities carried out on site

Activity		Blood and Cells		Processes	
Collection	☐	Whole blood	☐	Whole blood donation	☐
Testing	☐	Erythrocytes	☐	Apheresis	☐
Processing	☐	Thrombocytes	☐	Washing	☐
Storage	☐	Fresh Frozen Plasma	☐	Cryopreservation	☐
Distribution	☐	Plasma for fractionation	☐	Cell selection	☐
Importation	☐	Cryoprecipitates	☐	Cell depletion	☐
Exportation	☐	Lymphocytes	☐	4°C Storage	☐
		Granulocytes	☐		
		Stem cells	☐		
		Others (please specify)	☐		

Regulatory Inspection by Competent Authority

ANNEX II
EUBIS INSPECTION REPORT BY COMPETENT AUTHORITY

Accreditation / designation / licensing number
Inspection date
Name of Inspectors
Introduction
- Description of activity profile and processes
- Date of previous inspection
- Major changes since last inspection

Report on the inspection activites undertaken
Inspection findings and observations
List of Non-Compliances (classified)
Suggestions
Summary and conclusion
Final statement

Annexes

Annex II EuBIS Inspection report by competent authority

Blood Inspection Report

Inspected site(s)	Name and full address of the inspected site
Activities carried out	Collection: In-house / External stationary sites / Mobile units Processing: from whole blood / by apheresis Laboratory testing: Storage and transportation / Distribution Source plasma for fractionation / Cryoprecipitate Other: (please define)
Inspection date	Day, month, year
Inspector(s)	Name of inspector(s)
	Name of expert / assessor (if applicable)
	Name of the Competent Authority
References	Accreditation/designation/authorisation/licensing number or date

Regulatory Inspection by Competent Authority

Inspection classification according to the EuBIS Manual (6.3, pag.56)

❑ Authorisation inspection: *takes place in order to assess a particular situation (new BE, new facility, new activity)*

❑ Routine inspection: *implies a visit to the BE at least every two years (Directive 2002/98/EC, article 8)*

❑ Product/process related inspection: *to look at a particular product/process related change (process change affecting the product specification)*

❑ Event-related inspection: *in cases of serious adverse events or reactions reported by the BE (specific risk assessment by the CA)*

❑ Non-routine/unannounced inspection: *as a consequence of a suspected "illegal" activity or serious breach of legal requirements*

Regulatory Inspection by Competent Authority

Type of inspection

1. **General system evaluation:** *it focuses on the quality management through the evaluation of documented evidence (site master file, quality manual, quality policy, document change control….)*

2. ***Technical and process evaluation:*** it concentrates on assessing practical performance during work hours *(handling procedures and qualification of the staff involved during collection, processing and testing of blood and blood components)*

Regulatory Inspection by Competent Authority

Non-compliance classification

- ❑ Critical non -compliance: *any non-compliance in a process or a written procedure which directly affects the safety of donors or patients*
- ❑ Major non-compliance: *a serious non-compliance in a process or a written procedure but does not in its own affect the safety of donors or patients*
- ❑ Other significant non-compliance: *a non-compliance in a system or process not classifiable as critical or major (minor)*
- ❑ Observation: *an inadequacy in a system or process that is not a failure to comply with standard*

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EuBIS Inspection guide - content

A training guide
Practical information / guidance
Provides:

- Detailed audit criteria
  - Critical control points in processes / procedures
  - Example evidence to confirm conformance
- Cross references to audit standards:
  - Primary: EU Blood Directives
  - Secondary: GMP, EDQM (CoE), PIC/S
- Document templates
  - Self inspection record / audit trail.
  - Self inspection summary report

Training guide (WP5)

Structure follows
Directive 2005/62/EC

Cross-referenced to
Directive 2002/98/EC
Directive 2004/33/EC
Directive 2005/61/EC
Directive 2005/627EC

GMP
PIC/S
EDQM (CoE Guide)

Risk-Management - Legal and normative basis

• **EuBIS manual and guide (Chapter 5 and 3)** - Quality Risk Management „ Integration of quality risk management into self-inspection“

- **GMP-Guideline (EudraLex – Annex 20) referring to medicinal products (Directive 2001/83/EC)**

- **Blood Directive 2002/98/EC**
- **Blood Directive 2004/33/EC**
- **Blood Directive 2005/61/EC**
- **Blood Directive 2005/62/EC**
- **EDQM – Council of Europe Guide**
- **PIC/S**

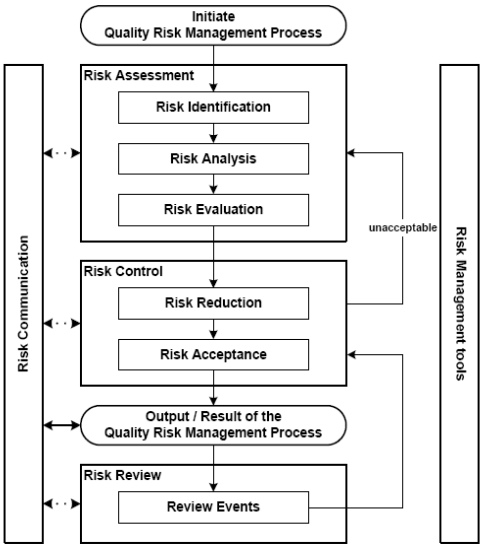
- National Legal Requirements: e.g. AMG §63a/b:
- ISO standards

Risk-Management – EuBIS manuals

EuBIS manual (Chapter 5.3)
-Quality Risk Management
„ Integration of quality risk management into self-inspection“
GMP-Guideline (EudraLex – Annex 20)

EuBIS guide (Chapter 3)
- „Equipment and materials“ (Chapt. 3.4)
- „Blood collection, testing and processing“ (Chapt. 3.5)
- „Non-Conformance“ (Chapt. 3.8)
- „Self-Inspections, audits and imporvements“ (Chapt.3.9)
- „Traceability and notification of serious adverse reactions and events“ (Chapt. 3.10)

EuBIS manual (Chapter 5.3) - Quality Risk Management – **Page 34**
„ Integration of quality risk management into self-inspection“



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European Blood Inspection System
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EuBIS Self-inspection record / audit trail

An easily adopted, comprehensive record of audit

- Document control (of form) section
- Audit detail:
  - Audit date and reference number
  - Department, audit scope, processes covered
  - Auditor(s) / auditee attendance lists / signatures
- Audit findings
  - Criterion number/code (e.g. ref. EuBIS inspection guide)
  - Details of inspection criterion / area examined
  - Auditors findings including evidence of non-conformance
  - Conclusion for each criterion – Is there a non-conformance? What is the severity?

EuBIS
European Blood Inspection System
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	Quality Management System	EuBIS
EU-Inspection	Self-Inspection Record / Audit Trail	Page 5 of 5
Scope: (Name the departments / processes to be inspected		> <

EuBIS	Record	Version: XYZ

Criterion No.	Inspection Criterion or Clause / Area examined	Findings / Evidence	Conclusion / NCR / Severity*
PO 001	**Example of an inspection criterion:** Sufficient qualified personnel to carry out all the tasks which are the responsibility of the manufacturer. Individual responsibilities are clearly understood by the individuals and recorded. Roles and responsibilities are defined within the organisation.		
PO 001	**Example of a Clause / Area** Clause: 2002/98/EC, Article 10, 2005/62/EC, Annex 2.0 and GMP Chap. 2., Annex 16 Area: Personnel in General		
Etc.			

NCR=Non-Compliance Reference (e.g. NCR 1); Severity = Classification of NCRs using following classification: critical, major, other (other significant) and observations – see EuBIS Manual (Inspection standards and criteria)
* Clause: The standard used for the self-inspection (e.g. GMP)

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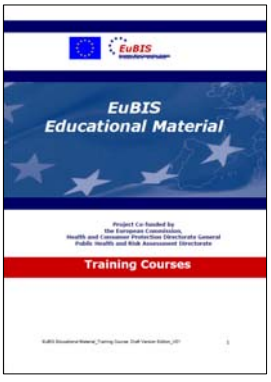


EuBIS – Training programme

Section 1 – Course (Educational material)

Basic and advanced
Exercises/Quiz/Case Studies/RolePlay/

Section 2 – Experimental audits/inspections

Joint inspections (On site visits)
Familiarisation visit to BE
Workshop(s) adapted to national requirements

based on the manuals

EuBIS – Training programme

Table of Contents:

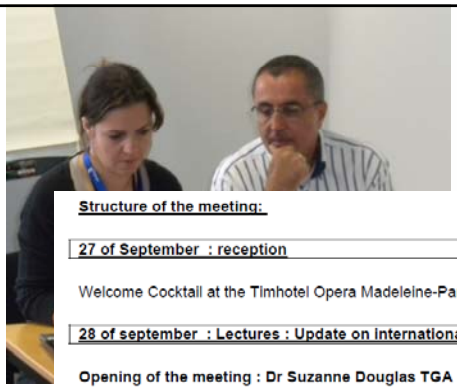
Training (HU) hosted by HBTS 14th – 18th of April 2010

EuBIS - Experimental Audit

organised by CNS in cooperation with EuBIS

CENTRO NAZIONALE SANGUE

Ancona
Udine
Palmanova
Gorizia



PIC/S FIRST ANNOUNCEMENT

Paris February 2010

17th PIC/S EXPERT CIRCLE ON HUMAN BLOOD AND TISSUE

The French Health Pr… Safety Agency …ctors …int-

Structure of the meeting:

27 of September : reception

Welcome Cocktail at the Timhotel Opera Madeleine-Paris : Fewzi Teskrat and Suz… Douglas

28 of september : Lectures : Update on international activities.

Opening of the meeting : Dr Suzanne Douglas TGA (Chairman of the PICS)

IAEA : Keys elements of inspection of irradiation facilities and processes (Dr Jan …)

ISO : The development of ISO standards (Dr Gabrielle Troscher)

ISO : application of risk management to viable material of human origin used for the … of medicinal products (a new ISO norm) (Pr Sabine Klopt)

EUBIS : Achievements of the project (Pr Christian Seidl)

PIC/S : The PIC/S Aide Memoire on Inspection of Testing Laboratories (Dr Patrick …MB)

SOHO V&S project (new EU project: Vigilance and Surveillance of Substances of … Origin) (Dr Deirdr… Fehily and Dr Fewzi Teskrat)

AATB : Accreditation versus inspection of tissue establishments (Dr Scott Brubaker…)

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- EuBIS Manual
- EuBIS Inspection guide

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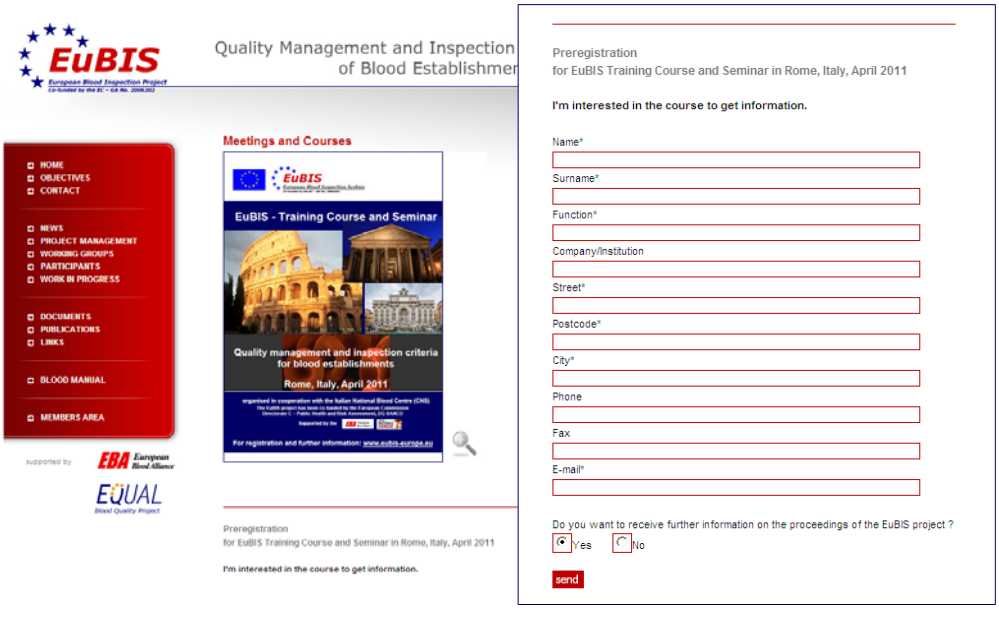

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www. equal-lood.eu / eubis-europe.eu

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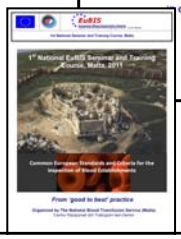
EuBIS Academy Courses



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Thank you