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

Prof. Dr. Christian Seidl

Regulatory blood inspections: the European framework
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

EU legislation – substances of human origin


  - 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.'


Directive 2004/33/EC — Tech. Requirements
Directive 2005/61/EC — Traceability and SAR / SAE

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)
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.
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


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
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.
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 worldwide*

<table>
<thead>
<tr>
<th>Europe</th>
<th>Worldwide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
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</tr>
<tr>
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<td>- Scotland</td>
<td>Philippines</td>
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<td>Rep. of Macedonia</td>
</tr>
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</table>

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**EuBIS - General Objectives**


3. **develop a training programme for inspectors**
EuBIS Project:
Working group participants and collaborating partners

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),

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

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
**EuBIS Survey – Blood establishments activity profiles**

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

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

- ISO certification or accreditation in process
- ISO certified or accredited
- GMP standards used
- CoE
- GLP
- national standards/guidelines
- WHO
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
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
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

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
Section H – Haemovigilance
Section I – Complaints and product recall
Section J – Risk Management System
Section K – Quality System
ANNEX II
EUBIS INSPECTION REPORT BY COMPETENT AUTHORITY

Accrediation / 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 activities undertaken
Inspection findings and observations
List of Non-Compliances (classified)
Suggestions
Summary and conclusion
Final statement

Annexes

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
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)

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
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

<table>
<thead>
<tr>
<th>Training guide (WP5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 INTRODUCTION</td>
</tr>
<tr>
<td>3 GENERAL INFORMATION (HOW TO USE THIS TRAINING MANUAL)</td>
</tr>
<tr>
<td>4 INSPECTION GUIDE</td>
</tr>
<tr>
<td>4.1 Licensing requirements</td>
</tr>
<tr>
<td>4.2 General principles – Quality system and quality assurance</td>
</tr>
<tr>
<td>4.3 Personnel and organisation</td>
</tr>
<tr>
<td>4.4 Premises</td>
</tr>
<tr>
<td>4.4.1 Blood donor and collection area</td>
</tr>
<tr>
<td>4.4.2 Blood testing and processing areas</td>
</tr>
<tr>
<td>4.4.3 Storage area including blood</td>
</tr>
<tr>
<td>4.4.4 Waste disposal area</td>
</tr>
<tr>
<td>4.5 Equipment and materials</td>
</tr>
<tr>
<td>4.6 Documentation</td>
</tr>
<tr>
<td>4.7 Blood collection, testing and processing</td>
</tr>
<tr>
<td>4.7.1 Donor eligibility</td>
</tr>
<tr>
<td>4.7.2 Collection of blood and blood components</td>
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<tr>
<td>4.7.3 Laboratory testing</td>
</tr>
<tr>
<td>4.7.4 Processing and validation</td>
</tr>
<tr>
<td>4.7.5 Labelling</td>
</tr>
<tr>
<td>4.7.6 Release of blood and blood components</td>
</tr>
<tr>
<td>4.8 Storage and distribution</td>
</tr>
<tr>
<td>4.9 Contract management</td>
</tr>
<tr>
<td>4.10 Non-conformance</td>
</tr>
<tr>
<td>4.11 Self-Inspection, audits and improvements</td>
</tr>
<tr>
<td>4.12 Traceability and notification of serious adverse reactions and events</td>
</tr>
<tr>
<td>4.13 Information Technology (IT)</td>
</tr>
<tr>
<td>5 ANNEX I – PREPARATORY DOCUMENTS</td>
</tr>
<tr>
<td>Self-Inspection record / trail</td>
</tr>
<tr>
<td>Self-Inspection Summary Report</td>
</tr>
<tr>
<td>6 ANNEX II DOCUMENTS CROSS-REFERENCED</td>
</tr>
<tr>
<td>7 ANNEX II – ADDITIONAL REFERENCES</td>
</tr>
<tr>
<td>8 ANNEX III – PROJECT PUBLICATIONS</td>
</tr>
<tr>
<td>9 ANNEX IV – TERMINOLOGY</td>
</tr>
<tr>
<td>10 ANNEX V – PROJECT PARTICIPANTS AND COLLABORATING INSTITUTIONS</td>
</tr>
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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
- 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 improvements“ (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“

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 – 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

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**Quality Management System**

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<th>Version: XYZ</th>
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**Criterion No.**

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<th>Inspection Criterion or Clause / Area examined</th>
<th>Findings / Evidence</th>
<th>Conclusion / NCR / Severity*</th>
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**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:
  - Area: Personnel in General

Etc.

NCR=Non-Conformance 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)
EuBIS – Training programme

Table of Contents:

<table>
<thead>
<tr>
<th>Subject</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quiz</td>
<td></td>
</tr>
<tr>
<td>Donor Eligibility / Blood donation</td>
<td>7</td>
</tr>
<tr>
<td>Self Inspection</td>
<td>9</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>12</td>
</tr>
<tr>
<td>Case Studies</td>
<td></td>
</tr>
<tr>
<td>Designing an self inspection</td>
<td>15</td>
</tr>
<tr>
<td>Blood processing</td>
<td>22</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>23</td>
</tr>
<tr>
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</tr>
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<td>Role plays</td>
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<tr>
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</tr>
<tr>
<td>Blood testing</td>
<td>26</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>27</td>
</tr>
<tr>
<td>Real life video’s</td>
<td></td>
</tr>
<tr>
<td>Blood processing observation forms</td>
<td>29</td>
</tr>
<tr>
<td>Blood collection observation form</td>
<td>33</td>
</tr>
<tr>
<td>Evaluation form</td>
<td>34</td>
</tr>
</tbody>
</table>
EuBIS - Experimental Audit
organised by CNS in cooperation with EuBIS

EuBIS - Experimental Audit
National Network on Standards and Certification of Blood Establishments
Ancona, 27 - 28 May 2005

Congress president: Dr. F. Testkrat

Korea
Australia
Ireland
Israel
USA
Brazil
Canada
Malaysia
Finland
Portugal
Estonia
USA
Latvia
Luxembourg
Belgium
Schweden
Hungary
Romania
Greece
China
Estonia
Singapore
Cyprus
Canada
Malta
The Netherlands
Austria
Germany

Structure of the meeting:

27 of September: reception
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 Gabriele Treschter)
ISO: Application of risk management to viable material of human origin used for the production of medical products (a new ISO norm) (Dr Sabine Klop)
EU BIS: Achievements of the project (Ir Christian Seidt)
PICS: The PICS Aid Memoire on inspection of Testing Laboratories (Dr Patrick)
SOHO V&S project (new EU project: Vigilance and Surveillance of Substances of Phytosanitary and Dr Pevzner Testar)
AATB: Accreditation versus inspection of tissue establishments (Dr Scott Brubaker)
EuBIS – www.eubis-europe.eu Manuals / e-books

Free copies as PDF
- Eu-Blood-SOP
- EuBIS Manual
- EuBIS Inspection guide

Europe
- Austria
- Belgium
- Bulgaria
- Cyprus
- Denmark
- France
- Germany
- Greece
- Iceland
- Ireland
- Italy
- Norway
- Poland
- Romania
- Spain
- United Kingdom
  - England
  - Scotland

World Wide
- Argentina
- South Korea
- Russia
- Switzerland
- Indonesia
- Nigeria
- Sudan
- South Africa
- Pakistan
- USA

EuBIS – www.eubis-europe.eu Training Courses

Meetings and Courses

Preregistration

I am interested in the course to get information.

Name*
Surname*
Email*
Company/institution*
Address*
Postcode*
City*
Phone
Fax
Email*

Do you want to receive further information on the proceedings of the EuBIS project?

[ ] Yes  [ ] No
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www.equal-lood.eu/eubis-europe.eu

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Jose Manuel Cardenas (Spain)
Petr Turek, GTH (Czech Republic)
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Carme Talu, BCT (Romania)
Dan Roänner, BCT (Romania)
Simona Parvu, MoR (Romania)
Corna Posus, MoH-BTS (Romania)
Harald Schennach, ABTS (Austria)
Tatjana Plahova, NEBC (Estonia)
Riina Niidás, NEBC (Estonia)
Svetlana Orlova, ECA (Estonia)
Zoe Sideras MoH (Cyprus)
Sveinn Gudmundsson IBTS (Iceland)
Ina Björg Hjalmarsdotir (Iceland)
Alex Aquilina NBTs (Malta)
Richard Zammit MoH (Malta)
Frances M. Delaney, FMD (Luxembourg)
Angus McMillan Douglas, AMD (Scotland)
Dragoslav Domanovic, BTS-CS (Slovenia)
Irena Razborsek, BTS-CS (Slovenia)
Andriana Tivadar, JAZMP (Slovenia)

EuBIS Academy Courses

EuBIS Senior and Training
Quality management and inspection criteria for blood establishments
14th–15th April 2011, Rome, Italy

From ‘good to best’ practices
organized by the EuBIS Academy
cooperating with Centro Biologico di Scienze (CNS)
**EuBIS Academy Courses**

<table>
<thead>
<tr>
<th>Manual and Guide Drafting Group:</th>
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<tbody>
<tr>
<td>Christian Seidl</td>
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<tr>
<td>Frances Delaney</td>
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<tr>
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<td>Fewzi Teskrat</td>
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<th>Educational Material Drafting Group:</th>
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<tr>
<td>Jan Peter Jansen van Galen</td>
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<tr>
<td>Boudewijn Hinloopen</td>
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<tr>
<td>Svetla Bakalova</td>
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<td>Jan Ceulemans</td>
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<th>WP leaders:</th>
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<tbody>
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<th>Advisory Board:</th>
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<tbody>
<tr>
<td>Erhard Seifried</td>
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<tr>
<td>Frances Delaney</td>
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<tr>
<td>Angus Macmillan Douglas</td>
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<td>Jeroen de Wit</td>
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<th>Training Course Organiser:</th>
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<tbody>
<tr>
<td>Klara Baroti Toth</td>
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<td>Zuzana Cermakova</td>
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<tr>
<td>Giulinano Grazzini</td>
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<tr>
<td>Simonetta Pupella</td>
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<td>Alex Aquilina</td>
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**Thank you**

[EuBIS Academy Courses](http://www.eubis-europe.eu)