EuBIS
European Blood Inspection System
Initiated under the Public Health Programme of the European Commission, DG Sanco, EC – GA No. 2006202

Funded by

11th EuBIS Seminar and Training

'Good practices in blood components and medicinal products referring to GPG and GMP'

Quality management and inspection criteria for blood establishments and pharmaceutical products

6th – 8th of March 2019, Florence, Italy

Programme

organised by the EuBIS Academy
in cooperation with the Centro Nazionale Sangue (CNS)
with the patronage of the Regione Toscana

REGIONE TOSCANA

11th International Seminar and Training Course - Florence, 6th – 8th of March 2019

Welcome

Dear participants,

Quality management and inspection of blood establishments are a key stone in achieving best practice and guaranteeing the safety of blood and blood components for transfusion of patients. The European Blood Inspection System (EuBIS), initiated under the Public Health Programme of the European Commission, Directorate General SANCO, has developed a manual and training guide containing standards and guidelines for quality management and the inspection of blood establishments.

Based on the EuBIS manual and guide the EuBIS Academy has organised training seminars and courses in order to promote knowledge in the area of quality and safety of blood and blood components throughout Europe and worldwide. Following the 1st International seminar during the ISBT congress in Berlin, Germany, the 2nd, 3rd, 4th, 5th, 6th 7th, 8th , 9th and 10th Year Anniversary International Seminar and Training Course have been organised in cooperation with the Centro Nazionale Sangue, Ministry of Health in Rome (Italy, 2011), the Belgium Red Cross Flanders in Leuven (Belgium, 2012) the Irish Blood Transfusion Service (Dublin, 2013), the Turkish Red Crescent in cooperation with PIC/S (Istanbul, 2014),the Saudi Society for Transfusion Medicine / Saudi Food & Drug Authority (Ryadh, 2015 and Jeddah 2016), the Centro Nazionale Sangue (CNS) in Rome (2016), the joint workshop with PIC/S (Rome 2015, Hongkong 2016), the ISBT developing Country Award EuBIS workshop and training at the National Institute of Haematology and Blood Transfusion (NIHBT, Hanoi, Vietnam 2017) and the Centro Nazionale Sangue (CNS) in Rome (2018) and in Palermo (2018) the training has received extensive international reputation with participants from EU member states (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Luxembourg, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, The Netherlands, Poland, Portugal, Romania, Spain, Sweden, United Kingdom) and world-wide (Columbia, El Salvator, Norway, Switzerland, Kosovo, Kuweit, Turkey, Brazil, Curacao, Algeria, Lebanon, Morocco, Macedonia, Nigeria, Singapore, Saudi Arabia, Yemen, Qatar, South Africa, South Korea, Vietnam, Ukraine, United State of America).
The 11th International EuBIS Seminar and Training Course is organised by the EuBIS Academy in cooperation with the National Italian Blood Center (CNS) under the patronage of the Regione Toscana and funded by the Istituto Superiore di Sanità (ISS) will be a further milestone in the objectives of EuBIS to give assistance in promoting its mission 'from good to best practice in transfusion medicine'.
On behalf of all EuBIS Project participants, Collaborating partners and the Academy trainers, we are happy to welcome you in Florence and hope that we will have an exciting training including fruitful discussions and extensive exchange of ideas.

Prof. Dr. Giancarlo M. Liumbruno
General Director
Centro Nazionale Sangue (CNS)

Prof. Dr. Christian Seidl
Coordinator EuBIS Academy
Vice Medical Director, GRCBDS

Dr. Simonetta Pupella
Director Medical Affairs
& Blood Inspection System – CNS

Dr. Fewzi Teskrat
International Relations, EuBIS Academy
Senior Expert Tissues & Cells, ART

With the patronage of the Regione Toscana

Dr. Monica Calamai
Director of Citizenships Rights and Social Cohesion Department
Tuscany Region

Dr. Simona Carli
Director of Regional Blood Center
Tuscany Region

11th International Seminar and Training Course – Florence, 6th – 8th of March 2019

General Information

EuBIS Academy Members:

Dr. Fewzi Teskrat, ART-Clinic, Malta
Dr. Alex Aquilina, MBTS, Malta
Mr. Jan Ceulemans, HBRC-RKV, Belgium
Dr. Jose Manuel Cardenas, CVTB, Spain
Prof. Dr. Giuliano Grazzini, CNS, Italy
Dr. Simonetta Pupella, CNS, Italy
Prof. Dr. Giancarlo Maria Liumbruno, CNS, Italy
Dr. Jan Peter Jansen van Galen, emer. Sanquin, NL
Dr. Paul Strengers, Sanquin, The Netherlands
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Dr. Margarethe Heiden, PEI, Germany
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Wiebke Siegel, GMP-Insp. Germany
Mr. Mark Nightingale, NHSBT, United Kingdom
Prof. Dr. Christian Seidl, GRCBTS, Germany
Prof. Dr. Dr. Erhard Seifried,GRCBTS and N-E, Germany
Dr. Jeroen de Wit, Sanquin, The Netherlands
Prof. Dr. Philippe Vandekerckhove, EBA, Belgium
Amr Yousef Maqnas, SFDA, Saudi Arabia
Lesley Bust, AfSBT, South Africa

Organisers:

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Coordinator EuBIS Academy
Vice Medical Director, German Red Cross Blood Donor Service (GRCBDS), Frankfurt am Main, Germany

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International Relations Officer – EuBIS Academy
Senior Expert Tisssues & Cells and ART, Responsible Person ART Clinic, Malta

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General Director CNS, Istituto Superiore di Sanità

Dr.ssa Simonetta Pupella
Director Medical Affairs & Blood Inspection System – CNS, Istituto Superiore di Sanità

Andrea Aguzzi
Administration, CNS, Istituto Superiore di Sanità

Dr.ssa Livia Cannata
International Relation, CNS, Istituto Superiore di Sanità

Tanja Knoth
Administration, Project management, GRCBDS, EuBIS-Officer

With the patronage of the Regione Toscana

Dr. Monica Calamai
Director of Citizenships Rights and Social
Cohesion Department
Tuscany Region

Dr. Simona Carli
Director of Regional Blood Center
Tuscany Region

Associates:

Prof. Dr. Dr. h. c. Erhard Seifried
CEO and General Medical Director, GRCBTS and GRC North-East, Germany

Seminar and training – From Good Practice (GP) to Good manufacturing Practice (GMP) – blood components and medicinal products

The seminar will build on previous EuBIS training courses with the scope to train on the impact of the new regulation of Good Practice for blood and blood components in the European Union.

The seminars will comprise lectures and group work in a face-to-face fashion based on cases covering several aspects of GP and GMP such as: GP Guidelines, Inspection/Audit, Validation, Change Control, Corrective actions, Risk Assessment.

Previous participation in a EuBIS/Catie course is beneficial but not a prerequisite.

Training course language: **English**

Participants are offered an examination (optional in English or Italian) with an additional certificate of successful participation on the test by the EuBIS Academy / CNS.

Training course participants:

- Qualified as inspectors by a Competent Authority
- Individuals working in a blood establishment in the area of quality management.

***Contact E-MAIL for information**:
EuBIS@blutspende.de
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Registration: www.eubis-europe.eu (Meetings and Courses)

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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 (DG Sanco).

Disclaimer:

The content of the manual, guide or the educational material does not necessarily reflect the views of the European Commission. Neither the Commission nor any person acting on its behalf can be held responsible for any use that may be made of the information in this report.

Neither the EuBIS Academy members nor the European Commission assume any responsibility for the use that may be made of the information in the manual and training material.

11th International Seminar and Training Course – Florence, 6th – 8th of March 2019

Wednesday, the 6th of March 2019

Room: Hospital Careggi, Florence

9:00-10:00	**Preparing the Meeting Office and Venue** (Tanja Knoth, Andrea Aguzzi)
10:00	**Registration Office / Participants** Tanja Knoth, Andrea Aguzzi
10:30-12:30	**Seminar I – Quality management and inspections** **EuBIS Manual and Training Guide**
10:30	Opening and Welcome *Dr. Monica Calamai, Director CRSCD, Regione Toscana* *Dr. Simona Carli, RBC Regione Toscana* *Prof. Dr. Giancarlo M. Liumbruno, CNS* *Dr. Simonetta Pupella, CNS* *Prof. Dr. Christian Seidl, EuBIS* Introduction of the participants 'Break the Ice' *Dr. Fewzi Teskrat*
11:15 – 12:00	Common regulatory requirements and quality standards (*EuBIS manual and guide*) and updated cross-references to GMP/GP guidelines. *Prof. Dr. Christian Seidl*
12:00 – 12:30	The GP Guidelines (Directive 2016/1214): Essential elements of quality management of blood establishments amending Directive 2005/62/EC. *Dr. Simonetta Pupella*
12:30 – 13:30	Lunch break
13:30 – 16:30	**Workshop 1 – Training exercises**
13:30-15:30	**Exercise 1 – Classification of Non-compliances ('real cases')** *Facilitator: Dr. Jose Manuel Cardenas* Introduction Group Work (non compliances – '*Real Life*' Cases) Plenary Discussion
15:30-16:00	Coffee break
16:00-16:30	General requirements for risk identification and analysis *Dr. Margarida Amil*

11th International Seminar and Training Course – Florence, 6th – 8th of March 2019

Thursday, the 7th of March 2019

Room: Hospital Careggi, Florence

09:00	**Registration Office / Participants** Tanja Knoth, Andrea Aguzzi
9:30 – 10:00	**Seminar II – Quality management and inspections** **EuBIS Manual and Training Guide**
9:30-10:00	Good practice for blood components and source plasma for fractionation with reference to the EuBIS manual and guide *(GMP and GP guidelines)* *Dr. Jose Manuel Cardenas*
10:00-10:30	Coffee break
10:30 – 16:30	**Workshop 2 – Training exercise**
10:30 -12:00	**Exercise 2 – Analyse - Act and React (Risk Assessment)** *Facilitator: Dr. Alex Aquilina* *Introduction* Group Work (6 Cases) assisted by trainers - Licensing and Authorisation - Validation and Qualification - Facility Management - Change Control - Storage and Distribution - Collection and Labelling Plenary Discussion: Reporters and Comments
12:00 – 13:00	Lunch break

11th International Seminar and Training Course – Florence, 6th – 8th of March 2019

Thursday, the 7th of March 2019

Room: Hospital Careggi, Florence

13:00-14:00 **Exercise 3 – Personal and Organisation (Job description)**
Facilitator: Dr. Fewzi Teskrat

Individual Work (2 job description testing and collection of blood)

Plenary Discussion: Reporters and Comments
Facilitator – Learning points and summary of exercise

14:00-14:30 Coffee break

14:30 – 16:00 **Exercise 4 – Communication skills – Inspection completion** (BE/CA)

Practice your skills (Role Play)
Facilitator: Dr. Fewzi Teskrat, Dr. Alex Aquilina

Introduction : Case and background information by *Dr. Jose Manuel Cardenas*
Group C: Observers
Briefing: *Dr. Alex Aquilina and Dr. Fewzi Teskrat*
Group A (BE): group representing blood establishment
Group B (CA): group representing competent authority

Role play (group BE / group CA) Opening meeting – Findings – Closing meeting

Plenary: Comments by observers
Facilitator – Learning points and summary of exercise

16:00 – 16:30 – 'Fresh up' what you learned
Facilitator: Dr. Simonetta Pupella, Prof. Christian Seidl

20:00 Joint Dinner (EuBIS Academy and Participants) – tbc

11th International Seminar and Training Course – Florence, 6th – 8th of March 2019

Friday, the 8th of March 2019

Room: Hospital Careggi, Florence

09:00	**Registration Office / Participants** Tanja Knoth, Andrea Aguzzi
09:30 – 10:30	**MC-'EXAMINATION' (optional) (English or Italian)** *Facilitator: Prof. Dr. Christian Seidl, Dr.ssa Simonetta Pupella* *Individual work: Test with multiple-choice question related to the training workshop in English or Italian Language*
10:30 – 11:00	Coffee break
11:00 – 15:00	**Workshop 3 Training exercises**
11:00-12:00	**Exercise 5 – Inspection completion** **Report observations, prepare the closing meeting and prepare/evaluate an action plan** *Facilitator: Prof. Dr. Christian Seidl* *Introduction* ● Blood Collection – Donor department ● Blood Testing – Laboratory Department ● Blood Processing ● Blood Storage and distribution *Cases /Examples* of observations (real life) will be presented. Based on these cases/examples a response of the BE to the CA report is given to the participants. Participants are asked to evaluate the action plan and prepare corrections/modifications if required. Participants are asked to classify these, write a statement and use those reports to prepare the closing meeting summarising the findings of the inspection report. Group Work (assisted by trainers)
12:00-13:00	Lunch break

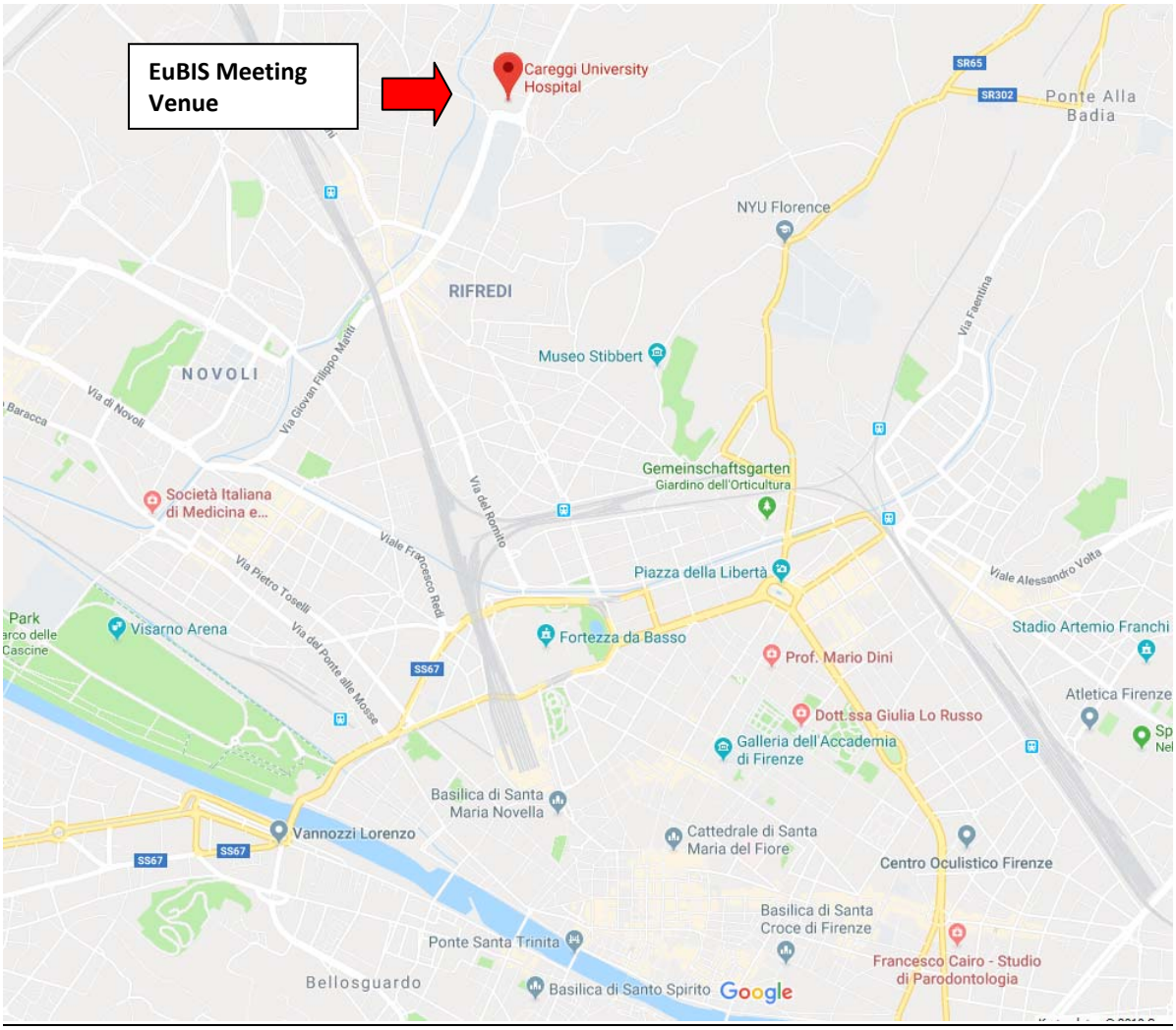
Friday, the 8th of March 2019

13:00-14:00	**Exercise 5 – Inspection completion (continued)** **Report observations, prepare the closing meeting and prepare/evaluate an action plan** *Facilitator: Prof. Dr. Christian Seidl* ● Blood Collection – Donor department ● Blood Testing – Laboratory Department ● Blood Processing ● Blood Storage and distribution Plenary Discussion: Reporters and Comments Facilitator – Learning points and summary of exercise
14:00-14:15	Break
14:15-15:15	**Exercise 6 – Case work-Observations by BE of non-conformance of apheresis plasma units - Risk identification and analysis – SAE/SAR** *Facilitator: Dr. Simonetta Pupella* Introduction: Case background and principle of SAE/SAR Individual work (assisted by trainers) Plenary Discussion: Reporters and Comments Facilitator – Learning points and summary of exercise
15:15 – 15:45	Coffee break and EuBIS training course evaluation form
15:45 – 16:00	**Concluding remarks and *EuBIS Training Certificates*** *Dr.ssa Simonetta Pupella* *Prof. Dr. Christian Seidl*
16:00	**End of meeting**

Meeting Venue

Hospital Careggi, Florence

Largo G. Alessandro Brambilla, 3, 50134 Firenze FI, Italy



Meeting Venue (MAP) – indicated by RED point

Meeting Venue: Hospital Careggi, Florence

Largo G. Alessandro Brambilla, 3,
50134 Firenze FI, Italy
Phone: +39 055 794111

Development of pan-European standards and criteria for the inspection of blood establishments (EU-Blood-Inspection) – EUBIS

Ensuring that '*patients who receive blood transfusion in the European Union are given safe blood' is a* major objective within the framework of public health on the national and European level.

The objective of EuBIS is to set out a methodology for inspecting blood establishments based on the European Commission's directive requirements related to ensuring the quality and safety of blood.

It is the result of a collaborative effort of representatives from 27 governmental institutions, blood establishments and competent authorities participating in the EuBIS project co-funded by the European Commission under area 2.2.4 of the Public Health Programme (2003-2008) – Call 2006 – addressing the quality and safety of blood.

The project has developed a manual and guide 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 and training guide as a reference for the implementation process of the European blood legislation related to regulatory inspections.*

Using commonalities between Member States and the requirements and definitions given by the EU blood legislation, the manual and guide summarises good practice standards. The implementation of these standards will improve the safety of blood.

An electronic form can be ordered via the EuBIS website

(www.eubis-europe.eu).

Project cooperation with other European initiatives or organisations related to inspection schemes of pharmaceutical products and tissue and cells: The project is aware of other European initiatives or organisations that have developed inspection standards used in the area of pharmaceutical products and tissues and cells.
The EuBIS and EU-Q-Blood-SOP Manuals have been distributed by request to more than 300 blood establishments, competent authorities and governmental institutions in 52 countries in Europe and world wide.

Austria, Ethiopia, Australia, Belgium, Bulgaria, Cyprus, Denmark, Finland, France, Germany, Greece, Island, Ireland, Italy, Latvia, Lithuania, Luxembourg, Poland, Portugal, Romania, Slovak Republic, Slovenia, Croatia, Spain, United Kingdom, Abu Dhabi, Afghanistan, Argentina, Brazil, Canada, Chile, China, Croatia, Dubai, Egypt, Guatemala, Hong Kong, Israel, Indonesia, India, Kuwait, Korea, Nigeria, Japan, Marocco, Mexico, Montenegro, Palaestine, Pakistan, Peru, Philippines, Rep. of Macedonia, Russia, Switzerland, Saudi Arabia, Quatar, South Afrika, Turkey, Sri Lanka, USA

EuBIS Training Courses are announced for pre-registration under the projects homepage (www.eubis-europe.eu):

EuBIS Academy Members and Organisers

Name	Institution	Member State
Prof. Dr. Christian Seidl	EuBIS Academy Coordinator Vice Medical Director German Red Cross Blood Donation Service (GRCBDS) , Frankfurt/Main	**Germany**
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Dr. Jose Manuel Cardenas Díaz de Espada	Advisor MoH-Spain (MSSSI) Director (emeritus), Centro Vasco de Transfusion y Tejidos Humanos (CVTTH) - Bilbao/San Sebastian	**Spain**

Participants

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Participants (cont.)

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