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 - Overview for registration www.eubis-

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

REGIONE TOSCANA

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

Invitation

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, Norway, Switzerland, Kosovo, Kuweit, Turkey, Brazil, Curacao, Algeria, Lebanon, Morocco, Macedonia, Nigeria, Singapore, Saudi Arabia, Yemen, Qatar, South Africa, South Korea, Vietnam, 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) and funded by the Istituto Superiore di Sanità (ISS) with the patronage of the Regione Toscana and 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 invite you to 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)
Istituto Superiore di Sanità

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

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

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

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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 (group work in English or Italian language)**
Course fees European/International participants: 470,- €
Course fee for Italian participants: 210,- €*
* reduced fee for Italian participants (CNS partially covers the registration fee)

Registration: www.eubis-europe.eu (Meetings and Courses)

Participants are offered an examination (optional) with a certificate of successful participation in the examination by EuBIS Academy / CNS.
The examination will be in **English language**.

Training course participants:

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

Training places are limited: Selection of training participants and confirmation of participation will be on the basis on time of registration.

***Contact E-MAIL for information**:
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Meeting Venue - Training Location:

Careggi University Hospital

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

Azienda Ospedaliero Universitaria Careggi

UNIVERSITÀ DEGLI STUDI FIRENZE

The **Careggi University Hospital** is a Trust integrated with the University of Florence and is characterized by the health care activities of hospitalization, specialized outpatient services and Emergency Room /Urgent care services. It has aapr. 1300 beds with close to 50.000 admissions to ordinary hospitalisation and performs unified and indivisible functions of joint patient care activities, education, didactics and research, and is a structural element of the National Health Service, in particular of the Healthcare System of the Tuscan Region, and of the University System.

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Wednesday, the 6th of March 2019

10:00	Registration (coffee)
10:30-12:30	**Seminar I – Quality management and inspections - EuBIS Manual and Training Guide**
Lecture	Common regulatory requirements and quality standards (*EuBIS manual and guide*) and updated cross-references to GMP/GP guidelines.
Lecture	The GP Guidelines (Directive 2016/1214): Essential elements of quality management of blood establishments amending Directive 2005/62/EC.
13:30 - 16:30	**Workshop 1 – Training exercises**
13:30-15:30	**Exercise 1 - Classification of Non-compliances ('real cases')**
16:00-16:30	Lecture - General requirements for risk identification and analysis

Thursday, the 7th of March 2019

9:00	Registration office
9:30 - 10:00	**Seminar II - Quality management and inspections** **EuBIS Manual and Training Guide**
Lecture	Good practice for blood components and source plasma for fractionation with reference to the EuBIS manual and guide *(GMP and GP guidelines)*
10:30 - 16:30	**Workshop 2 - Training exercise**
10:30 -12:00	**Exercise 2 - Analyse - Act and React (risk assessment)**
13:00-14:00	**Exercise 3 – Personal and organisation (Job description)**

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

Thursday, the 7th of March 2019 (continued)

14:30-16:00	**Exercise 6 – Communication skills – Inspection completion** (BE/CA)
16:00 -16:30 –	**'Fresh up' what you have learned**

20:00 Joint Dinner (EuBIS Academy and Participants)

Friday, the 8th of March 2019

9:00	Registration office
9:30 - 10:30	**MC-'EXAMINATION' (optional) (English or Italian)**
11:00-12:45	**Exercise 5 – Inspection completion** **Report observations, prepare the closing meeting, prepare/evaluate an action plan** ● Blood Collection – Donor department ● Blood Testing – Laboratory Department ● Blood Processing ● Blood Storage and distribution
13:45 – 15:15	**Workshop 3 Training exercises**
13:45 - 15:15	**Exercise 6 – Case work –Observations by BE of non-conformance of apheresis plasma units - Risk identification and analysis – SAE/SAR**
15:30 - 16:00	**Concluding remarks and *EuBIS Training Certificates***
16:00	End of meeting