



# 14<sup>th</sup> 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

18<sup>th</sup> – 20<sup>th</sup> of April 2023, Rome, Italy



**1<sup>st</sup> Announcement** for registration [www.eubis-europe.eu](http://www.eubis-europe.eu)

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



## 14<sup>th</sup> International Seminar and Training Course - Rome, 18<sup>th</sup> – 20<sup>th</sup> of April 2023

### 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 seminar and 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, Kuwait, Turkey, Brazil, Curacao, Algeria, Lebanon, Morocco, Macedonia, Nigeria, Singapore, Saudi Arabia, Yemen, Qatar, South Africa, South Korea, Vietnam, United State of America, etc.).*

*During the Pandemic, the EuBIS academy has organised Virtual seminars but is now offering again 'Face-to-Face' seminars. Based on the EuBIS-CNS courses jointly organised together with the Centro Nazionale Sangue (CNS) and funded by the Istituto Superiore di Sanità (ISS) in Rome (2018) and in Palermo (2018) the 14<sup>th</sup> International EuBIS Seminar and Training Course 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 Rome and hope that we will have an exciting training including fruitful discussions and extensive exchange of ideas.*

*Dr. Vincenzo De Angelis  
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*

*Dr. Livia Canata  
Head of International Relation - CNS  
Istituto Superiore di Sanità*



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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.

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 (International): [www.eubis-europe.eu](http://www.eubis-europe.eu) (Meetings and Courses)**

**\*Registration Italian: CNS Administration (Laura Di Marco):**

[segreteria generale.cns@iss.it](mailto:segreteria generale.cns@iss.it)

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 (EuBIS office):**

[EuBIS@blutspende.de](mailto:EuBIS@blutspende.de)

**CNS Headquarter Administration (Dr. Andrea Aguzzi):**

[andrea.aguzzi@iss.it](mailto:andrea.aguzzi@iss.it)

Front page taken from [Wikipedia Commons/Category Rome St.Peters and Vatikan Museum Round Hall \(Sala Rotonda\)](#)



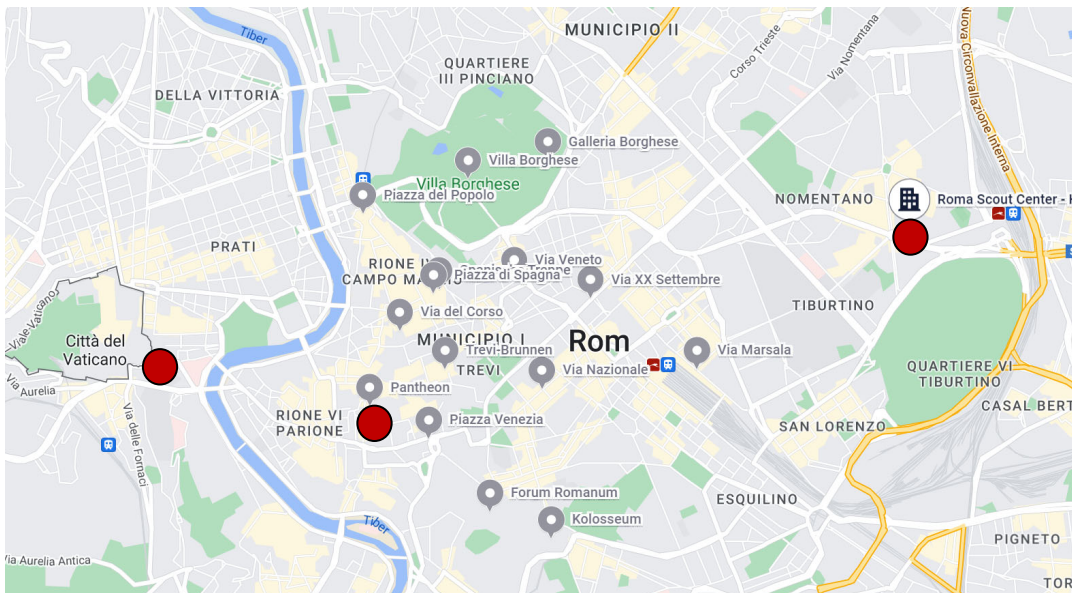


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**Meeting Venue - Training Location:**

**Scout Center**

Largo Dello Scautismo 1, Nomentano, Roma, Italy



**Roma Scout Meeting Center and - Hostel** is located in Nomentano, a neighbourhood in Rome, and is near a metro station. Spanish Steps and Trevi Fountain are notable landmarks, and the area's natural beauty can be seen at Villa Borghese.



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### Tuesday, the 18<sup>th</sup> of April 2023

- 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

### Wednesday, the 19<sup>th</sup> of April 2023

- 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**



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**Wednesday, the 19<sup>th</sup> of April 2023 (continued)**

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

16:00 -16:30 – ‘Fresh up’ what you have learned

**20:00 Joint Dinner (EuBIS Academy and Participants)**

**Thursday, the 20<sup>th</sup> of April 2023**

9:00 Registration office

9:30 - 10:30 **Remote and Virtual Inspection (RVI)**

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 – Haemovigilance, Increased number of septic complications after platelet transfusion – Risk identification and analysis – SAE/SAR**

15:30 - 16:00 **Concluding remarks and *EuBIS Training Certificates***

16:00 End of meeting



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### EuBIS Academy Members and Organisers

Name	Institution	Member State
<b>Prof. Dr. Christian Seidl</b>	EuBIS Academy Coordinator Vice Medical Director German Red Cross Blood Donation Service (GRCBDS) , Frankfurt/Main	<b>Germany</b>
<b>Dr Vincenzo De Angelis</b>	General Director Italian National Blood Center (CNS) Istituto Superiore di Sanità (ISS), Rome	<b>Italy</b>
<b>Dr. Simonetta Pupella</b>	Director Medical Affairs & Blood Inspection System – CNS Istituto Superiore di Sanità (ISS), Rome	<b>Italy</b>
<b>Dr. Andrea Aguzzi</b>	Headquarter Administration Italian National Blood Center, CNS, Istituto Superiore di Sanità (ISS), Rome	<b>Italy</b>
<b>Dr. Livia Cannata</b>	Head International Relations Italian National Blood Centre, CNS, Istituto Superiore di Sanità (ISS), Rome	<b>Italy</b>
<b>Dr. Laura Di Marco</b>	Italian National Blood Center (CNS) Istituto Superiore di Sanità (ISS), Rome	<b>Italy</b>
<b>Kristina Echt</b>	Administrative Officer – EuBIS Academy Participants registration, Financial Budget	<b>Germany</b>
<b>Dr. Fewzi Teskrat</b>	International Counciller – EuBIS Academy Senior Expert Tissues & Cells and ART, France	<b>France</b>
<b>Dr. Alex Aquilina</b>	Director (emeritus), National Blood Transfusion Service Malta, La Mangia EuBIS Academy Expert on regulatory aspects for blood and blood components	<b>Malta</b>
<b>Dr. Margarida Amil</b>	Responsible Person (emeritus) Hospital Blood Bank and Transfusion Medicine, Hospital St António, Centro Hospitalar do Porto EuBIS Academy Expert on regulatory aspects for blood and blood components, Porto	<b>Portugal</b>
<b>Dr. Jose Manuel Cardenas Díaz de Espada</b>	Senior expert blood and blood components, Advisor MoH-Spain (MSSSI) Director (emeritus), Centro Vasco de Transfusion y Tejidos Humanos (CVTTH) - Bilbao/San Sebastian	<b>Spain</b>