

## **16<sup>th</sup> EuBIS Seminar and Training**

*Seminar and Training for blood establishments and competent authorities referring to GPG and GMP' for blood and blood components (SoHO)*

### **The Risk-based Approach**

**“From the Design to the Implementation of the Quality System”**



AMENDMENTS BY THE EUROPEAN PARLIAMENT\*  
to the Commission proposal  
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REGULATION (EU) 2024/...  
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of ...  
on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC  
(Text with EEA relevance)  
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

**5<sup>th</sup> – 7<sup>th</sup> of November 2024, 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)**



## 16<sup>th</sup> International Seminar and Training Course - Rome, 5<sup>th</sup> – 7<sup>th</sup> of November 2024

### 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), Palermo (2018), Florence (2019) and Rome (2023).

The 16<sup>th</sup> International EuBIS Seminar and Training Course has been designed with the requirement of "Risk-based-Approach" to be implemented in quality systems. With the revised exercises and methodology, the 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 would like 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  
VMD, German Red Cross, BTS

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

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

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



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### Seminar and training – The Risk-based Approach “from the design to the implementation of the quality system” for blood and blood components

This new version of EUBIS training aims to further expand on previous EuBIS courses and provides insights in more recent challenges and developments.

The training material has been revised to take into account in more detail and complexity the Risk-based Approach as required by the regulation of Good Practice (GPG) for blood and blood components in the European Union. In addition, the training will address the new “*Regulation on standards of quality and safety for substances of human origin intended for human application (SoHO)*” (COM(2022)0338 – C9-0226/2022 – 2022/0216(COD)), that has been approved on the 24 April by the European Parliament and adopted on the 27 May 2024 by the Council, reinforcing the Risk based Approach.

The seminars will comprise lectures and group work in a face-to-face fashion based on cases covering several aspects of **GPG** and **GMP** such as:

- **Risk analysis and risk management,**
- **Inspection/Audit practice,**
- **Process design and risk assessment,**
- **Validation and Qualification,**
- **Change Control and change management,**

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

Training course participants:

- Qualified or trainee inspectors from 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.

#### **Registration and Payment**

Training course language: **English (group work in English or Italian language)**

Course fees European/International participants: **470,- €\***

\* reduced fee for Italian participants (CNS partially covers the registration fee)

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

[https://www.eubis-europe.eu/eubis\\_italy\\_2023.php](https://www.eubis-europe.eu/eubis_italy_2023.php)

**Fill-in your name and contact data/address via the EuBIS-website !!**

#### **For further information:**

International Participants: Contact E-MAIL for information (EuBIS office): [EuBIS@blutspende.de](mailto:EuBIS@blutspende.de)

Italian Participants: CNS Headquarter Administration (Dr. Andrea Aguzzi): [andrea.aguzzi@iss.it](mailto:andrea.aguzzi@iss.it)

Front page picture kindly provided by romeexpress

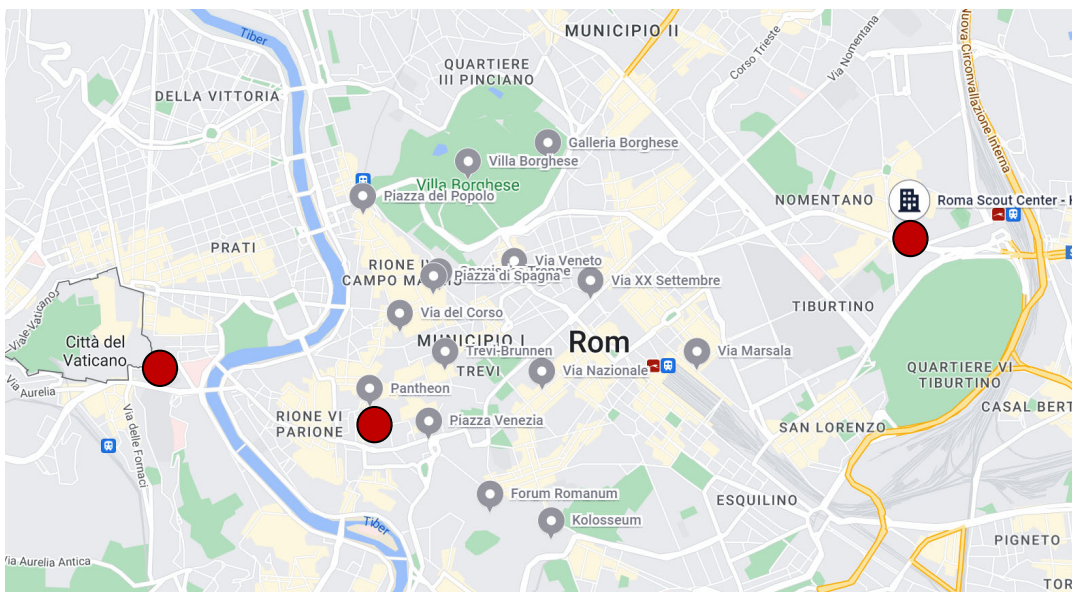


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**Meeting Venue - Training Location:**

**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.





## 16<sup>th</sup> International Seminar and Training Course - Rome, 5<sup>th</sup> – 7<sup>th</sup> of November 2024

### General Information

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#### **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. Vincenzo de Angelis, CNS, Italy*

*Dr. Jan Peter Jansen van Galen, emer. Sanquin, NL*

*Dr. Paul Strengers, Sanquin, The Netherlands*

*Dr. Margarida Amil, HBB Porto, Portugal*

*Dr. Margarethe Heiden, PEI, Germany*

*Dr. Helga Marie Huber, PEI, Germany*

*Wiebke Siegel, GMP-Insp. Germany*

*Mr. Mark Nightingale, NHSBT, United Kingdom*

*Prof. Dr. Christian Seidl, GRCBTS, Germany*

*Prof. Dr. Torsten Tonn, 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:**

##### **Prof. Dr. Christian Seidl**

*Coordinator EuBIS Academy*

*Vice Medical Director, German Red Cross Blood Donor Service (GRCBDS),*

*Frankfurt am Main, Germany*

##### **Dr. Fewzi Teskrat**

*International Counciler – EuBIS Academy*

*Senior Expert Tissues & Cells and ART, France*

##### **Dr. Vincenzo De Angelis**

*General Director CNS, Istituto Superiore di Sanità*

##### **Dr.ssa Simonetta Pupella**

*Director Medical Affairs & Blood Inspection System – CNS*

*Istituto Superiore di Sanità*

##### **Dr Andrea Aguzzi**

*Headquarter Administration, CNS, Istituto Superiore di Sanità*

##### **Dr.ssa Livia Cannata**

*Head - International Relation, CNS, Istituto Superiore di Sanità*



## 16<sup>th</sup> International Seminar and Training Course - Rome, 5<sup>th</sup> – 7<sup>th</sup> of November 2024

### Tuesday, the 5<sup>th</sup> of November 2024

**10:30-12:30 Seminar I – Quality management and inspections**

11:00-11:30 Lecture 1 Common regulatory requirements and quality standards (*EuBIS manual and guide*) and cross-references to GMP/GP guidelines (Directive 2016/1214).

11:30-12:00 Lecture 2 The New regulation COM (2022) 338: Overview and comparison between GPG and GMP

**13:30 - 16:30 Workshop 1 – Implementing a risk-based approach**

Lecture 3 - General requirements for risk identification and analysis

14:00-16:30 **Exercise 1 - Application of a risk-based approach for the classification of non-compliances ('real cases')**

16:00 -16:30 Quiz: 'Fresh up' what you have learned

### Wednesday, the 6<sup>th</sup> of November 2024

**9:30 - 12:30 Seminar II – Process design and risk analysis**

9:30-10:00 Lecture 4 - Risk management and Assessment: Extended requirements and tools including root cause analysis.

**10:00 - 16:30 Workshop 2 – Safeguard the introduction of a new process: Pro and Con**

10:00 -12:30 **Exercise 2 – Blood donation, processing and quality control**

13:30-14:00 Lecture 5 - Change control and change management.

14:00-16:30 **Exercise 3 – Change control of processes**  
Blood collection and Mobile blood sessions.

16:30 - 17:30 **Exercise 4 – Communication skills – Inspection completion (BE/CA)**



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**Thursday, the 7<sup>th</sup> of November 2024**

**9:30 – 12:30 Seminar III – Validation and Qualification: from theory to praxis**

9:30 – 10:00 Lecture 6 – Validation and Qualification: from good to best practice

**10:00 – 14:30 Workshop 3 - From Donation to Blood Products**

**10:00-12:30 Exercise 5 - Pre-donation testing, transport and storage, testing and production**

**12:30-13:00 Closing Session and EuBIS Training Certificates**

Concluding remarks and *EuBIS Training Certificates*

Comment: Italian participants will receive the opportunity to participate in an electronic evaluation to receive credits from ISS

**13:00-14:00 'Fare-Well' – Lunch**



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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>Dr. Fewzi Teskrat</b>	International Councillor – 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>	Past-president of the Spanish Society of Blood Transfusion and Cellular Therapy Director (emeritus), Centro Vasco de Transfusion y Tejidos Humanos (CVTTH) - San Sebastian EuBIS Academy Expert on regulatory aspects for blood and blood components.	<b>Spain</b>