



**EuBIS**

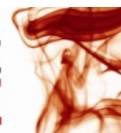
**European Blood Inspection System**

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

Funded by



**CENTRO  
NAZIONALE  
SANGUE**



# 10<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

24<sup>th</sup> – 26<sup>th</sup> of October 2018, Palermo, Italy



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

[Programme Overview](#) for registration [www.eubis-europe.eu](http://www.eubis-europe.eu)



## 10<sup>th</sup> International Seminar and Training Course - Palermo, 24<sup>th</sup> - 26<sup>st</sup> of October 2018

### 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 and International participants: 470,- €**

Special course fee for Italian participants: 210,- €\* (sponsored by ISS)

\*reduced fee for inspectors engaged by CNS for regulatory inspections

**Registration: [www.eubis-europe.eu](http://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 or Italian 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.

One additional courses are foreseen to be organised in Italy (March 2019).

More details will be shared in due time.

**\*Contact E-MAIL for information:**

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

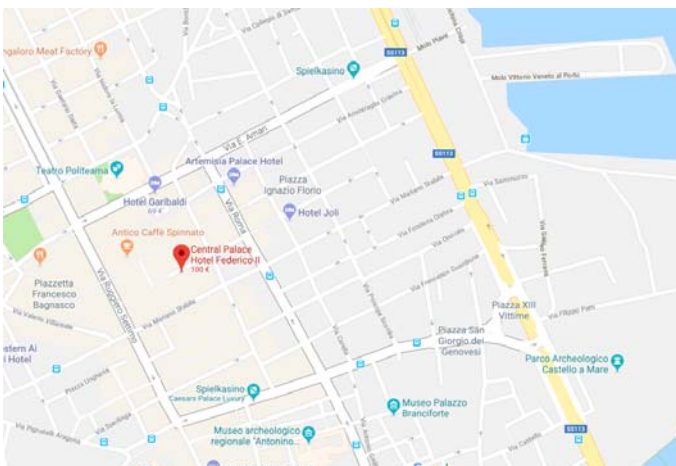
[Andrea.aguzzi@iss.it](mailto:Andrea.aguzzi@iss.it)



## 10<sup>th</sup> International Seminar and Training Course - Palermo, 24<sup>th</sup> - 26<sup>st</sup> of October 2018

Meeting Venue - Hotel Federico II Central Palace

Via Principe di Granatelli, 60, 90139 Palermo PA, Italien







## 10<sup>th</sup> International Seminar and Training Course - Palermo, 24<sup>th</sup> - 26<sup>st</sup> of October 2018

### Wednesday, the 24<sup>th</sup> of October 2018

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')

Lecture General requirements for risk identification and analysis

### Thursday, the 25<sup>th</sup> of October 2018

#### 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 -12:30 Exercise 2 - Analyse - Act and React (risk assessment)

13:30-15:00 **Exercise 3 – 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



## 10<sup>th</sup> International Seminar and Training Course - Palermo, 24<sup>th</sup> - 26<sup>st</sup> of October 2018

### Thursday, the 25<sup>th</sup> of October 2018 (continued)

15:30-16:30    **Exercise 4 – Personal and organisation (Job description)**

16:30 -17:00 – ‘Fresh up’ what you have learned

### Friday, the 26<sup>th</sup> of October 2018

9:30 - 10:30    **MC-‘EXAMINATION’ (optional) (English or Italian)**

**11:00 – 15:00    Workshop 3 Training exercises**

11:00-13:00    **Exercise 5 – Case work –Observations by BE of non-conformance of apheresis plasma units  
- Risk identification and analysis – SAE/SAR**

13:45-15:00    **Exercise 6 – Communication skills – Inspection completion (BE/CA)**

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

16:00            End of meeting

# 10<sup>th</sup> EuBIS Seminar and Training – Travel Information

24<sup>th</sup> – 26<sup>th</sup> of October 2018, Palermo, Italy

**International Airport of Palermo can be reached via numerous International Airlines**

<http://www.gesap.it/aeroporto/voli/compagnie-aeree/>



or National Italian flights via



**Tourist and Hotel Information on the City of Palermo and Sicily:**

visit palermo <https://www.visitpalermo.it>

We are Palermo <http://wearepalermo.com/what-to-see/>



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