PROVIDER N.2224

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

18-20 April 2023

organized by

ISTITUTO SUPERIORE DI SANITÀ
Italian National Blood Centre

GERMAN RED CROSS BLOOD DONOR SERVICE (GRCBDS)
European Blood Inspection System (EuBIS) Academy

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N° ID: 133C23-P

Rationale
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. 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.

Aim and objectives
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.

Specific objectives
At the end of the course participants will be able to:
1. apply the new regulations descending from GPG and GMP guidelines;
2. carry out inspections on blood establishments according to GPG and GMP guidelines.

Didactic method
The seminar 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.

PROGRAMME

Tuesday, 18 April

10.00 Registration

10.30 Opening and Welcome
Vincenzo De Angelis, Head of the Italian National Blood Centre at the Istituto Superiore di Sanità
Simonetta Pupella, Director of Medical Affairs & Blood Inspection System of the Italian National Blood Centre at the Istituto Superiore di Sanità
Christian Seidl, EuBIS Academy Coordinator

11.00 Introduction of the participants 'Break the Ice'
Fewzi Teskrat

SEMINAR I – QUALITY MANAGEMENT AND INSPECTIONS - EUBIS MANUAL AND TRAINING GUIDE

11.15 *Common regulatory requirements and quality standards (EuBIS manual and guide) and updated cross-references to GMP/GP guidelines*
Christian Seidl

12.00 *The GP Guidelines (Directive 2016/1214): Essential elements of quality management of blood establishments amending Directive 2005/62/EC*
Simonetta Pupella

12.30 Lunch break

Workshop 1 - Training exercises

13.30 Exercise 1 - *Classification of Non-compliances ('real cases')*
Facilitator: **José Manuel Cardenas**

Introduction
Group Work (non-compliances – 'Real Life' Cases)
Plenary Discussion

15.30 Coffee break

16.00 *General requirements for risk identification and analysis*
Margarida Amil

16.30 Closing of the day

Wednesday, 19 April

9.00 Registration

SEMINAR II - QUALITY MANAGEMENT AND INSPECTIONS - EUBIS MANUAL AND TRAINING GUIDE

9.30 *Good practice for blood components and source plasma for fractionation with reference to the EuBIS manual and guide (GMP and GP guidelines)*
José Manuel Cardenas

10.00 Coffee break

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Workshop 2 - Training exercise

10.30 Exercise 2 - *Analyse - Act and React (risk assessment)*
Facilitators: **Alex Aquilina**, **Fewzi Teskrat**

Introduction
Group Work (4 Cases) assisted by trainers
Licensing / authorization
Validation and Qualification
Facility Management
Change control
Storage and Distribution
Collection and Labelling

Plenary Discussion: Reporters and Comments

12.00 Lunch break

13.00 *Personal and Qualification/Re-Qualification*
Christian Seidl

13.30 Exercise 3 - *Personal and Qualification/Re-Qualification*
Facilitators: **Alex Aqulina**, **Fewzi Teskrat**

Plenary Discussion: MC with Polling
Learning points and summary of exercise

14.00 Coffee break

14.30 Exercise 4 - *Communication skills – Inspection completion (BE/CA)*

Practice your skills (Role Play)
Facilitators: **Fewzi Teskrat**, **Alex Aquilina**

Introduction: Case and background information by **José Manuel Cardenas**
Group C: Observers

Briefing: **Alex Aquilina**, **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 Closing of the day

Thursday, 20 April

9.00 Registration

9.30 *Lecture on Remote-Virtual Inspection (RVI)*
Fewzi Teskrat

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10.00 Plenary Discussion / Round-table Discussion
Plus and Minus of Inspection 'On-site' versus 'RVI'

10.30 Coffee break

Workshop 3 - Training exercises

11.00 Exercise 5 - *Inspection completion*

Report observations, prepare the closing meeting, prepare/evaluate an action plan
Facilitator: **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

Participants are asked to classify them, write a statement and use those reports to prepare the closing meeting summarizing the findings of the inspection report.

Group Work (assisted by trainers)

12.00 Lunch break

13.00 Exercise 6 - *Inspection completion (Action Plan)*

Report observations, prepare the closing meeting, prepare/evaluate an action plan
Facilitator: **Christian Seidl**

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.

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 Coffee break

14.30 Exercise 7 – *Hemovigilance, Increased number of septic complications after platelets transfusion*

Risk identification and analysis – SAE/SAR
Facilitator: **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

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15.15 EuBIS course training evaluation

15.45 Concluding remarks and EuBIS Training Certificates
Vincenzo De Angelis, **Simonetta Pupella**, **Christian Seidl**

16.00 End of meeting

TRAINERS

Margarida Amil – Hospital Blood Bank and Transfusion Medicine, Hospital St. António, Centro Hospitalar do Porto, Portugal
Alex Aquilina – National Blood Transfusion Service, Malta
José Manuel Cardenas – Centro Vasco de Transfusion y Tejidos Humanos (CVTTH) - Bilbao/San Sebastian, Spain
Simonetta Pupella – Italian National Blood Centre, Istituto Superiore di Sanità, Rome, Italy
Christian Seidl – German Red Cross Blood Donation Service, Frankfurt, Germany
Fewzi Teskrat – European Blood Inspection System (EuBIS) Academy, France

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GENERAL INFORMATION

Venue

Scout Center
Largo Dello Scautismo 1, Rome, Italy

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Attendance
The course is primarily addressed to inspectors of blood establishments qualified by a Competent Authority and to individuals working in a blood establishment in the area of quality management.
Maximum 40 attendees.

Offcial language
English

Registration and fees
The registration form is available on the EuBIS Academy web site:
https://www.eubis-europe.eu/eubis_italy_2023.php.

Course fees:
- European/International participants: 470,00 €
- Italian participants: 210,00 €*

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

Selection
Places in the course will be assigned according to pre-established criteria: firstly on the basis of the registration time and then, in the event that the number of registrations exceeds the maximum number of attendees, priority will be given to those who have never participated in previous courses of the EuBIS Academy.

Learning assessment procedures
Learning outcomes will be assessed by filling out a multiple-choice questionnaire on the last day of the course. This final test is compulsory for all participants to obtain the certificate of attendance.

Satisfaction questionnaire
At the end of the course, all participants should complete a quality assessment survey.

CME credits
This event does not provide any CME credits.

Certification
Attendance certificates indicating the hours of training will be issued on request to participants who complete at least 80% of the course.

For any further information, please contact the Organizational Secretariat.

[Firma elettronica del Presidente]

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