ISBT Academy – Workshop and training on quality management – Bangkok, Thailand, Monday, the 18th of November 2019, from 13:30 – 15:00

'GMP/GP standards and their implication for the safety of blood and blood components’

Training seminar and workshop:

organised by the Working Party on Quality Management
supported by the EuBIS Academy
in cooperation with IPFA
ISBT Academy – Workshop and training on quality management – Bangkok, Thailand, Monday, the 18th of November 2019, from 13:30 – 15:00

**Topic:** 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. The seminar will be based on a manual and guide to assist

- **blood establishments in need to optimise their quality system and self-inspection process related to Good practice or GMP.**
- **blood establishments to prepare for regulatory inspections by competent authorities, and**
- **competent authorities, which wish to use the manual and training guide as a reference for the implementation process of blood legislation related to regulatory inspections.**

**Learning Outcome:**

- Good Practice in quality management of transfusion services
- Risk based approach for audits and inspections with classification of non-compliances

The seminar and training will also contain Training material and Handouts (Exercises and 2 booklets, EuBIS guide and manual). Therefore, we would like to ask those who are interested to give us a pre-registration notice (https://www.eubis-europe.eu/academy/)

**Pre-Registration:**

- [www.eubis-europe.eu](https://www.eubis-europe.eu)
- Christian Seidl (Chairman ISBT Working Party on Quality Management)
- e-mail: c.seidl@blutspende.de

35 participants

**Programme - Training seminar and workshop** (Monday, the 18th from 13:30-15:00)

13:30  GP/GMP requirements for substances of human origin (SoHO).

13.50  Benefits of human blood and plasma, and the manufacture and supply of medicines derived from human plasma.

14:10  Quality monitoring and assessment in blood establishments

14:30  **Exercises and cases on Non-compliances including risk assessment**

The classification of non-compliances (EuBIS Inspection Training Guide and Manual)

4 ‘real life’ - Cases are given to the participants.

Participants will work in small groups. each working group – 4-5 Groups

Plenary session: Presentation of result of each working group/participants Discussion

Summary and conclusion (facilitator proposal)

15:00  End of training seminar