Blood and **beyond**

Result 2.2.2

Inspection questionnaire and assessment

Dr. W. Martin Smid, Managing Director
Prof. Wim de Kort
Sanquin Consulting Sevices

EU Twinning: Strentghening Blood Safety System in Georgia

Sanquin

Outline

- Purpose of questionnaire
- Assesment
  - Starting point or 0-measure for organizational change
  - Starting point for quality system
- Inspection Questionnaire and self assessment
  - Standards for inspection
  - EUBIS (Manual & Training for Inspectors

Purpose of questionnaire

- Self assessment form 2018 was used.
- Is the data available?
- Data still valid, evaluated and usable for 2020?
- Update of the self assessment in 2020 provides data that can be used as starting point or zero measurement
- From here the transition from the present to the desired new situation can start.

Transition

- Present situation:
  - Decentralised, commercial and government, remunerated donation

- Desired future:
  - Centralized, non-profit, voluntary non-remunerated donation

Transition

- Continuity of the supply is probably the most important

- NL it started bottom up and it took more than a decade to centralize. (voluntary non remunerated donations and non-profit were already in the system)

- It will take time to change to the desired situation
- It will take time to build a quality system

Scenario's

- Scenario's on each side of a spectrum
- On the one side a merger of all blood banks that together will form a centralized non-profit blood bank.
- On the opposite side a new centralized blood bank starts and takes over the activities of the present blood banks step by step. Top down ordered by the ministry

Questionnaire

- Summary general comments provided by NL experts before:
- Structure of the questionnaire:
  - Start with general information about the blood bank (organization, premises, mobiles when applicable, including floor plans, number of donations, numbers of products processed and issued, number and kind of staff.
  - Quality manual including the SOP, description of blood bank information system
- This information can also be available in a so-called blood bank dossier that can be considered a requirement

Questionnaire

- Specific attention for the Quality manual
- In essence the process and procedures are leading and executed as described in the SOP.
- Equipment and consumables used are tools and should fit the purpose of the procedure.

- Next to these general remarks detailed feedback was given per section when applicable.

Questionnaire

- Use of questionnaire can be two fold:
  - The blood bank can use it as self assessment of the quality system in order to prepare for inspection
  - Inspection can use it as a inspection list.

- The questionnaire will develop overtime and the comparison of the inspection questionnaire with the most recent Good Practices Guide of the Council of Europe can be recommended as a first step for regular revision of the document.

EU legal framework: responsibilities

Supervision of blood and blood components collection, testing, processing, storage and distribution

Designation, authorisation, accreditation or licensing of blood establishments

Inspection and control measures

Quality systems

Traceability

Notification of Serious Adverse Events and Reactions (SAE/SAR)

EU 2005:62 annex

1 General Principles

2 Personnel and Organisation

3 Premises

4 Equipment and Materials

5 Documentation

6 Blood collection, testing and processing

- 6.1 Donor eligibility 6.2 Collection of blood and blood components 6.3 Laboratory testing 6.4 Processing and validation 6.5 Labelling 6.6 Release of blood and blood components

7 Storage and distribution

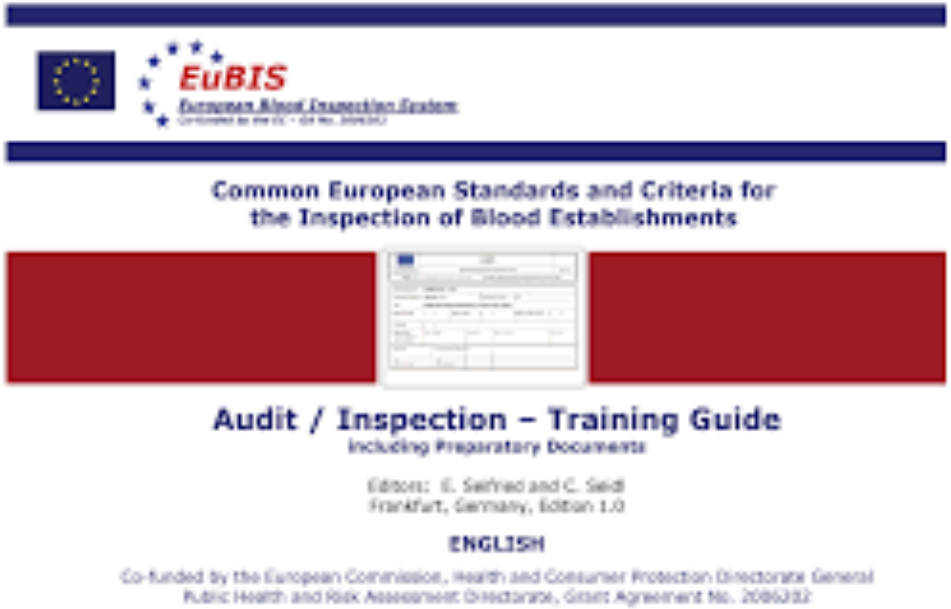
8 Contract Management

9 Non-Conformance

- 9.1 Deviations 9.2 Complains 9.3 Recall 9.4 Corrective and preventive actions (CAPA)

10 Self-inspection, audits and improvements


EuBIS
Co-funded by the European Commission
Health and Consumer Protection Directorate General
Public Health and Risk Assessment Directorate
Grant Agreement No. 2006202
Manual
European Inspection and Self-Inspection Guide
for Blood Establishments
Reflecting common European standards and
criteria for best practice within the area
addressing the quality and safety of blood
ENGLISH


EuBIS
European Blood Inspection System
Common European Standards and Criteria for
the Inspection of Blood Establishments
Audit / Inspection – Training Guide
Including Preparatory Documents
Editors: E. Seifried and C. Seidl
Frankfurt, Germany, Edition 1.0
ENGLISH
Co-funded by the European Commission, Health and Consumer Protection Directorate General
Public Health and Risk Assessment Directorate, Grant Agreement No. 2006202

Projects objectives:

The overall objective of the Project is to develop and implement commonly accepted criteria and standards to ensure equivalent recognition of inspection of blood establishments among Member States.

It will deliver this through the development of a manual that will define:

1. common inspection criteria and standards for the inspection of blood establishment
2. requirements for the implementation or expansion of quality management systems to be inspected
3. the development of inspection checklists which closely follow Directive 2002/98/EC and its technical annexes
4. evaluation criteria for inspections and a benchmark system for deviations and improvements

The manual will be used as a basis of a training programme for the inspectors of blood establishments. This will ensure that the standards and criteria are commonly accepted.

EUBIS Manual: contents

Conclusion

- Questionnaire purpuse:
  - Zero measurement for:
    - organizational change and upgrading of QS to comply with EU directives.
  - Inspections
    - Self assessment tool and preparation for inspection
    - Inspection tool with “inspection assessment form”
- Standards Good Practices CoEU and EUBIS and PIC/S (EUBIS specific training programme for inspectors)

Questions?