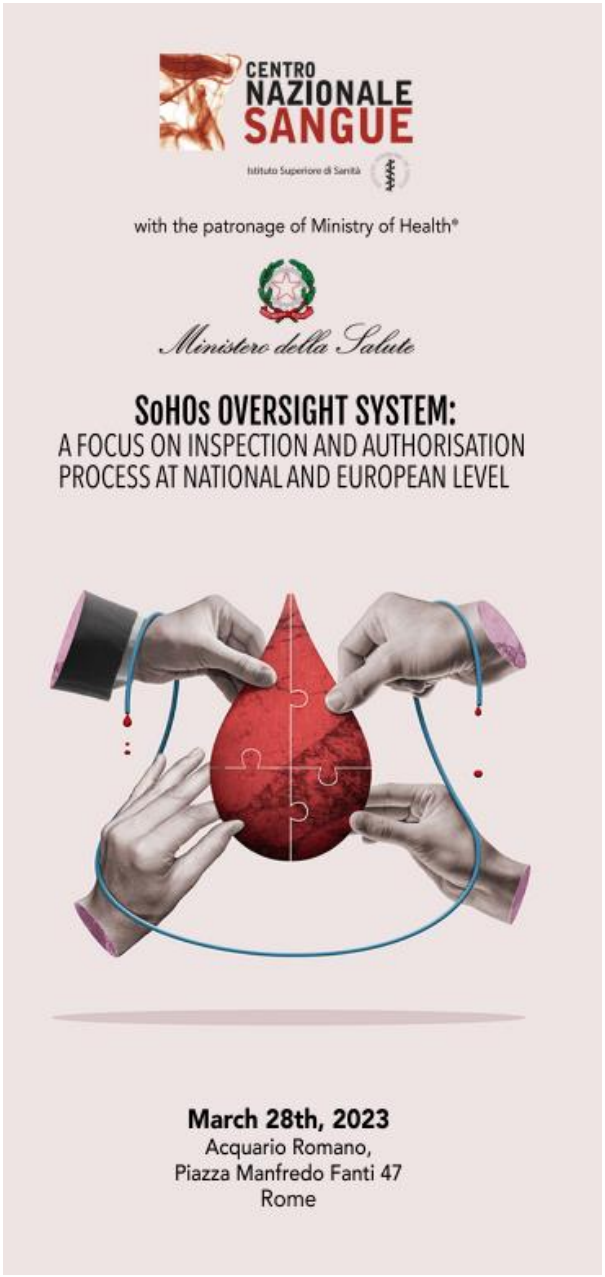
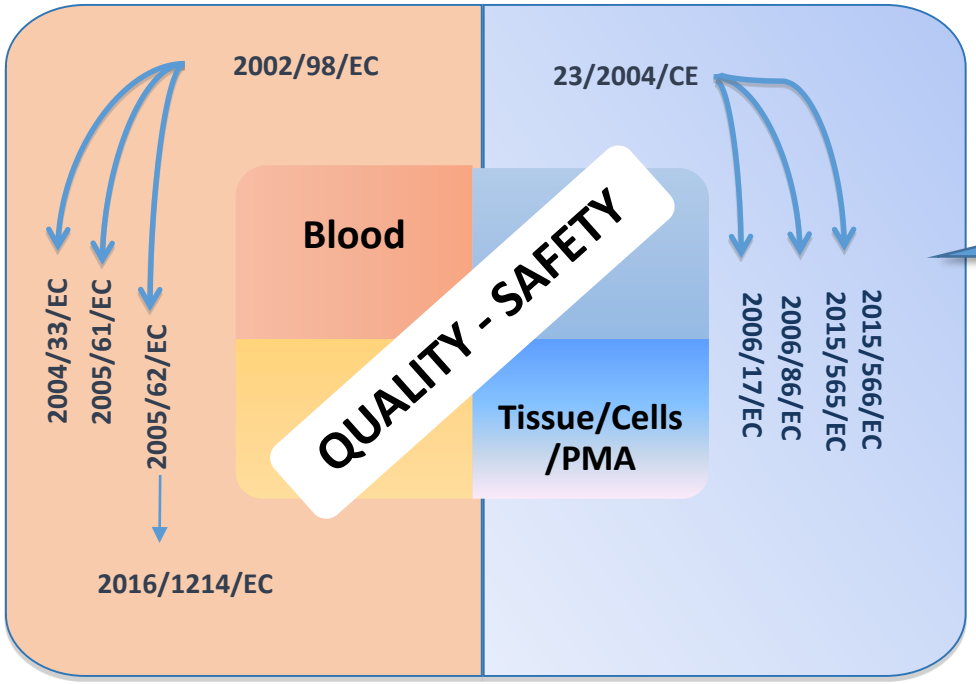


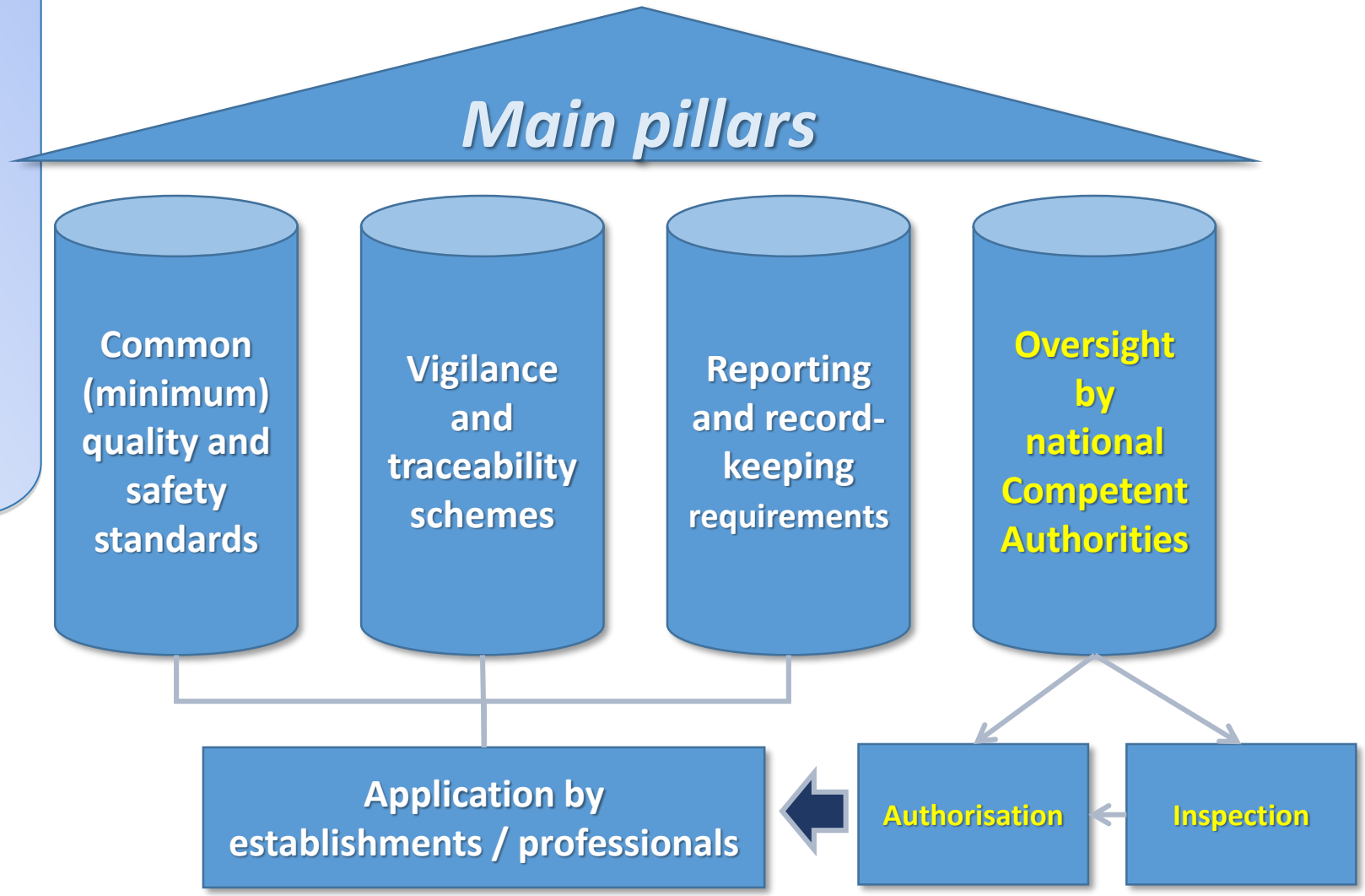
European Inspection Guidelines

Fewzi Teskrat

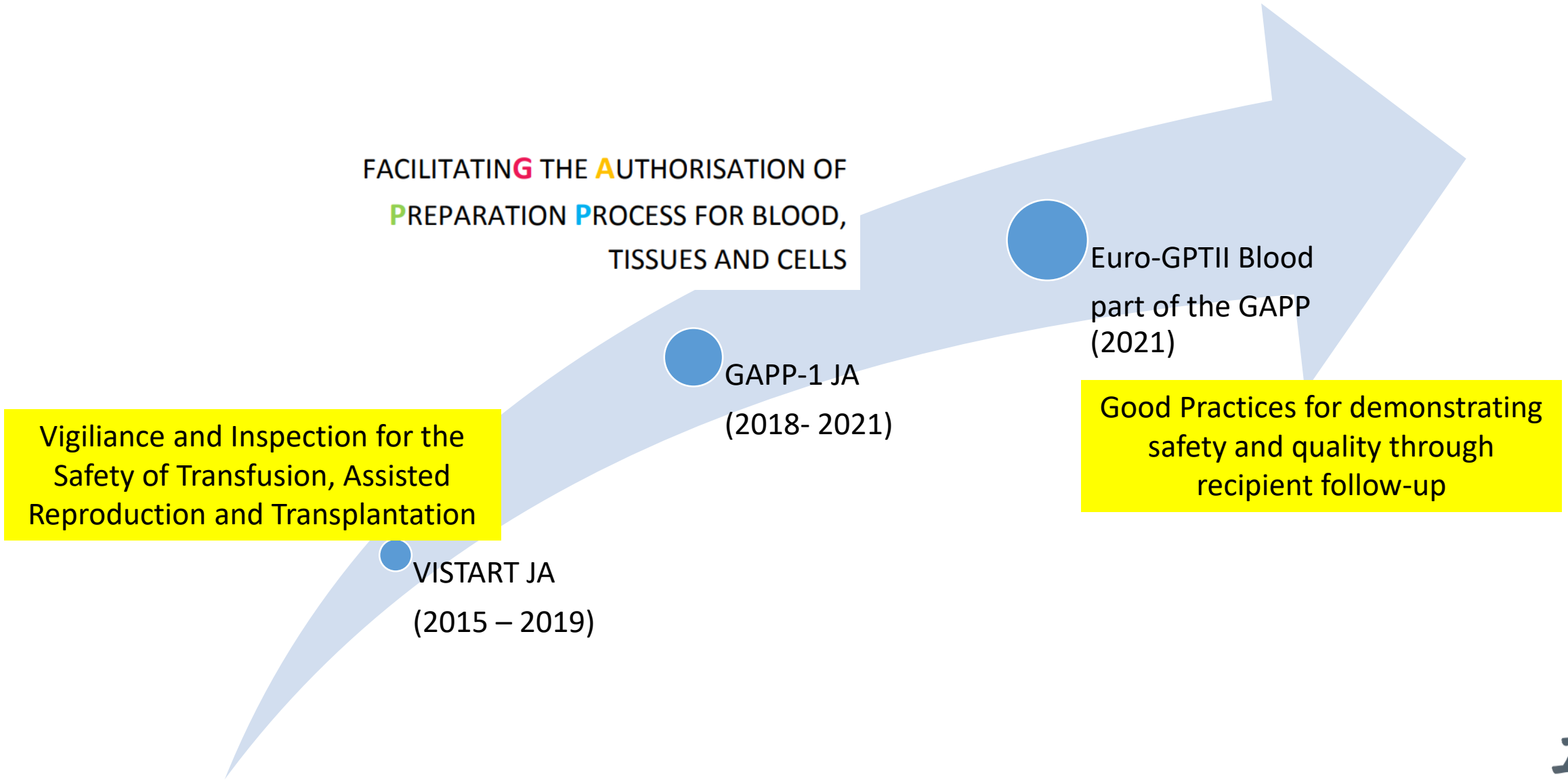
(IES - The EU Commission Expert Sub-Group on Inspections in the Blood, Tissues and Cells sectors)

Current regulatory framework of the oversight activities in the SoHO fields





EU Joint actions & projects aiming to harmonise the SoHO fields in regard of the Oversight Activities



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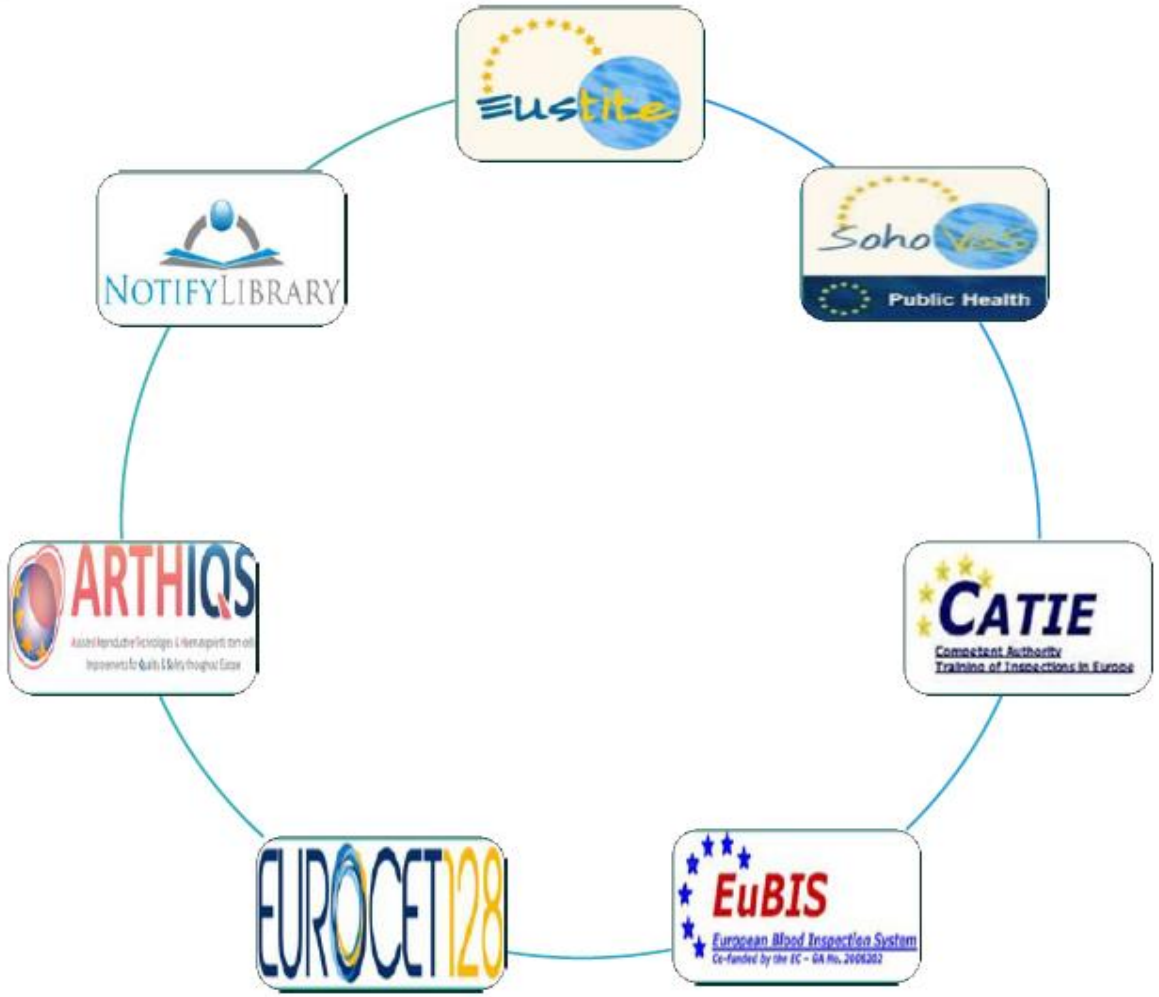
VIGILANCE AND INSPECTION FOR THE SAFETY OF TRANSFUSION ASSISTED REPRODUCTION AND TRANSPLANTATION

Progetti precedenti



General objectives

- ✓ To promote **harmonization** of the approach/methodology for inspection/authorization/vigilance in the different SoHO fields.
- ✓ To improve the cooperation and mutual trust among MS regarding the inspection and vigilance programmes.

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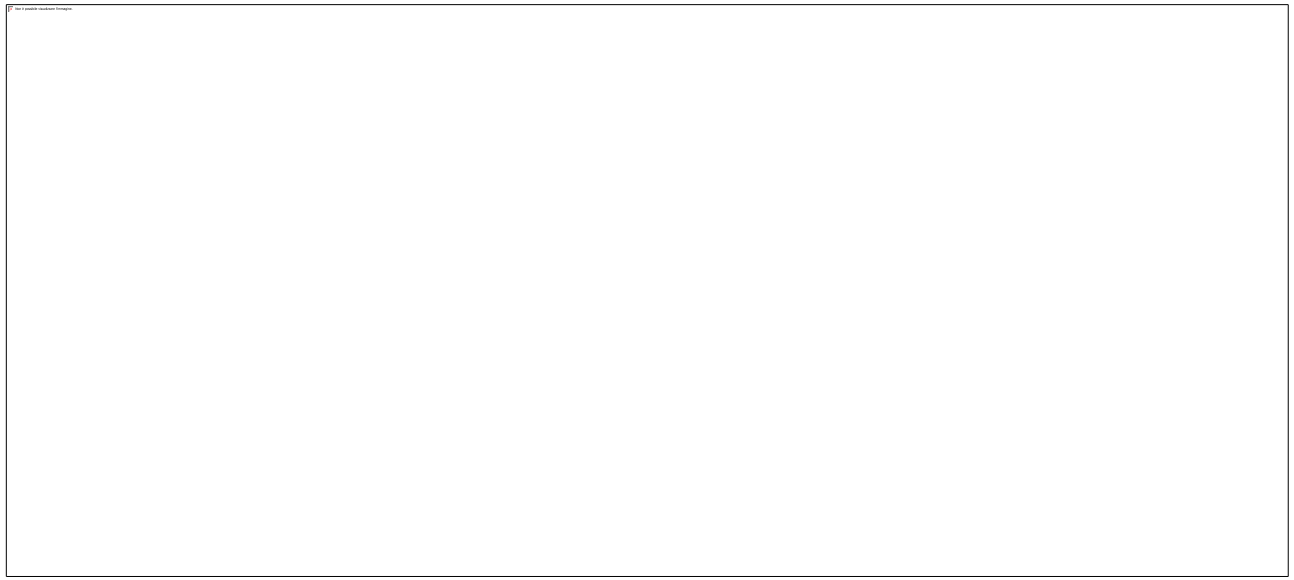
SWOT ANALYSIS

INSPECTION SYSTEM IN PLACE

Figure 1 summarises the aforementioned aspects.

STRENGTHS	•Single CA •Centralised inspectorate •Independence of the inspector
WEAKNESSES	•Inspections not covering T&C procurement and blood collection site
OPPORTUNITIES	•Clear definition of the principle of independence and recommendation to implement it in the WP6 Inspection Guidelines
THREATS	•Risk of lack of objectivity and neutrality of the inspector •Lack of control of T&C procurement and blood collection •sin the WP6 Inspection Guidelines

INSPECTORATE QMS



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SWOT ANALYSIS

INSPECTOR QUALIFICATION

Figure 3 summarises the aforementioned aspects.

STRENGTHS	•Common educational profile of the inspector
WEAKNESSES	•Lack of a formal qualification process for new inspectors
OPPORTUNITIES	•Overcome inspectors' categorization and focus on the qualification and its maintenance, as well as the assessment of the performance
THREATS	•Lack of practical knowledge of processes and risk management in the content of the qualification process •No sufficient consideration to the maintenance of the qualification

INSPECTION METHODOLOGY

Figure 4 summarises the aforementioned aspects.

STRENGTHS	•The empowerment of inspectors (to take immediate actions) is similar among MS
WEAKNESSES	•No homogeneity of the inspection processes •No diffuse application of the inspection tools proposed by Eubis, Eustite and Catie projects
OPPORTUNITIES	•All these aspects should be considered in the WP6 Guidelines as ways of improvement
THREATS	•Inspection results are not available for other CAs and/or EU

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Technical Workpackages

WP 4
Vigilance reporting for blood, tissues and cells

Portogallo

WP 5
International Collaboration for Vigilance Communication and Preparation Process Development

Italia (CNT)

WP 6
Inspection Guidelines for the Competent Authorities on Blood, Tissues and Cells

Francia

WP 7
Training of blood, tissues and cells inspectors with sharing of expertise across Member States

Italia (CNS)

WP 8
Establishment of a framework for joint inspections

Croazia

WP 9
A Voluntary Programme of Inter-MS Inspection System Auditing

Irlanda

WP 10
Implementation of the Single European Coding system in tissue establishments

Italia (CNT)

OBJECTIVE:

- ✓ **To provide Inspection Guidelines for the EU CAs responsible for the inspection and authorization of Blood and Tissue establishments.**

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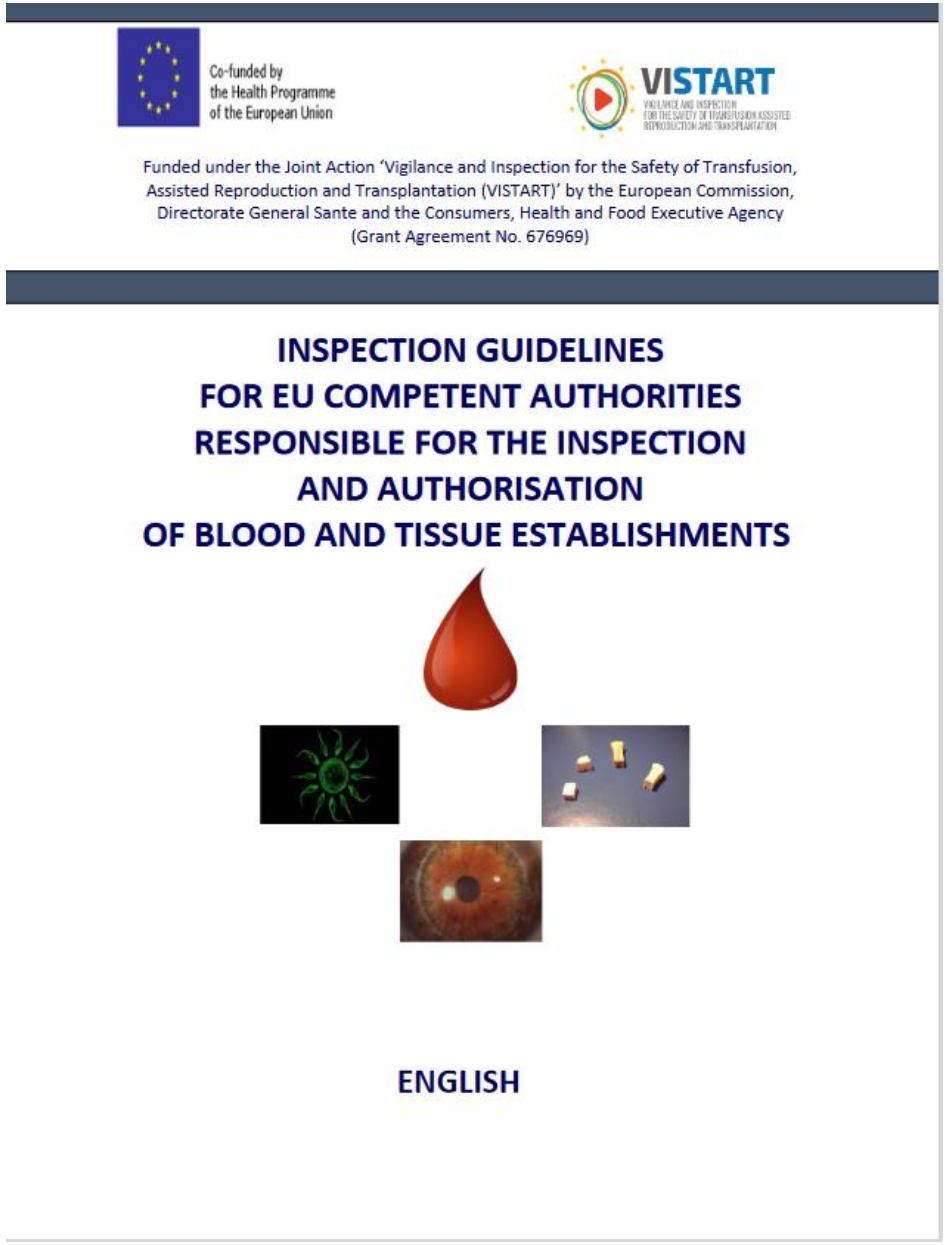


OBJECTIVES

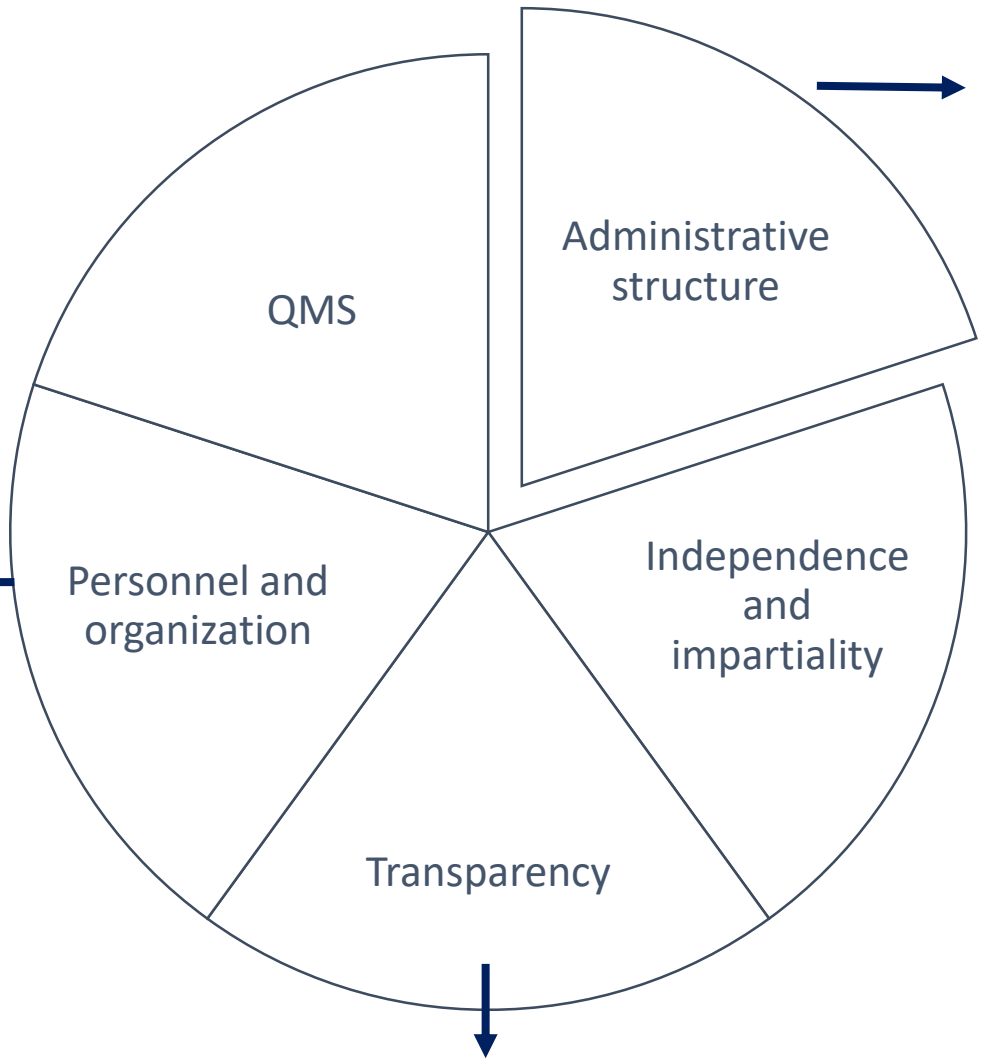
- General governance and quality management principles for CAs,
- Key procedures and documents for licensing blood and tissue establishments,
- Authorisation of processing methods,
- Scheduling, preparation, conduct and follow-up of inspections,
- Recruitment, training and management of inspectors,
- Control of import and export.

References

- Competent Authority Training of Inspections in Europe (developed by EU funded project CATIE),
- Common Criteria for the Inspection of Blood Establishments (developed by EU funded project EUBIS – European Blood Inspection Project),
- European Union Standards and Training in the Inspection of Tissue Establishments (developed by EU funded project EuSTITE),
- Inspection of tissue and cell procurement and tissue establishments - Operational Manual for Competent Authorities (developed by EU funded project),
- Compilation of Community Procedures on Inspections and Exchange of Information (EMA/572454/2014 Rev 17),
- EN ISO 17020.

GOVERNANCE OF THE INSPECTORATE

- Planning and performing inspections
- Inspector recruitment and training
- Management of non-routine inspections (control measures)
- Management of illegal activities
- Authorization of BTC establishments
- Revoke/suspend authorizations



Adequate human resources in terms of number and qualification

Public information

QUALITY MANAGEMENT SYSTEM (QMS)

Quality policy and manual

Documentation and change control

Control and access to records

Internal and external audit

Quality improvement

Management of risks arising from the activities of an inspectorate

QUALITY MANAGEMENT SYSTEM (QMS)

Procedures for taking urgent measures for the protection of public health

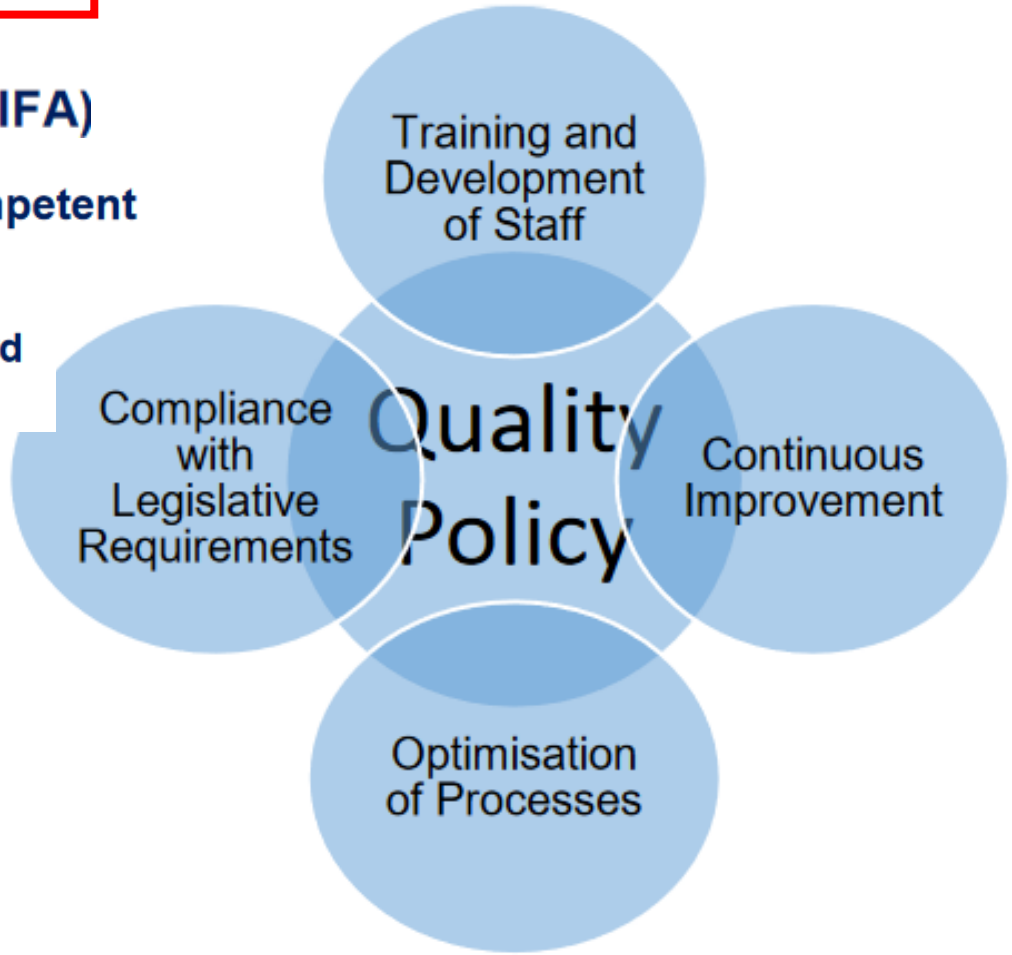
Procedures for identifying illegal and fraudulent activity (IFA)

Exchange of information between EU Member States/Competent Authorities

Exchange of information with other regulatory authorities or third countries

Management of complaints

Management of conflicts of interest



Management of risks arising from the activities of an inspectorate

Table 1: Example of a Risk Register

Risk	Causes	Effects	Mitigating Factors	Additional Actions Taken
Inconsistency of inspectors in applying legislation, regulations or standards.	• Insufficient training of inspectors • Inadequate guidance/procedures for inspectors to follow.	• Loss of stakeholder confidence. • Increased risk of challenges to regulatory decisions. • Risk to public health.	• Quality assurance of inspection reports. • Mentoring new inspectors. • Continuous training and development.	• Audit of inspection reports. • Audit of Inspection Evidence Forms. • Review of training programme.

PREPARATION PROCESS AUTHORIZATION

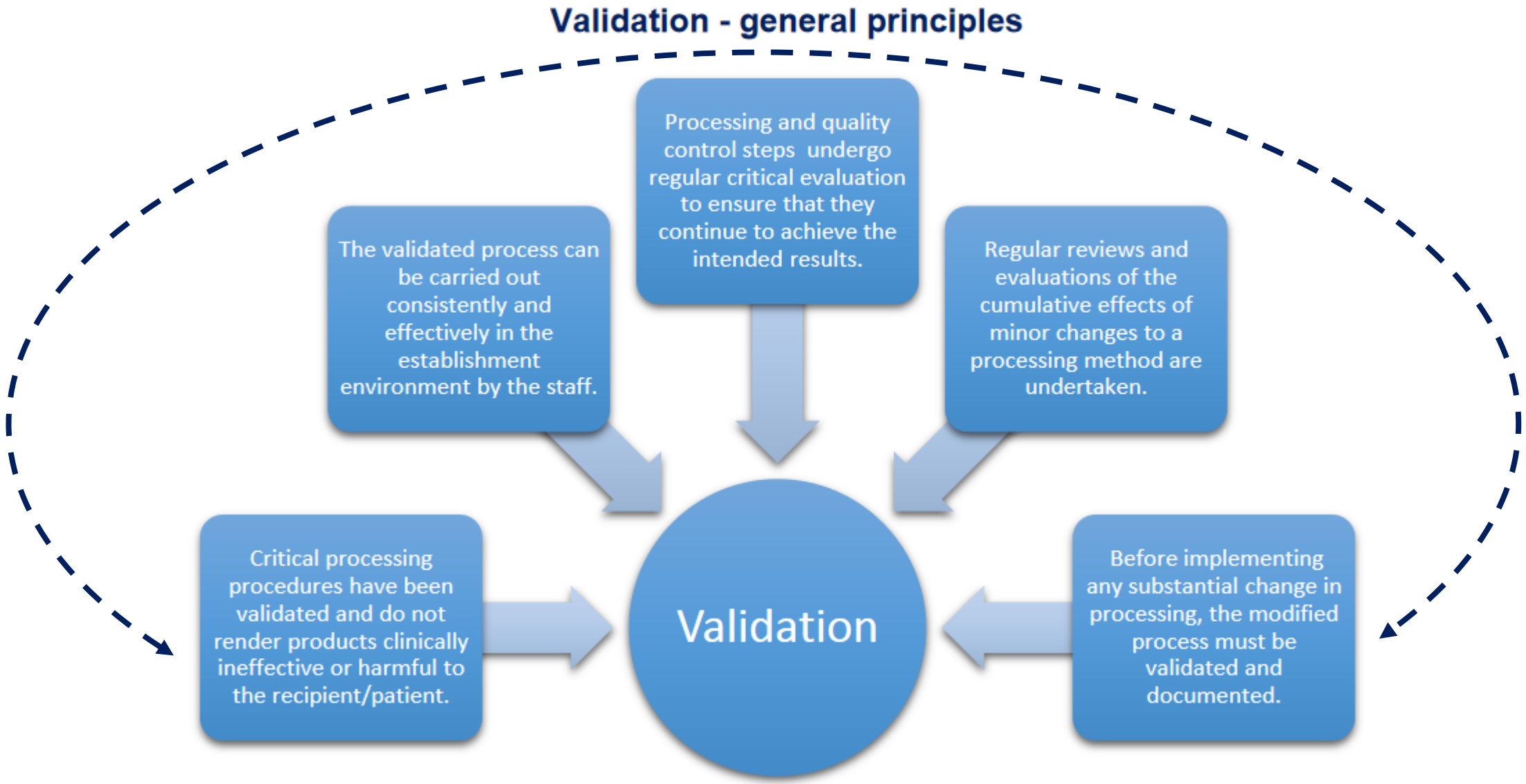


Figure 2: Principles of validation

4 Inspections

Blood Directive 2002/98/EC, Article 3 defines an inspection as:

Inspection shall mean formal and objective control according to adopted standards to assess compliance with this Directive and other relevant national legislation and to identify problems.

- general systems inspections,
- thematic inspections,
- desk-based reviews,
- inspections of third parties,
- EU joint inspections,
- re-inspections.

Implementing a risk-based approach to inspection scheduling

Risk rating

Inspection preparation

Pre-inspection document review

Licence status and history

- Establishment Dossier
- Previous Inspection Report
- Non-compliances and follow-up
- Preparation process dossier (where relevant)
- Significant changes since the last inspection e.g. premises, equipment, perso

Activities

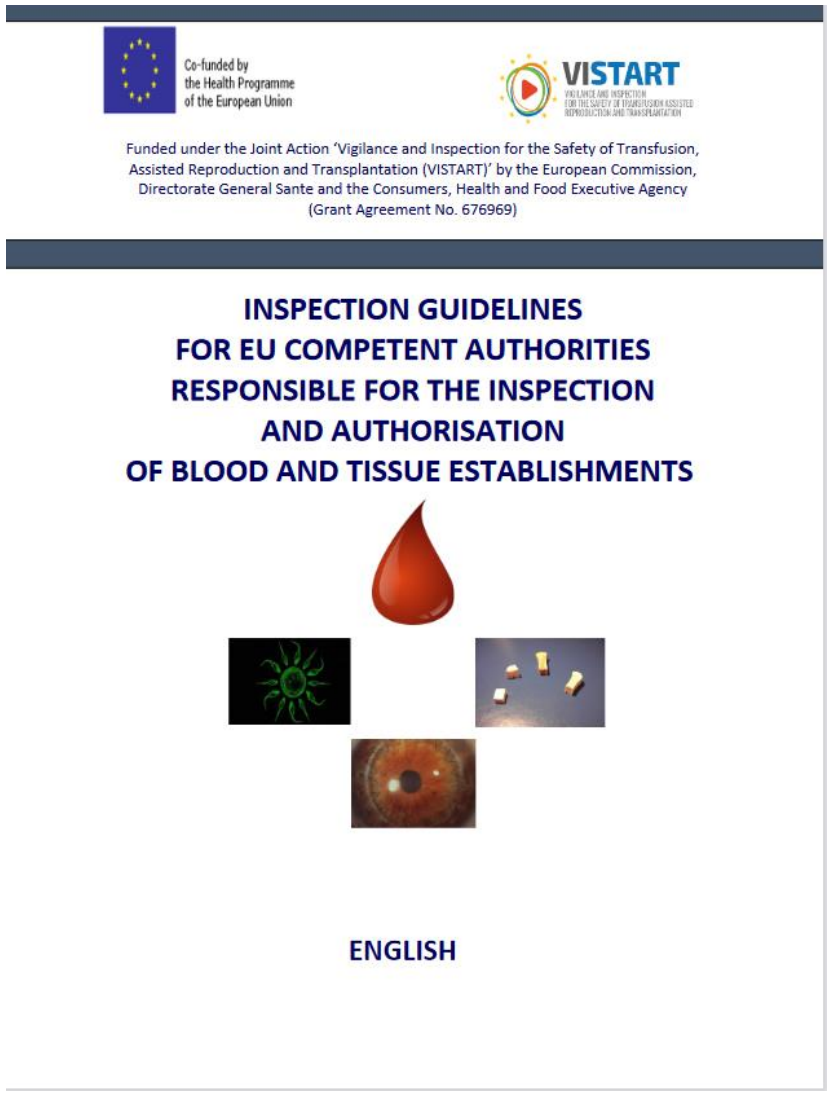
- Volume and Complexity
- Processes and products
- Procurement and testing arrangements
- Import
- Third parties/sub-contractors

Other

- Serious Adverse Events and Reactions, Recalls
- External intelligence e.g. from another regulator
- Complaints/whistleblowing
- Annual activity data

Gathering evidence during an inspection

INSPECTION GUIDELINE TOOLS



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VISTART

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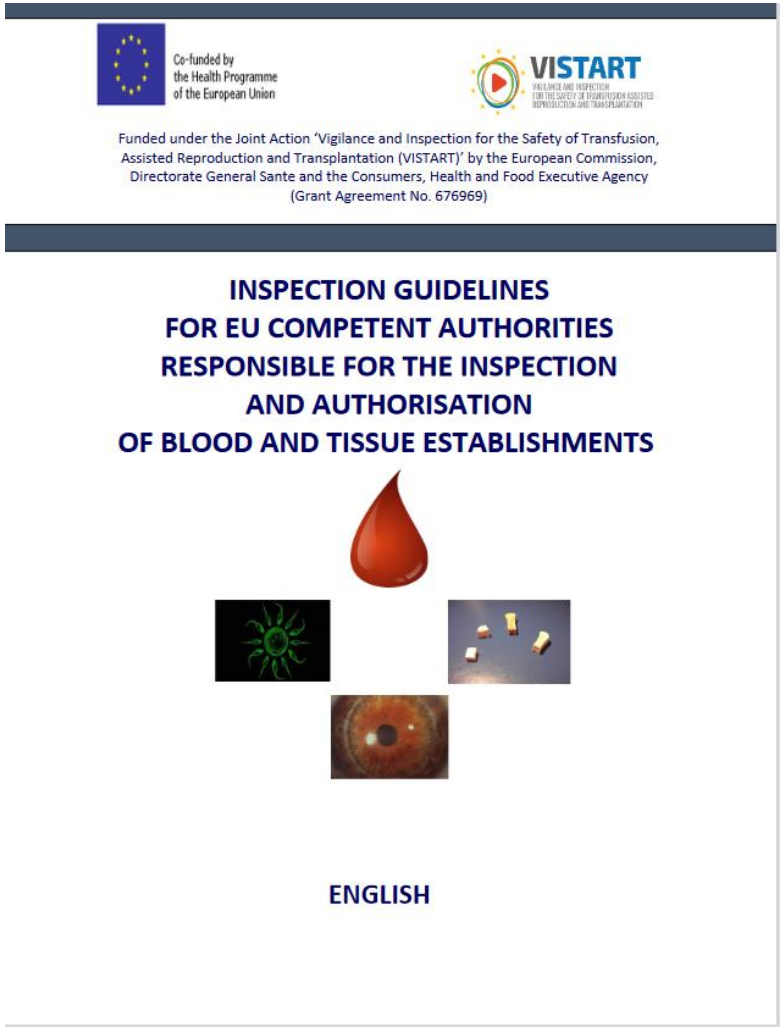
INSPECTION GUIDELINES
FOR EU COMPETENT AUTHORITIES
RESPONSIBLE FOR THE INSPECTION
AND AUTHORISATION
OF BLOOD AND TISSUE ESTABLISHMENTS

ENGLISH



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