
# European Directorate for the Quality of Medicines & HealthCare

## Council of Europe

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
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# Ensuring the Quality and Safety of Substances of Human Origin Council of Europe/EDQM's role

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European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe

SoHO Oversight System

*8 April 2025*

# European Directorate for the Quality of Medicines & HealthCare


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# Council of Europe

- ★ Established in **1949**
- ★ **46 member states**
- ★ Based in **Strasbourg**
- ★ Founded on three main values: **human rights, democracy and the rule of law**


Committee of Ministers

Parliamentary Assembly

Congress of Local and Regional authorities

European Court of Human Rights

Commissioner of Human Rights

Conference of INGOs

# EDQM

- ★ Founded in **1964**
- ★ Partial agreement
  (39 members states & the EU
  + 33 observers)
- ★ Contributes to **public health and access to good quality medicines and healthcare in Europe**
- ★ Wide scope of activities


* EU: European Union; TFDA: Taiwan Food and Drug Administration; WHO: World Health Organization

## Our vision

**Together for better health, for all**

## Our mission

To contribute to public health protection by engaging with an international community of experts and stakeholders

# Four policy areas & a wide portfolio of activities

## Medicinal products

Official standards for manufacture and quality control of pharmaceuticals
**European Pharmacopoeia (documentary & reference standards), Biological Standardisation Programme (BSP)**

Certificates of Suitability confirming compliance with European Pharmacopoeia and inspections
**Certification of suitability**

Control of medicines
**Network of Official Medicines Control Laboratories (OMCLs)**

## Substances of human origin

Quality & safety standards

Biovigilance, data collection and harmonisation

Improving quality system / capacity building of Blood and Tissues & Cells Establishments

Addressing SoHO supply

## Pharmaceutical care

Policies & model approaches for the safe use of medicines

Cooperation to combat falsification of medical products

## Consumer health

Safety standards for cosmetics, tattoo inks and food contact materials

Control of cosmetics
**Network of Official Cosmetics Control Laboratories (OCCLs)**

# Governance of SoHO activities

**EDQM**

**Intergovernmental Committees and Networks Department (ICND)**
**SoHO Division**

**COMMITTEES**

**European Committee on Organ Transplantation (CD-P-TO)**
**European Committee on blood Transfusion (CD-P-TS)**
**39 Member States (MS) including the 27 EU MS**

**PRINCIPLES**

- **Non-commercialisation of substances of human origin**
- **Mutual assistance**
- **Protection of donors & recipients**

**WORKING GROUPS**

**ACTIVITIES**

**1. Standard-setting: legal instruments, technical standards, policies**


**2. Monitoring data & practices Annual reports (Blood and Transplant)**

**3. Capacity building supporting SoHO establishments in implementing CoE standards & EU legislation**

# EDQM and EU cooperation

COOPERATION MODALITIES

Regular **High level meetings** since 2018

**High-level dialogue**

**Mutual representation**

**Representation** in respective committees

**~ 40 agreements** signed since 1991

**Technical cooperation (Joint programmes)**

**Regulatory/Legal cooperation**

A number of EDQM standards and activities **referred into the EU legislation**

- **The EDQM - a regulatory and technical partner of the EU**
  - **60 years of collaboration in the field of medicinal products**
  - **15 years of collaboration in the field of SoHO**

# New EU SoHO legislation and EDQM Role

Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

From the scope:

- SoHO intended for human application and SoHO used to manufacture products regulated by other Union legislation, as referred to in paragraph 6, and intended for human application
- SoHO are substances collected from the human body, whether contain cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of such substance
- solid organs are excluded from the scope of this Regulation (covered in Directive 2010/53/EU)

Entry into force: 7 August 2024
Application date: 7 August 2027 = 3-year transitional period

**EDQM Role: *"SoHO entities shall follow the highest available levels of standards (Art. 56 & 59)"*** standards are to be based on the fundamental principle that the human body or its parts as such are not to be a source of financial gain (in accordance with Article 3 of the Charter of Fundamental Rights of the European Union)

# New EU SoHO legislation and EDQM role

## Implementation of high-level standards through technical guidelines - staying up to date with the science

**Level 1**

Commission Implementing Legislation → "where the Commission deems necessary" *Article 56, 59*

**If none:**

**Level 2**

a. Technical Guidance on the EU SoHO Platform → Published & updated by ECDC/**EDQM**

Shall be considered as **standards**
*Articles*
*27 inspection-standards recognition;*
*37 QMS;*
*39 authorisation-monographs;*
*56 donor protection;*
*59 recipients/offspring protection.*

**OR:**

b. "Equivalent" Guidance → Deemed by CAs to achieve equivalent standards

"When adopting such other guidelines, Member States should verify and document that those guidelines achieve **compliance with** the (EDQM or ECDC) standards"

**If none:**

**Level 3**

Methods based on international standards or scientific evidence

Compliance with the standard to be demonstrated at the entity level

# The CoE/EDQM and the EU in SoHO field

**Council of Europe/EDQM**

- Leading standard-setting organisation in the field of SoHO
- Develops legally binding texts on the topic (1997 Oviedo Convention and the Additional Protocol on transplantation of organs and tissues of human origin, 2015 Convention against Trafficking in Human Organs)
- Non-legally binding texts: recommendations, resolutions, technical guides, reports and other publications

**The European Union/European Commission**

- Address risks emerging SoHO through its mandate to set high standards of quality and safety of SoHO, in accordance with Art. 168(4)(a) of the Treaty on the functioning of the EU
- Undertake a range of activities, drafting legislation and developing guidance, assisting national authorities with its implementation, conducting vigilance activities and supporting projects

**COMMON GOAL:**

**TO PROTECT CITIZENS**

# Selected activities under the Contribution Agreement 2025-27

- Revision of the Guides - Blood, Tissues and Cells, Organs
  - Scientific-evidence re-enforcement
  - Digitalised – interactive web-based format
- Harmonisation of SoHO activity reporting datasets
  - Extended to blood
- Supporting the exchange and implementation of good practices and the development of an action plan for achieving and maintaining sustainable supplies of SoHO – Blood and plasma, Tissues and Cells, Organs
  - new in the Contribution Agreement

# Standard-setting on quality and safety


- Comprehensive guidelines **based on best available scientific evidence** to provide professionals with a useful overview of the most recent developments in the field.
- Ensure **high level of quality and safety.**
- Contribute to the **harmonisation of standards and practices** among European countries.
- **Continuous update** and maintenance.
- **Consensus documents** elaborated by working groups (under the aegis of the CD-P-TO, CD-P-TS) composed of experts nominated by Member States and observers (including professional associations).

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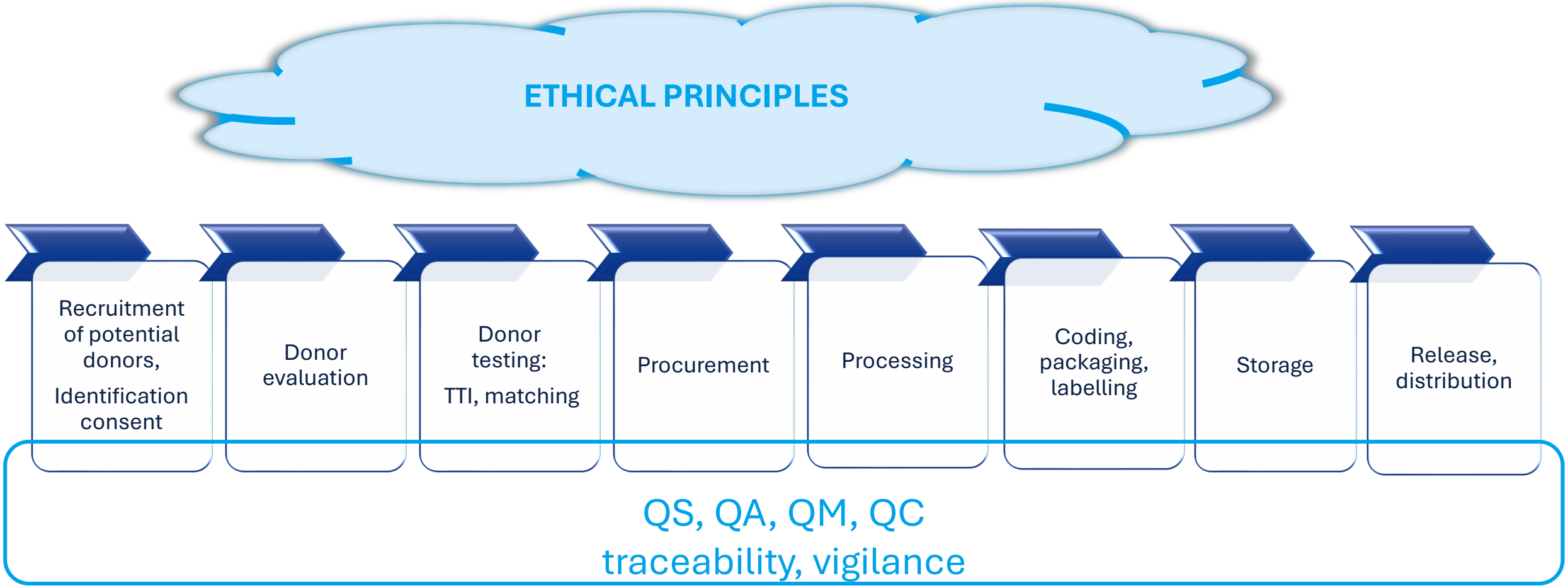
Implemented by the Council of Europe

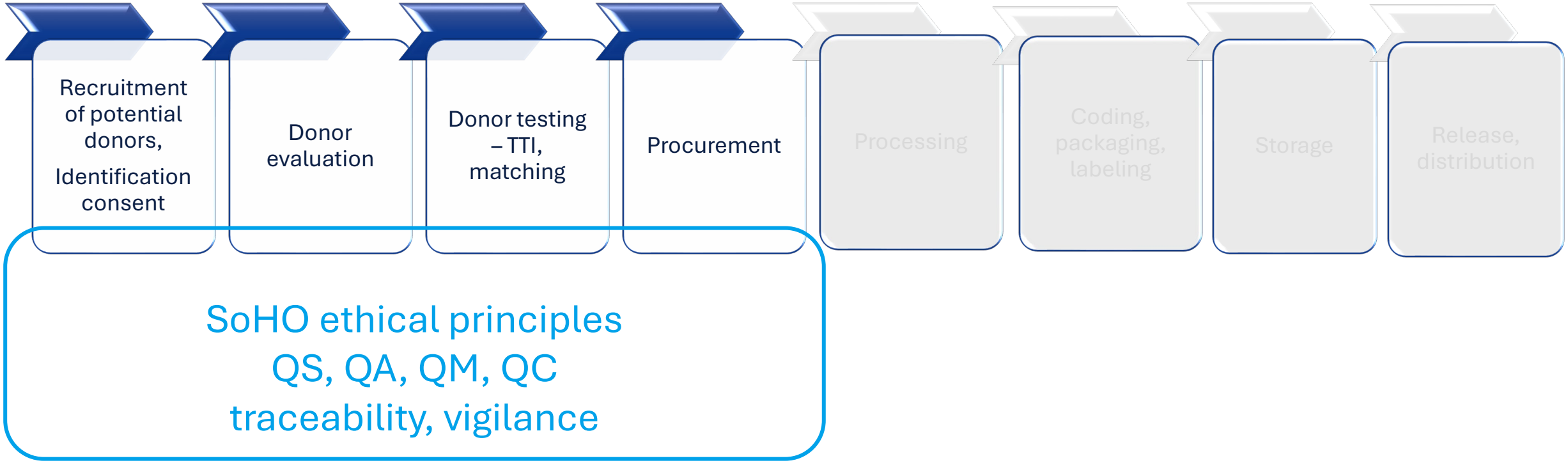
▶ **INCREASED QUALITY AND SAFETY OF ORGANS, BLOOD, TISSUES & CELLS**

▶ **IMPROVED CLINICAL OUTCOMES**

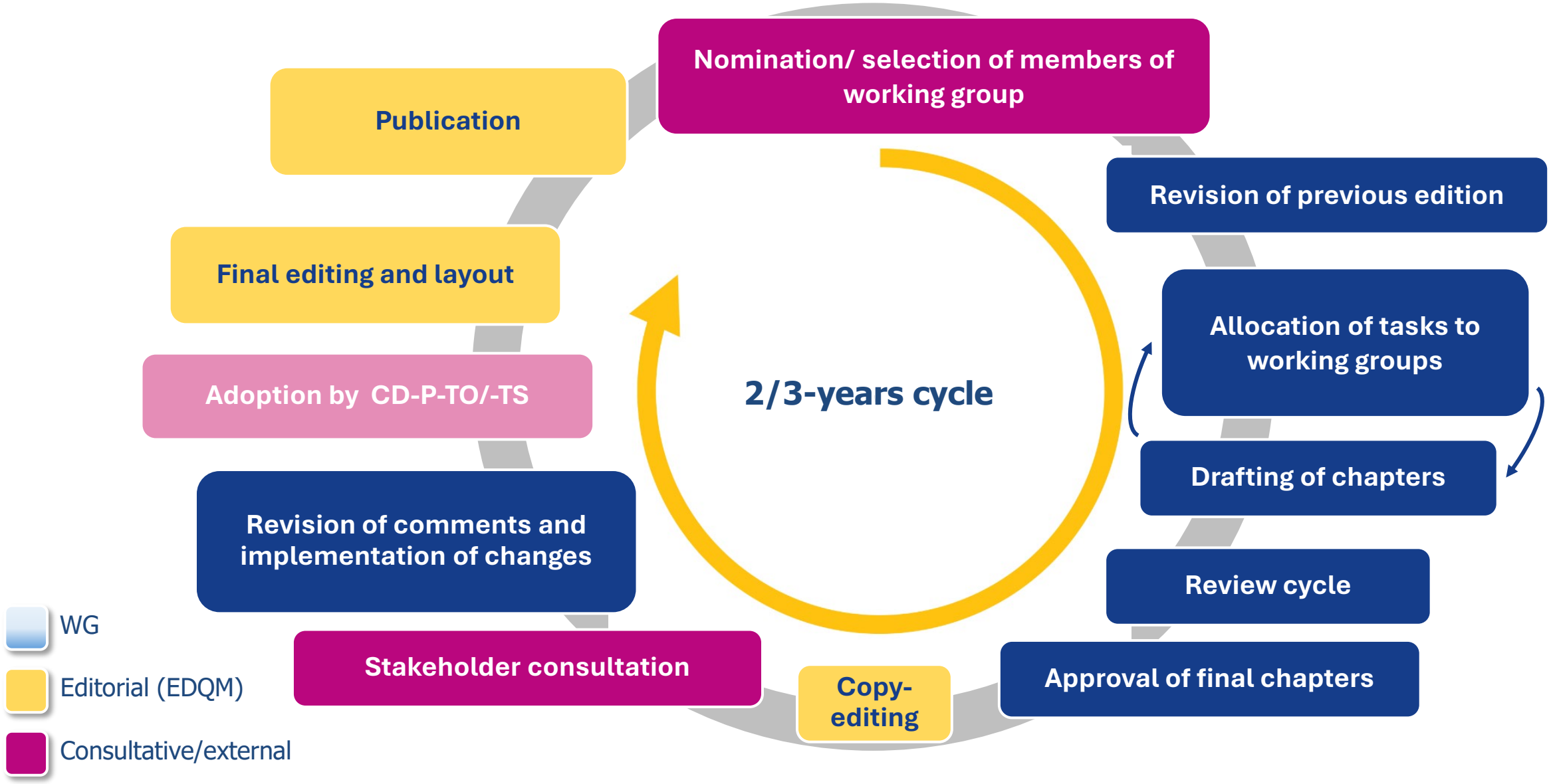
# Scope of the EDQM Guides on quality and safety of SoHO for human application



# Scope of the EDQM Guides on quality and safety for all products, regardless their final destiny



# Development/revision cycle process



# Stakeholders' engagement throughout the cycle

## ★Working group

- Working group composed of 40 experts nominated by member states and observers (including professional associations).
- Final composition of WG is decided by the Secretariat and the Chairs of the CD-P-TO or CD-P-TS and the chair of the previous edition of the Guide, taking into account:
  a) technical and scientific expertise in the required fields experts
  b) drafting needs
  c) active participation in the elaboration of previous editions of the Guide
  d) broad and balanced geographic representation
- Declaration of interest form (DoI) and confidentiality undertaking form.

## ★Stakeholder consultation

- Invitations sent to National Health Authorities (via CD-P-TO and CD-P-TS members, participants and observers, and the EC NCA mailing list); relevant scientific/professional associations; and others designated by any of the above.
- Consultation period: 6 weeks.
- Each comment is assessed and decisions on acceptance are justified.

# Blood components monographs (37)



## Component monographs

### Part A. Whole Blood components

#### A-1. Whole Blood

**Definition and properties**

*Whole Blood* is blood taken from a suitable donor using a sterile and pyrogen-free anticoagulant and container. *Whole Blood* is a source material for *Whole Blood, Leucocyte-Depleted* and for component preparation, which is its major use.

*Whole Blood* for transfusion is used without further processing.

*Whole Blood* for transfusion should not contain irregular antibodies of clinical significance.

**Preparation**

By definition, no (post-donation) preparation is required to produce a unit of *Whole Blood*.

**Requirements and quality control**

Table 5A-1 lists the requirements for *Whole Blood* for direct transfusion. Additional testing may be required to comply with national requirements (see also Chapter 10, Screening for markers of transfusion-transmissible infection).

**Table 5A-1**

| Parameter to be checked | Requirements | Frequency of control |
|---|---|---|
| ABO, RhD | Grouping | All units |
| Anti-HIV 1 & 2 | Negative by approved screening test | All units |
| HBsAg | Negative by approved screening test | All units |
| Anti-HCV | Negative by approved screening test | All units |



| Parameter to be checked | Requirements | Frequency of control |
|---|---|---|
| Volume[a] | 450 mL ± 50 mL volume (excluding anticoagulant) | |
| A non-standard donation should be labelled accordingly | as determined by SPC | |
| Haemoglobin per final unit[a] | Minimum 45 g | as determined by SPC |
| Haemolysis at the end of storage[a] | < 0.8 % of red cell mass | as determined by SPC |

[a] A minimum of 90 % of units tested should meet the required value.

**Storage and transport**

*Whole Blood* for transfusion must be kept at a controlled temperature, i.e. between + 2 °C and + 6 °C *(Directive 2004/33/EC, Annex IV)*. The storage time depends on the anticoagulant/preservative solution used and should be validated.

Validated transport systems should ensure that the temperature d not go below + 1 °C or exceed + 10 °C over a maximum transit t of 24 hours. Transport times may exceed 24 hours if tempera conditions are maintained between + 2 °C and + 6 °C.

*Whole Blood* for preparation of blood components may be between + 2 °C and + 6 °C. Alternatively, it may be kept for up t hours between + 20 °C and + 24 °C, which is a prerequisite for production of platelet preparations from *Whole Blood*.

**Labelling**

The labelling should comply with relevant legislation and, whe place, international agreements. The following information on *W Blood* for transfusion must be shown on the label or contained in component information leaflet, as appropriate *(Directive 2002/9 Annex III)*:

- The name of the blood component and the applicable pro code;
- The volume or weight of the blood component;

## Blood component

- Definition and properties
- Preparation
- Requirements and quality control
- Storage and transportation
- Labelling
- Warnings



- The unique donation (identity) number;
- The producer's identification;
- The ABO and RhD groups;
- The date of expiry;
- The storage temperature;
- The name of the anticoagulant solution.

The following additional information should be shown on the label or contained in the component information leaflet, as appropriate:

- The date of donation;
- Blood group phenotypes other than ABO and RhD (optional);
- Additional component information: irradiated, etc. (if appropriate);
- That the component should not be used for transfusion if there is abnormal haemolysis or other deterioration;
- That the component should be administered through an approved blood administration set.

**Warnings**

Compatibility of *Whole Blood* for transfusion with the intended recipient should be verified by suitable pre-transfusion testing.

RhD-negative female recipients of childbearing age or younger should not be transfused with *Whole Blood* from RhD-positive donors.

Microaggregates may form on storage.

*Whole Blood* for transfusion is not recommended in cases of:

- Anaemia without blood volume loss;
- Plasma intolerance;
- Intolerance due to alloimmunisation against leucocyte antigens.

Adverse reactions include:

- Haemolytic transfusion reaction;
- Non-haemolytic transfusion reaction (mainly chills, fever and urticaria);
- Anaphylaxis;



- Alloimmunisation against red cell and HLA antigens;
- Transfusion-related acute lung injury (TRALI);
- Post-transfusion purpura;
- Transfusion-associated graft-versus-host disease (TA-GvHD);
- Sepsis due to inadvertent bacterial contamination;
- Viral transmission (hepatitis, HIV, etc.) is possible, despite careful donor selection and screening procedures;
- Syphilis can be transmitted if components are stored for less than 96 hours at + 4 °C;
- Protozoal transmission (e.g. malaria) may occur in rare instances;
- Transmission of other pathogens that are not tested for or recognised;
- Citrate toxicity in neonates and in patients with impaired liver function;
- Metabolic imbalance in massive transfusion (e.g. hyperkalaemia);
- Transfusion-associated circulatory overload (TACO);
- Iron overload.

#### A-2. Whole Blood, Leucocyte-Depleted

**Definition and properties**

*Whole Blood, Leucocyte-Depleted (LD)* is a component for transfusion or a source material for component preparation derived from *Whole Blood* by removing the leucocytes to a minimal residual content.

*Whole Blood, LD* contains a minimum haemoglobin content of 43 g.

*Whole Blood, LD* contains less than $1 \times 10^6$ leucocytes.

*Whole Blood, LD* for transfusion should not contain irregular antibodies of clinical significance.

**Preparation**

Generally a filtration technique is used to produce *Whole Blood, LD*. Pre-storage leucocyte depletion within 48 hours after donation is the standard.

# Tissue / Cell Monographs (43)





### 24.2. Haematopoietic progenitor cells from peripheral blood apheresis – HPC(A)

| Tissue/cell product | Haematopoietic progenitor cells from peripheral blood apheresis – HPC(A) |
|---|---|
| Definition | HPC(A) are procured by apheresis from the mononuclear cell fraction of circulating blood after their mobilisation from the bone marrow. The infused HPC(A) can originate from the recipient (autologous) or from another individual (allogeneic). They can be used as fresh unmanipulated product or further processed (e.g. cell selection, cryopreservation). |
| Established clinical indications | • Restoration of haematopoiesis after chemo- and/or radiation therapy (autologous and allogeneic transplantation).<br>• Establishment of donor chimerism (allogeneic transplantation). |
| Critical properties | • Cellularity/viability<br>*a.* for autologous transplantation:<br>– viable $CD34^+$ cell dose: ≥ $2.0 \times 10^6$/kg recipient body weight;<br>*b.* for allogeneic transplantation:<br>– target viable $CD34^+$ cell dose: approximately > $5.0 \times 10^6$/kg recipient body weight,<br>– minimum viable $CD34^+$ cell dose: 1.5-3.5 × $10^6$/kg body weight.<br>• Absence of microbial contamination (the presence of microbial contamination may not preclude release but may indicate the need for antibiotic treatment in the recipient).<br>• In case of ABO incompatibility, red cell volume should be limited to 0.2 to 0.4 mL/kg or 10-30 mL recipient weight.<br>• In case of cryopreserved HPC(A), DMSO volume should be less than 1 mL/kg recipient body weight. |
| Quality control requirements | • Nucleated cell count<br>• Viable $CD34^+$ cell enumeration<br>• Microbiological testing<br>• ABO Rh blood group for allogeneic products<br>• Measurement of residual ABO-incompatible red cell volume |
| Storage and transport | • Fresh HPC(A) can be stored and transported up to 72 hours at room temperature (15-25 °C) or refrigerated (2-8 °C), as requested by the transplant centre.<br>• Fresh HPC(A) can be stored up to 72 hours without cryopreservation.<br>• Cryopreserved HPC(A) are stored and transported at temperatures equal to or below – 140 °C.<br>• Cryopreserved HPC(A) can be stored for up to 10 years or longer.<br>• Thawed HPC(A) are stored and transported refrigerated (2-8 °C). |
| Special labelling and accompanying information | • Placed in a container, and when applicable the accompanying documentation, must be appropriately labelled with a uniquely identifying code.<br>• In the EU, when grafts are distributed for human application, they must be labelled with the Single European Code (SEC) as applicable.<br>• If applicable: warning statements and/or biohazard label.<br>• Specific information not coded in the SEC that must be included in accompanying documentation:<br>– donor name (autologous or related donors) or donor ID (unrelated donors)<br>– recipient name (if permitted), recipient ID (if applicable)<br>– viable $CD34^+$ cell enumeration<br>– ABO Rh blood group<br>– volume<br>– identity of the collection facility and /or donor registry<br>– identity of processing and distribution facility<br>– instructions for appropriate thawing (if applicable). |
| Special warnings | • Do not irradiate.<br>• Properly identify intended recipient and product.<br>• For use by intended recipient only.<br>• For autologous use only, if applicable.<br>• Do not use leukoreduction filters.<br>• Use immediately after thawing.<br>• If presence of microbial contamination, consider antibiotic treatment in the recipient. |



### 24.3. Mononuclear cells from unstimulated peripheral blood apheresis – MNC(A)

| Tissue/cell product | Mononuclear cells from unstimulated peripheral blood apheresis – MNC(A) |
|---|---|
| Definition | Unstimulated mononuclear cells are procured by apheresis from the circulating blood. The procured cells can originate from the recipient (autologous) or from another individual (allogeneic). Unstimulated mononuclear cells can be used as fresh non-manipulated products or further processed (e.g. cryopreservation, cell selection, starting material for ATMPs). |
| Established clinical indications | • MNC(A) after allogeneic stem cell transplantation from the original HPC donor are used in cases of relapse and mixed chimerism or as relapse prophylaxis to enhance the graft-*versus*-malignancy effect, to promote immune reconstitution and prevent infection complications.<br>• MNC(A) for generation of cellular therapies and ATMPs (e.g. NK-cell therapy, virus-specific T-cells, CAR-T cells). |
| Critical properties | • Cellularity/viability<br>*a.* After allogeneic transplantation to enhance immunity and graft-*versus*-malignancy effect:<br>– escalating cell doses of $CD3^+$ cells, depending on the clinical situation and the transplant setting (e.g. in case of relapse from $1.0 \times 10^6$/kg to $1.0 \times 10^6$/kg body weight),<br>– $CD3^+$ cell dose > $1.0 \times 10^6$/kg body weight per infusion should be avoided due to increased risk of graft-*versus*-host disease;<br>*b.* As starting material for generation of cellular therapy and ATMPs:<br>– required cell dose according to the specific protocol.<br>• Absence of microbial contamination (the presence of microbial contamination may not preclude release but may indicate the need for antibiotic treatment in the recipient). |
| Quality control requirements | • Nucleated and mononuclear cell count<br>• Viability<br>• Viable $CD3^+$ cells enumeration<br>• Microbiological testing<br>• ABO Rh blood group for allogeneic products |
| Storage and transport | • Fresh MNC(A) can be stored and transported up to 72 hours at room temperature (15-25 °C) or refrigerated (2-8 °C) as requested by the transplant centre.<br>• Fresh MNC(A) can be stored up to 72 hours without cryopreservation.<br>• Cryopreserved MNC(A) are stored and transported at temperatures equal to or below – 140 °C.<br>• Cryopreserved MNC(A) can be stored for up to 10 years or longer.<br>• Thawed MNC(A) are stored and transported refrigerated (2-8 °C). |
| Special labelling and accompanying information | • Placed in a container, and when applicable the accompanying documentation, must be appropriately labelled with a uniquely identifying code.<br>• In the EU, when grafts are distributed for human application, they must be labelled with the Single European Code (SEC) as applicable.<br>• If applicable: warning statements and/or biohazard label.<br>• Specific information not coded in the SEC that must be included in accompanying documentation:<br>– donor name (autologous or related donors) or donor ID (unrelated donors)<br>– recipient name, recipient ID (if applicable)<br>– total nucleated and mononuclear cell count<br>– viable $CD3^+$ cell count<br>– ABO Rh blood group (allogeneic products)<br>– volume<br>– identity of the collection facility and /or donor registry<br>– identity of processing and distribution facility<br>– instructions for appropriate thawing, if applicable. |
| Special warnings | • Do not irradiate.<br>• Properly identify intended recipient and product.<br>• For use by intended recipient only.<br>• For autologous use only, if applicable.<br>• Do not use leukoreduction filters.<br>• Use immediately after thawing (if applicable).<br>• If presence of microbial contamination, consider antibiotic treatment in the recipient. |

Haematopoietic progenitor cells

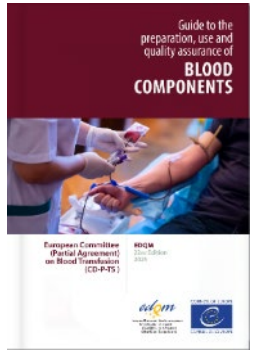
## Tissue/Cell product

- Definition
- Established clinical indications
- Critical properties
- Quality control requirements
- Storage and transportation
- Special labelling and accompanying information
- Special warnings

# Upcoming upgrades of the Guides

- **Scientific-evidence re-enforcement**
- **Digitalisation**
  - Advantages:
    - prompt upgrade/changes feasible
    - improved access to the content of the guides - quick search, advanced search and filters
    - user-customised home page (favourites, proposed content based on user profile, ...)
    - better visibility of changes
    - accurate publishing of additional useful information
  - elements:

# Editions and Timelines




22nd Edition of Guide – layout and design in progress - Publication expected April 2025

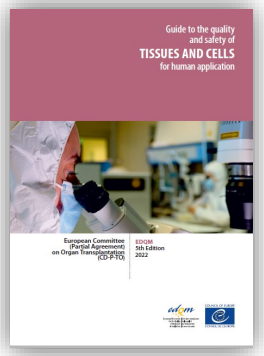
23rd Edition of Guide – Kick-off meeting 4-5 March 2025

- Publication Q2 2027 - tentative


9th Edition of Guide – layout and design in progress - Publication expected April 2025

10th Edition of Guide – scope of revision about to start

- Publication Q1 2028 - tentative



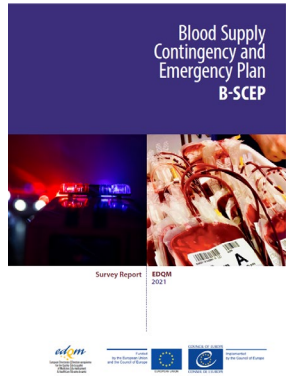

6th Edition of Guide – development in progress

- Publication expected October 2026

# Putting standards into practice

- **Monitoring data/practices**
  - Annual reports: Newsletter Transplant and Reports on the collection, testing, and use of blood and blood components in Europe;
  - Analysis of biovigilance data in the EU (Blood and Tissues & Cells) (SARE);
  - Harmonisation of data collection on T&C.


- **Capacity building activities**
  - Best practices:
    - Biovigilance best reporting practices (Blood and Tissues & Cells)
    - Optimal use of plasma and plasma-derived medicinal products (PDMP) and rare disease treatments
  - Quality management programmes

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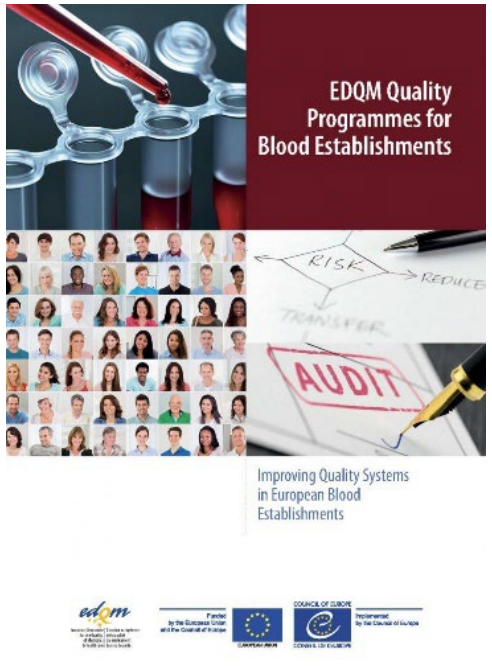
# Putting standards into practice – Quality Management Programme

- **Trainings**
- **Audits and training visits**
- **Blood-Proficiency Testing Scheme (B-PTS)**






**Nucleic Amplification Technique (NAT)**

HBV, HCV, HIV

**Serology**

Anti-HCV
Anti-HIV/p24
Anti-*Treponema*
HBsAg/Anti-HBC

**Immunohaematology**

ABO, Rhesus, Kell, extended phenotyping and irregular antibodies

**Bacterial testing**

https://www.edqm.eu/en/blood-conference

# Supply - Previous projects, deliverables and experience in Blood

**Blood Supply Contingency and Emergency Plan (B-SCEP) Project (2022)**

**Toolkit**

- **Recommendations**
  - Provides support in establishing, implementing and maintaining a B-SCEP
  - General Recommendations
  - Recommendations for Stakeholders
- **Model Preparedness Plan**
  - Provides a template to assist in developing a B-SCEP, building upon the Recommendations

https://www.edqm.eu/en/blood-supply-contingency-and-emergency-plan-b-scep-


**Plasma Stakeholder Event on Plasma Supply Continuity**

Jointly organised by EU Commission and EDQM – 26th and 27th March 2025

Attended by more than 150 participants from 33 countries


**Plasma Supply Management WG meeting**
Jointly organised by EU Commission and EDQM – 29th and 30th January 2019

**Proceedings**

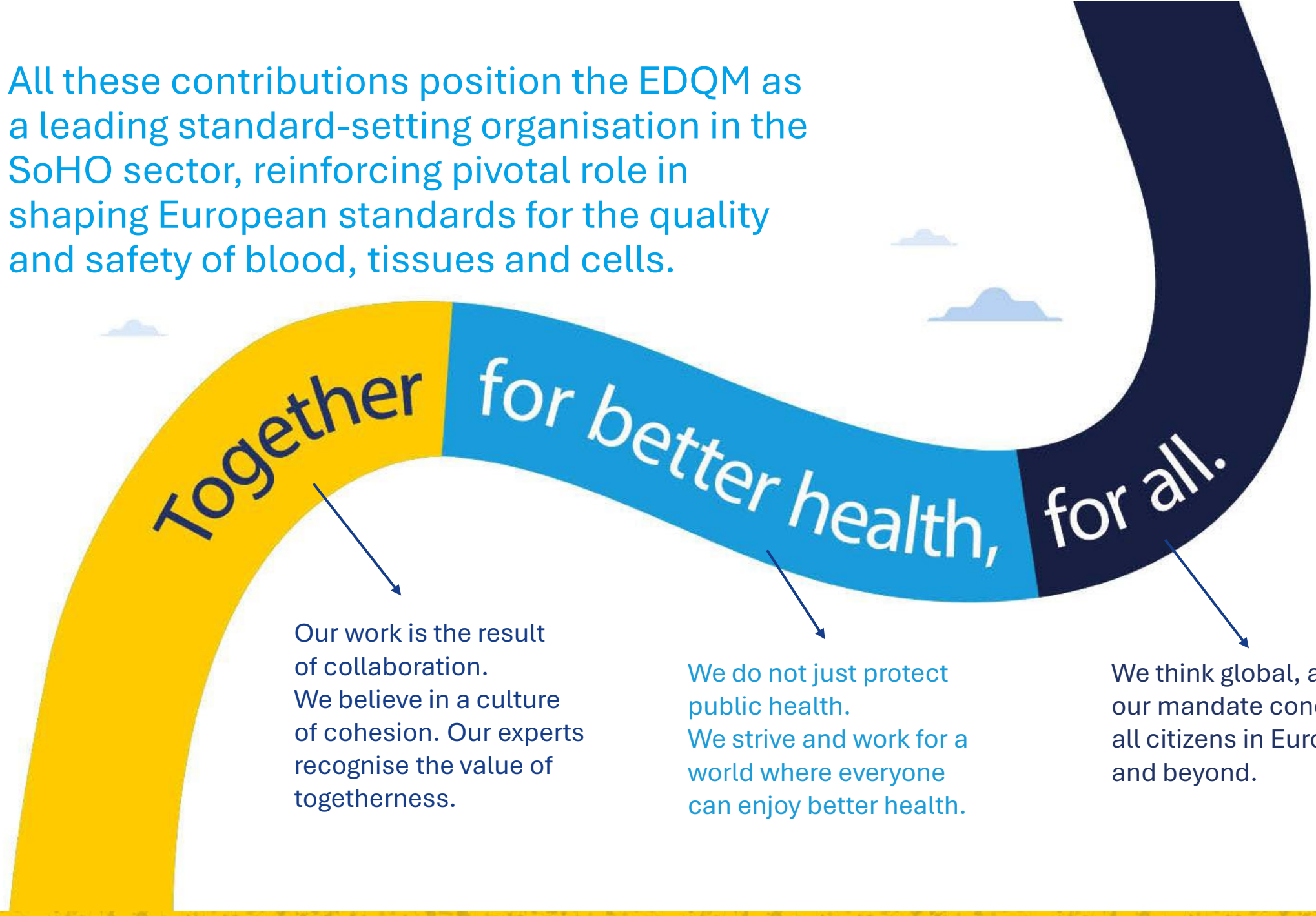
**Recommendations to stakeholders**
https://www.edqm.eu/en/plasma-supply-management

# Data harmonisation activities

- Data harmonisation - Tissues and Cells
  - Project started in 2019
  - Built on the experience from member states and relevant professional societies in the field of tissues and cells
  - Aimed at agreeing on a minimum dataset that would serve the purposes of transparency for citizens and as denominators for the EU biovigilance exercises
  - Agreement on the parameters, units and expected quality of the data to be collected
  - Produced recommendations on who should be accountable for the collection and validation of this data and ensure dissemination among all relevant stakeholders
  - Web page: Harmonising activity data collection exercises in the field of tissues and cells in Europe

  - Data harmonisation activities in Blood will run 2025-2027 and will rely on previous experience in Tissues and Cells field

All these contributions position the EDQM as a leading standard-setting organisation in the SoHO sector, reinforcing pivotal role in shaping European standards for the quality and safety of blood, tissues and cells.




Our work is the result of collaboration.
We believe in a culture of cohesion. Our experts recognise the value of togetherness.

We do not just protect public health.
We strive and work for a world where everyone can enjoy better health.

We think global, and our mandate concerns all citizens in Europe and beyond.


## More information

www.edqm.eu

https://go.edqm.eu/Newsletter

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