EDQM Blood Conference
Innovation in Blood Establishment Processes

14-15 January 2025
Strasbourg, France

EDQM session:
Blood Guide and blood transfusion programmes
(15:30 – 17:00)

Hosts: **EDQM - Substances of Human Origin (SoHO) Division**
Johanna Castrén, Chair of the CD-P-TS
Betina Samuelsen Sørensen, Chair of the GTS Working Group
Stephen Vardy, Chair of the B-QM Working Group

Please note:
- *Food and drink are not permitted in the conference rooms*
- *Photography & filming during the presentations are strictly forbidden*
- *Photos and videos may only be taken by Council of Europe staff members*
- *The session will be recorded for internal purposes only*

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Objectives

- Provide an overview of the EDQM/Council of Europe blood transfusion activities
  - European Committee on Blood Transfusion (CD-P-TS)
  - The Blood Guide
  - The Blood Quality Management (B-QM) Programme
  - The Blood Proficiency Testing Scheme (B-PTS) Programme

- Q&A session and discussion
  - Key priority areas
  - Feedback and collaboration

European Committee on Blood Transfusion (CD-P-TS)

Johanna Castrén
CD-P-TS Chair

Richard Forde
CD-P-TS Secretary, EDQM

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The European Committee on Blood Transfusion (CD-P-TS) – Overview

European Committee on Blood Transfusion (CD-P-TS)

VNRBD

Mutual assistance

Protection of donors & the recipients

1. Developing legal instruments, technical standards, policies

2. Monitoring data and best practices

3. Operational activities supporting BEs implementing technical standards & EU legislation

Funded by the European Union and the Council of Europe

Implemented by the Council of Europe

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CD-P-TS – Monitoring data and best practices

Reports https://www.edqm.eu/en/reports-blood

Since 2001

- The CD-P-TS collects annual activity data for the preparation of reports on the donation, collection, testing and use of blood and blood components.
- Each report provides activity data from the CD-P-TS member states and highlights new or changed practices, addressing trends in the blood sector in Europe.

2020 – 2023 Trend Report
Publication Q1 2025

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CD-P-TS – Harmonisation of data sets

Challenges

- European Blood Establishments (BEs) participate in a number of activity data collection exercises - different timeframes, collection or diverse/overlapping activity data
- Highlighted as a significant administrative burden
- EU SoHO regulatory obligations for reporting of minimum activity data

CD-P-TS highlighted a need for harmonisation and co-ordination of data collection exercises in the blood sector

Harmonising activity data collection exercises in the blood sector:

- Consistency across systems
- Streamlined reporting
- Benchmarking and best practices
- Informed control measures and policy decisions
- Improved transparency
- Enhanced interoperability in blood systems
- Resource efficiency

CD-P-TS to commence work on the harmonisation of data sets in 2025

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CD-P-TS – Blood supply continuity

Collaboration and co-ordination

- Supporting the exchange and implementation of good practices
- Facilitating communication and collaboration among stakeholders

Specific activities

- Blood Supply Contingency and Emergency Plan (B-SCEP)
- Revision of the Guide to the preparation, use and quality assurance of blood components (Blood Guide) – Guidelines on Emergency Planning
- Support the co-ordination of meetings concerning blood supply continuity and emergency planning
- Military/civilian co-operation – blood supply continuity

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CD-P-TS – Plasma supply continuity

Collaboration and co-ordination

- Supporting the exchange and implementation of good practices
- Facilitating communication and collaboration among stakeholders

Specific activities

- The Blood Guide revision
- Data collection and reporting
- Supporting the co-ordination of meetings concerning use of immunoglobulin (IgG) and treatment of rare diseases

Plasma supply stakeholder event
26 – 27 March 2025

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The EDQM's blood transfusion programmes

- The Blood Quality Management (B-QM) Programme
- The Blood Proficiency Testing Scheme (B-PTS) Programme

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The Blood Quality Management (B-QM) Programme

Stephen Vardy

Chair of the B-QM Working Group

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B-QM Programme – B-QM Working Group

Composed of 12 experts in the field of **quality management** with in-depth experience in the **blood sector**:

Margarida Amil Dias,
Portugal

Karen Byrne,
Ireland

Ína Björg Hjálmarsdóttir,
Iceland

Natalia Frączek-Chudzik,
Poland

Luca Giovanni Mascaretti,
Italy

Alina Mirella Dobrota,
Romania

Lolita Mitevska,
United Kingdom

Marie Riley,
Malta

Beate Rothe,
Germany

Mariëlle van Roosmalen,
The Netherlands

Stephen Vardy,
United Kingdom

Gregor Wachter,
Austria

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B-QM Programme – Aim

Assistance/Educational Programme to help BEs and hospital blood banks (HBBs) establish and develop a comprehensive and integrated **quality system** and enhance existing systems.

The programme offers **training courses** and **assessment schemes** (available on-site and virtually) tailored to the level of maturity of each BE or HBB's QMS.

'Quality system to be in place'
EU Directive 2005/62/EC; Good Practice Guidelines; Blood Guide

Since 2012:

over **49** auditing schemes covering

25 European countries,

8 training courses/conferences

Auditing schemes

Blood tailored expert support (B-TES)
Tailor-made support provided on technical and QMS topics, virtual only

Blood training visit (B-TV)
On-site visit and training session on technical and QMS issues based on observed non-compliances

Blood mutual joint visit (B-MJV)
Audit to check compliance with requirements
► Report and recommendations

Blood mutual joint audit (B-MJA)
Audit to check compliance with requirements
► Report and CAPA follow-up

Training courses/conferences

B-QM Programme – Assessment scheme programme

- Assess how European BEs and HBBs are **putting standards into practice**
- Provide them with **guidance** relying on standards laid out in EU legislation and the latest version of the EDQM/Council of Europe Good Practice Guidelines for BEs (*part of the Blood Guide*)

In 2027 the new "**Regulation on standards of quality and safety for substances of human origin intended for human application**" (2024/1938) will replace the current blood directives (art. 56 & 59).

The EDQM Guides are acknowledged as technical guidance

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B-QM Programme – Assessment scheme programme

Key outcomes:

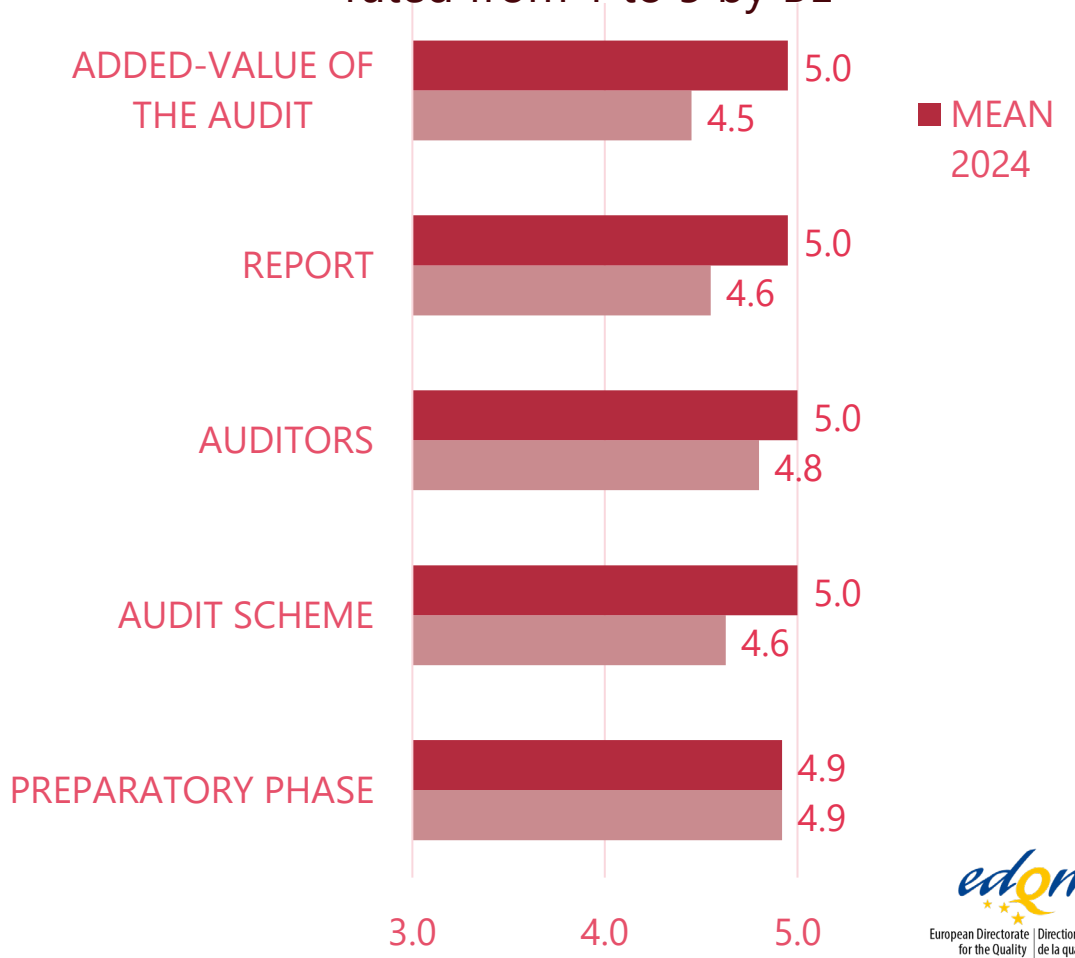
- Number of requests increasing
- Very good feedback from visited BEs

Most common findings and issues faced by BEs:

- **Risk management**
- **Change control**
- **Qualification/validation**
- **Cold chain management**

Scheme satisfaction survey:

rated from 1 to 5 by BE



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B-QM Programme – Key messages

Experts from European BEs ☞ **bring and share their experience & knowledge**

- B-QM activity **does not supersede/replace inspections** performed by authorities
- **Educational peer-to-peer** programme
  - **Product** & **process** approaches
  - Schemes focusing on **root causes;** probe deeper into the process; place technical staff in their field

  ☞ **Risk-based approach**

- Improve QMS but also **support BEs and HBBs** in changing their **QM culture** and **rethinking their processes/system**
- Raise awareness about **risk-based QM**
- **Cost-effective QM** to decrease costs and burdens

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B-QM Programme – More information

Apply using our **online form** before 15 September each year for your application to be considered for the year to come:
https://go.edqm.eu/BQMrequest

Blood Quality Management Programme web page:
https://www.edqm.eu/en/blood-quality-management-programme

If you have any further questions, please contact:
EDQM_B_QM@edqm.eu

B-QM scheme request

The Blood Quality Management (B-QM) programme is aimed at supporting European blood establishments and hospital blood banks in developing, implementing and improving their Quality Management System (QMS) and takes into account the specificities of the blood transfusion field.

The B-QM programme is an assistance and educational programme delivering virtual and onsite assessment schemes.

All activities carried out within the B-QM programme are open to blood establishments and hospital blood banks from the European Union and Council of Europe members states and are free of charge.

Please complete this form in order to request for an assessment scheme to be held in your blood establishment or hospital blood bank.

- *Please make sure to submit your request once duly filled out.*
- *Applications have to be submitted to the EDQM before 15 September of each year to be considered for the programme of the following year.*

B-QM Programme

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Co-funded by the European Union

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B-QM training courses

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For almost 10 years now!

A comprehensive range of virtual or in-person **quality management (QM) training courses, workshops and/or conferences** once a year

Tailored to the **needs of professionals working in the field** of blood transfusion

Designed to provide either **general training** in quality management or **more specific**, according to the identified needs

Needs **identified either by participants** in previous editions of the training course **or by the B-QM WG**.

Examples of specific training courses:

- "Statistical process control for Blood Establishments"
- "Audit practices in Blood Establishments"
- "Quality management review and key performance indicators"

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From 2025

- As part of the new Contribution Agreement between the European Commission and the Council of Europe/EDQM, there will be a yearly training course on “Quality management for Substances of Human Origin”

- Practical details:
  - Online
  - First edition in autumn 2025
  - For SoHO entities and SoHO establishments in Council of Europe members states

Please refer to our website to find more information on future training sessions: they are advertised in advance on the EDQM upcoming events and training web page, along with registration information and links

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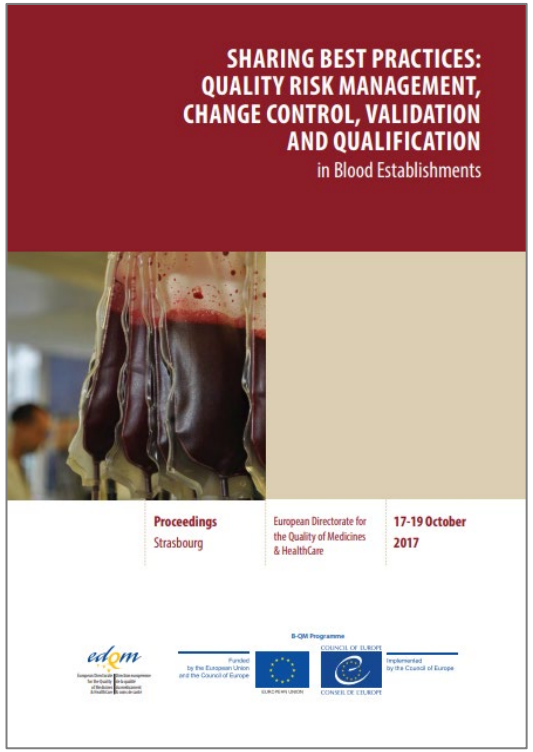
If you missed the previous editions…



A number of past events, training sessions and publications are available for free on the EDQM website:

Free publications: https://freepub.edqm.eu/publications/

Events: https://www.edqm.eu/en/e-learning

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The Blood Proficiency Testing Scheme (B-PTS) Programme

Perrine Arnould

SoHO Quality Section, EDQM

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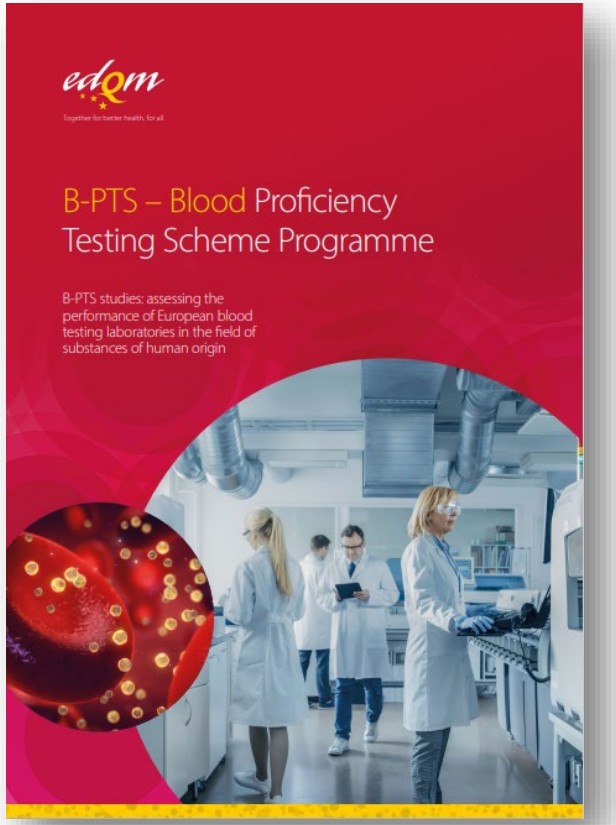
B-PTS Programme

- **E**xternal **Q**uality **A**ssessment **(EQA)**
- **Aim:**

  Improve the safety of blood components, plasma-derived medicinal products, organs and tissues and cells, and therefore **protect patients** receiving blood transfusions, undergoing a transplant or benefitting from medically assisted reproduction.

  Providing laboratories with objective means of assessing that the **testing results** for blood donations are **reliable.**

- This programme has been co-funded by the EDQM and the European Commission **since 2010**.



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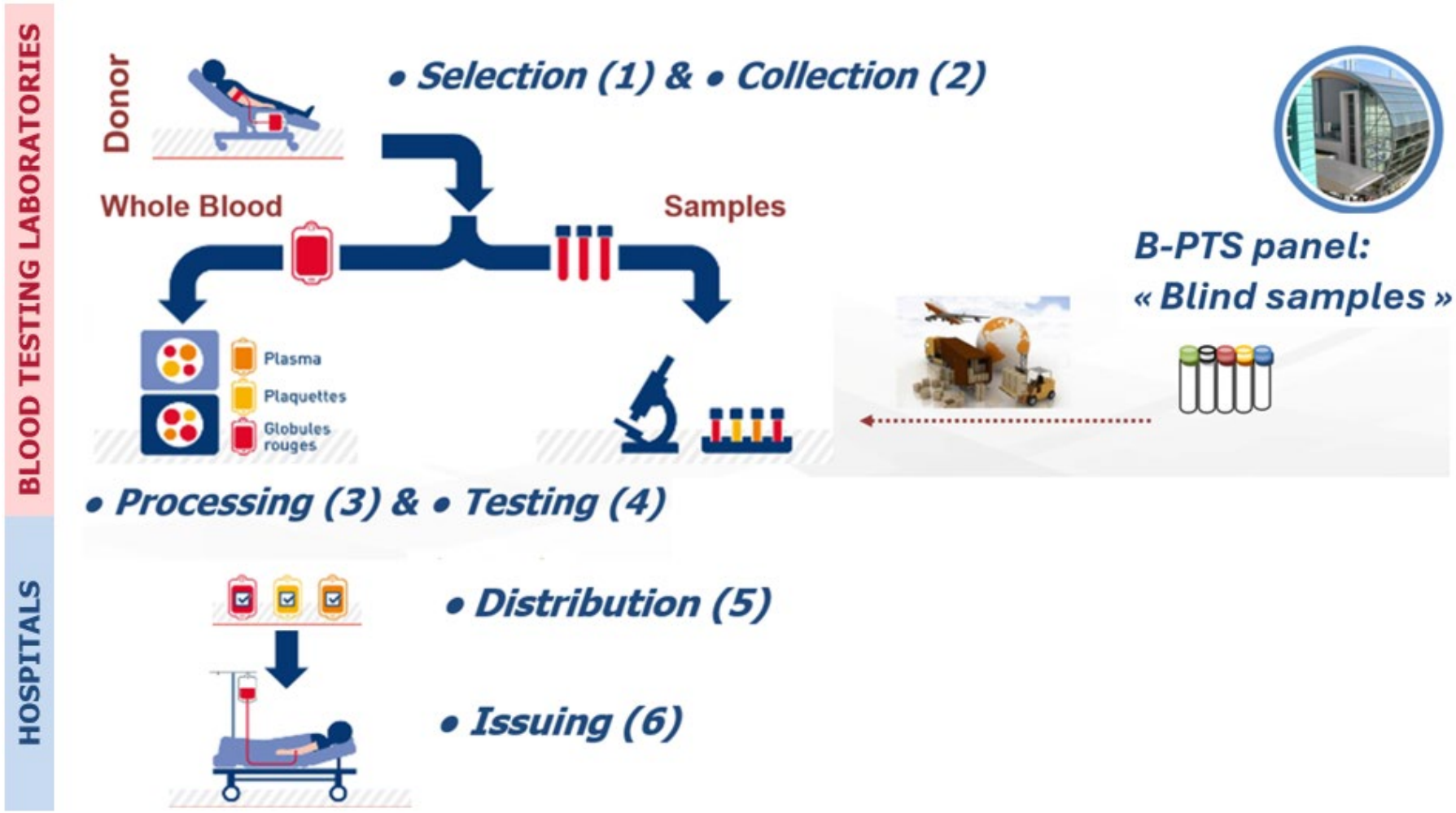
B-PTS Programme

At what stage do we intervene?



*Participants receive test panels, which consist of a combination of **genuine samples** that would typically be received by a blood testing laboratory.*

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B-PTS Programme

Dedicated to **BEs** and **laboratories performing testing on living organ, tissue and cell donors** from European Union and Council of Europe member states.

Nucleic acid amplification technique (NAT)

NAT for hepatitis B and C virus (HBV and HCV), human immunodeficiency virus (HIV)

Serology immuno-haematology

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

Immuno-haematology

ABO, Rhesus, Kell, extended phenotyping and irregular antibodies

Microbiology

Bacterial testing of platelet components

80	B-PTS studies conducted to date
69	Participating laboratories (on average, per study)
38	Participating European countries

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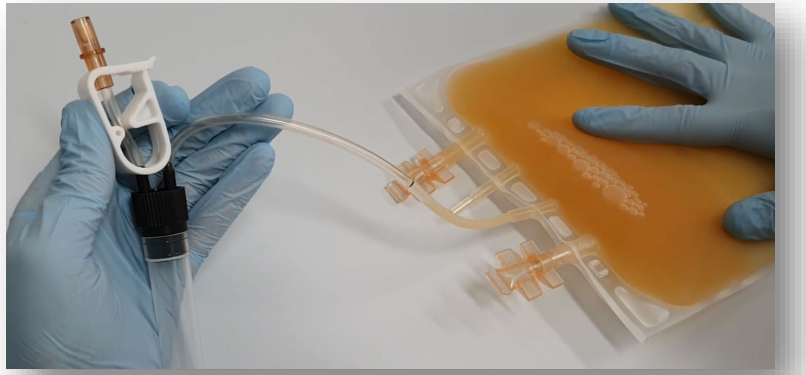
B-PTS Programme

Bacterial testing of platelet components

Platelet components (PC) are more likely than other blood components to be **contaminated with bacteria** due to their **storage at 20-24 °C**. Bacterial screening of PC provides a good indication of bacterial contamination.



Major challenge of a bacterial PTS study: provision of live bacterial cells in a defined, low quantity. To enable this, study participants are requested to prepare the final B-PTS samples on-site.

A **low-count inoculum** is provided in combination with a **spiking device** to ensure that all participants will have an identical contaminated PC sample.

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B-PTS Programme – More information

Apply using our **online form** before **15 January 2025** for your application to be considered for the year to come.

B-PTS Studies	Date of shipment
B-PTS081 Bacterial testing of platelet components	1st quarter
B-PTS082 HBV/HCV/HIV NAT	1st quarter
B-PTS083 Anti-HCV	2nd quarter
B-PTS084 HBsAg/Anti-HBc	2nd quarter
B-PTS085 Anti-*Treponema*	3rd quarter
B-PTS086 Anti-HIV/p24	3rd quarter
B-PTS087 ABO Rhesus, extended phenotyping and irregular antibodies	4th quarter

B-PTS Programme web page:
www.edqm.eu/en/blood-proficiency-testing-scheme-b-pts

If you have any further questions, please contact: **EDQM_B_PTS@edqm.eu**

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The EDQM Blood Guide

Rada M. Grubovic Rastvorceva

SoHO Standards Section, EDQM

Betina Samuelsen Sørensen

Chair of the GTS Working Group

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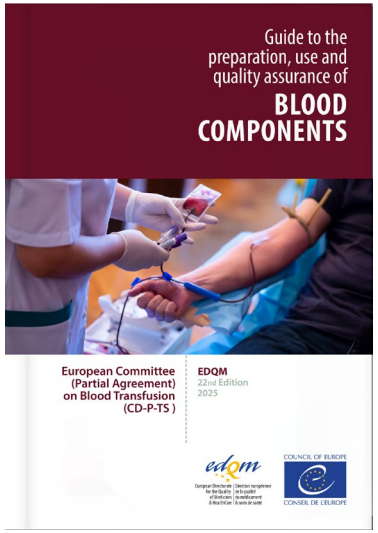
The Blood Guide

The Guide to the preparation, use and quality assurance of blood components is a compendium of widely accepted, harmonised, European standards that provide safety, efficacy and quality requirements for the preparation, use and quality control of blood components in Europe and beyond.



EDQM technical guides are recognised as a **formal point of reference** within the new SoHO regulation.

CHAPTERS

- GPG — Referenced in EU Directive 2016/1214
- Chapter 1 General notices
- Chapters 2-4 8-13
- Chapters 5, 6, 7 — 38 monographs
- Appen-dices — SPC, tables for calculation of blood/collection volumes, etc.

- **Technical annex to CoE Recommendation No. R(95)15**
- **Comprehensive guidelines** to provide professionals with a useful overview of the most recent advances and standards in the field
- Ensure stringent **quality and safety standards**
- Contribute to the **harmonisation** of these activities among European countries, facilitating uniform standards and practices
- **Continuously updated** and maintained
- Elaborated by experts **(GTS Working Group)** nominated by CD-P-TS members and observers
- The Blood Guide is intended for **all professionals** working in the donation, collection, testing, processing, storage, distribution and transfusion of blood and blood components, for BEs, HBBs, and healthcare and regulatory professionals in the blood sector.

INCREASED QUALITY, SAFETY AND EFFICACY OF BLOOD AND BLOOD COMPONENTS

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22nd edition – GTS Working Group

Chair: Betina Samuelsen Sørensen (DK)

Scientific Programme Manager, EDQM – Blood Guide: Rada M. Grubovic Rastvorceva

Members:

Alina Dobrota
Alvyda Naujokaite
Christian Schaerer
Constantina Politis
Cristina Caeiro
Diarmaid Ó Donghaile
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22nd edition – Timeline

GTS WG meeting (March 2023)

- Kick-off meeting; F2F
- Allocation of tasks and drafting

GTS WP meeting (October 2023)

- Drafting and review of chapters; F2F

GTS WG meeting (March 2024)

- Finalising drafts for consultation; F2F

Copy-editing (April 2024)

Stakeholder consultation (May/June 2024)

Revision of comments, implementation of changes, preparation of final drafts for adoption (July/September 2024)

GTS WP meeting (October 2024)

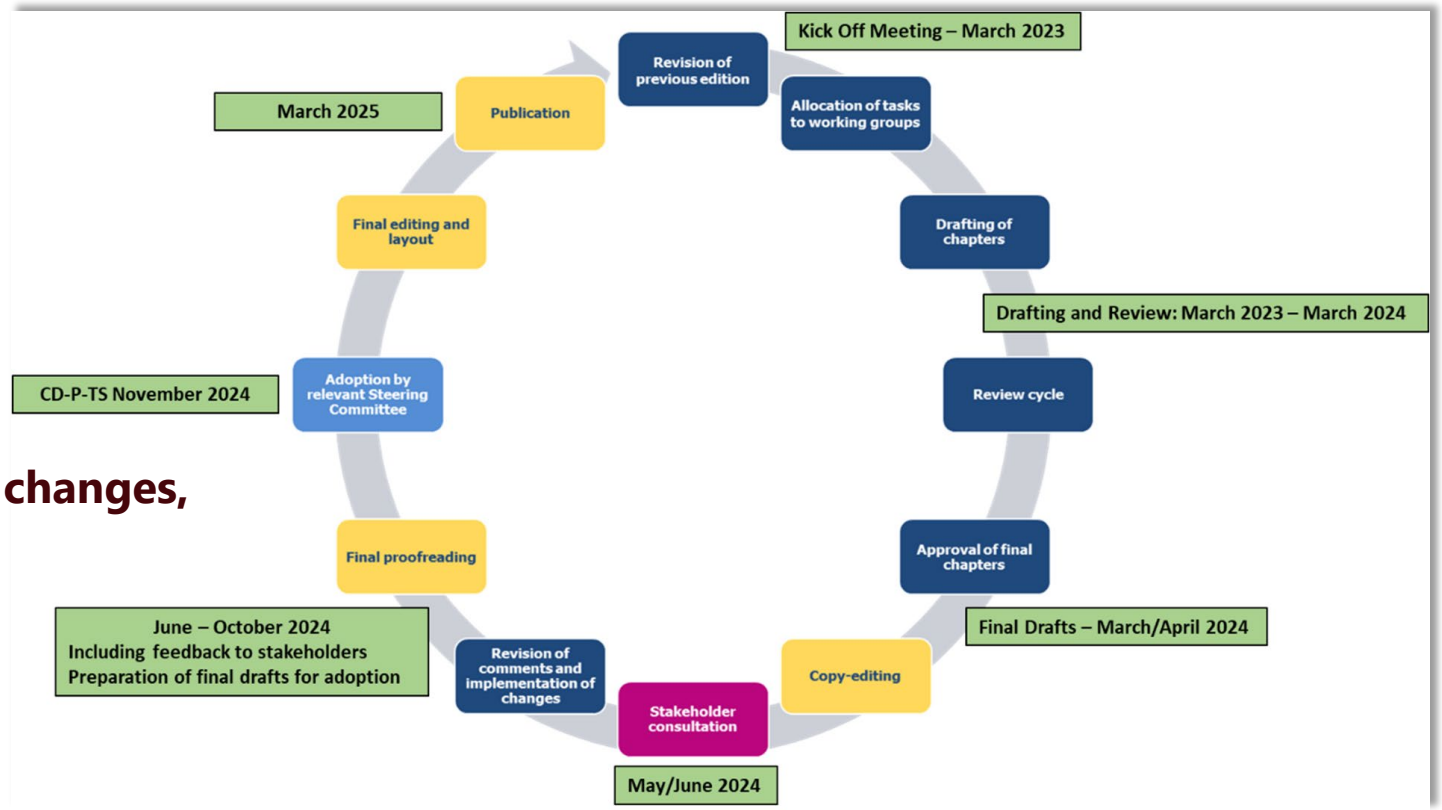
- Finalising drafts for adoption; F2F

Final proofreading (October 2024)

Adoption by CD-P-TS (November 2024)

Final editing and layout (November 2024/ February 2025)

Publication (March 2025) The 22nd edition of the Blood Guide will also be published in French.



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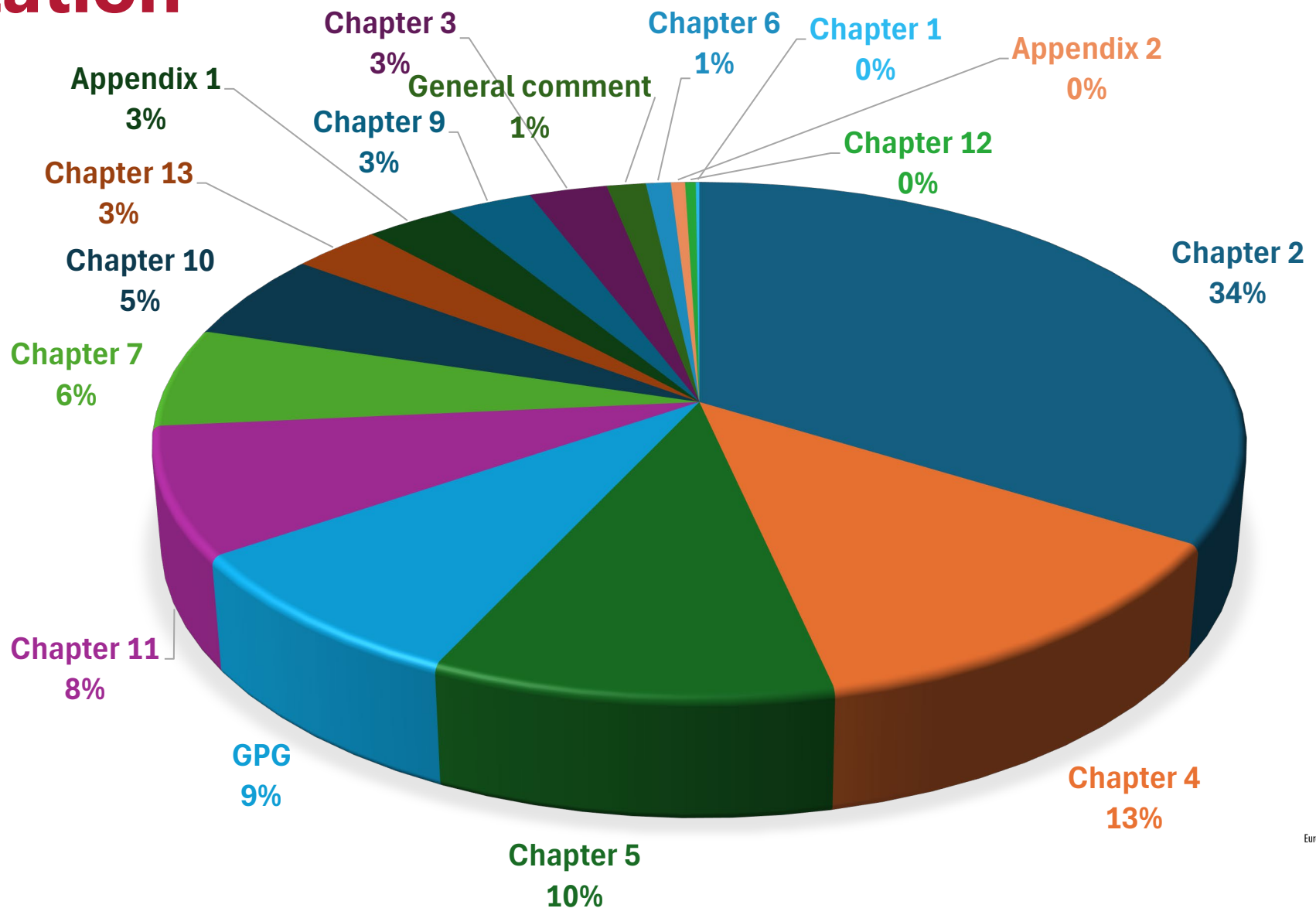
General feedback from the stakeholder consultation



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22nd edition – Changes

Donor selection

➢ Blood pressure and pulse

- Measurement of blood pressure or pulse is not required for determination of donor eligibility.
- The review of available literature on adverse reactions in blood donors (vasovagal reactions or cardiac ischaemia), did not identify any relevant data indicating that blood pressure and pulse were specific risk factors. Several countries around the world don't measure these parameters before donation.
- Subject to national policy and definition of accepted values, specific cases may benefit from these measurements (e.g. donors on antihypertensive treatment, new donors, donors over 60 years of age)
- Blood pressure and/or pulse can be measured as part of health screening of the donor, if the collection site wishes to do so.

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22nd edition – Changes

Donor selection

➢ vCJD

- There is no requirement to defer donors because of travel to or residency in geographical areas where cases of BSE or vCJD were identified.
- There is no requirement to impose any additional restrictions for donors who received transfusions in geographical areas where cases of BSE or vCJD were identified.

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22nd edition – Changes

➢ Malaria

- The malaria text has been completely re-written and summarised in 4 standards
- Rules for individuals who lived in malaria-endemic area or have a history of malaria or undiagnosed febrile illness:
  - Deferred for 4 months and then accepted if an antibody test is negative
  - If test is positive, donor deferred and re-evaluated after 3 years
  - If test is not performed, donor deferred until it has been done and is negative
- Visit to malaria-endemic area and without symptoms:
  - Donor deferred for 4 months and then accepted if an antibody test is negative
  - If no test is performed, donor deferred for 6 months
- Malaria antibody screening test should detect antibodies against malaria that pose a risk of transfusion transmission
- High-sensitivity molecular tests may represent a valuable complementary screening option for specific donor groups or in specific contexts, such as residents of non-endemic areas where autochthonous malaria cases are reported.

22nd edition – Changes

Donor selection

➢ Plasmapheresis

Standard plasma collection approach:

- The recommended minimum donation interval is at least 2 weeks.
- Total proteins must be measured at least annually and must not be less than 60 g/L (Directive 2004/33/EC, Annex III).
- IgG levels should be measured at least annually, be within local population reference ranges and should not fall below 6.0 g/L.
- In addition, total proteins and IgG levels should be measured at the first donation.

Individualised plasma collection approach:

- Where the competent authority approves a plasma programme where the donation interval is less than 2 weeks, there are additional requirements.
- Where a donation interval between 1 and 2 weeks is allowed, additional monitoring is required, such as more frequent monitoring of adverse reactions, IgG levels and iron stores.
- The donation interval should not be less than one week.
- Monitoring should prove that this approach is as safe as the standard plasma collection approach.

22nd edition – Changes

New chapter 7- Blood components for topical use or injection

The chapter introduces a monograph for **serum eye drops** (previously in the T&C Guide). Platelet preparations are transferred over directly from the T&C Guide, included as a background document in this edition.

Chapter 12 – Haemovigilance

A full review and update of the chapter in line with most recent developments and the best practice in haemovigilance.

New Chapter 13 on **Blood Supply Contingency and Emergency Planning**

Deliverables of the EDQM Blood Supply Contingency and Emergency Plan (B-SCEP) Project are used

Blood Guide – Continuous improvement of the revision processes

Change Log and Background Documents

Changes included in the 22nd edition of the Blood Guide are documented in a Change Log accompanied by Background Documents that detail the scientific rationale behind the changes made and decisions taken.

Both the Change Log and Background Documents will be published alongside the 22nd edition of the Guide.

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Digitalisation project

Online platform

Principal idea: in the future, the Blood Guide will be presented in an online, digital format, and not as a book.

3 ongoing IT-related projects around BTC guides:

1. A new **elaboration tool**: designed to streamline the drafting process for experts and the EDQM secretariat.
2. An online **consultation platform**: facilitates the revision process for experts and the EDQM secretariat and renders collection of comments during the consultation phase more efficient.
3. A modern **online platform**: provides easy access to the EDQM guides and integrates with the EU SoHO platform developed by the European Commission.

Concluding remarks

Richard Forde

CD-P-TS Secretary, EDQM

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Concluding remarks

- The Council of Europe/EDQM blood transfusion activities

  The CD-P-TS

  - The Blood Guide
  - The B-QM Programme
  - The B-PTS Programme
  - Training, conferences, events

- Questions and discussion
  - Key priority areas
  - Feedback and collaboration

Thank you for your collaboration and engagement!

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