Guide to the preparation, use and quality assurance of blood components

22nd Edition

State-of-the-art information and essential technical guidance for healthcare professionals based on the most recent advancements, to ensure the safety and quality of blood and blood components for transfusion

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

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Guide to the preparation, use and quality assurance of blood components

Purpose and background

The *Guide to the preparation, use and quality assurance of blood components* (Blood Guide) is a compendium of harmonised requirements designed to ensure the quality, safety and efficacy of blood and blood components. It provides technical guidelines based on up-to-date scientific information, offering a comprehensive overview of the most recent advances in the field. The Blood Guide also includes guiding principles for the donation of blood and blood components and comprises the Good Practice Guidelines (GPG), a collection of standards for the implementation of quality systems in blood establishments and, where applicable, hospital blood banks, which are referenced in European Commission Directive (EU) 2016/1214.

The Council of Europe is the leading standard-setting organisation in this field. Its work is co-ordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM) through the European Committee on Blood Transfusion (CD-P-TS), which oversees activities related to blood donation and transfusion. The CD-P-TS develops ethical, quality and safety standards in this field and promotes voluntary non-remunerated blood donation, mutual assistance, the optimal use of blood and blood components and the protection of donors and recipients. It also supervises the ad hoc Working Group on the Blood Guide (GTS), composed of dedicated, internationally recognised experts responsible for drafting and updating the Blood Guide.

Target audience

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 blood establishments, hospital blood banks, and healthcare and regulatory professionals in the blood sector.

New in the 22nd edition

Updated over the last two years, this new edition includes a complete review of all chapters, an in-depth revision of the *Haemovigilance* chapter and the addition of two new chapters, *Blood components for topical use or injection* and *Blood supply contingency and emergency planning*. Other significant changes relate to donor selection criteria (Creutzfeldt–Jakob disease, malaria, blood pressure and pulse, plasmapheresis, iron stores, donor age and insulin), along with the standardisation of terminology. All changes are documented in a change log to facilitate uptake of the new edition and are supported by background documents detailing the scientific rationale behind them.

How to obtain a copy

The ***Guide to the preparation, use and quality assurance of blood components*** is available in English and French, in print and electronic form. It can be downloaded from FreePub, the EDQM's free publications platform; the print version is available for purchase from the EDQM WebStore.

For more details, visit the EDQM website: https://go.edqm.eu/BTg.

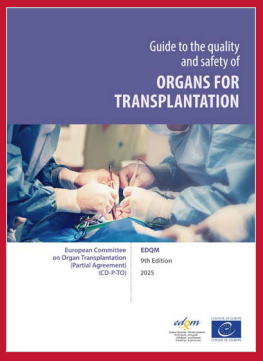
Additional guidance

Annual reports on the collection, testing and use of blood and blood components in Europe are available on the EDQM website: www.edqm.eu/en/reports-blood.

Additional guidance documents, reports and information on activities in the blood transfusion field for governments, professionals and the general public are available at www.edqm.eu/en/blood.

Other benchmark technical guides on substances of human origin

- ***Guide to the quality and safety of organs for transplantation*** – Technical guidance to improve organ transplantation procedures and outcomes: https://go.edqm.eu/OTg
- ***Guide to the quality and safety of tissues and cells for human application*** – Technical guidance on the donation and human application of tissues and cells of human origin: https://go.edqm.eu/TCg



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