



Guide to the preparation, use and quality assurance of **BLOOD COMPONENTS**



www.edqm.eu

 Facebook: @EDQMCouncilofEurope

 Twitter: @edqm_news

EDQM
21st Edition
2023

PURPOSE AND BACKGROUND

■ The *Guide to the preparation, use and quality assurance of blood components* (the "Blood Guide") is a compendium of harmonised requirements designed to ensure the quality, safety and efficacy of blood and blood components.

■ Now in its 21st edition, the Blood Guide is elaborated by a dedicated working group (the GTS) composed of internationally recognised experts. The GTS works under the aegis of the European Committee on Blood Transfusion (CD-P-TS), the steering committee responsible for blood transfusion activities at the Council of Europe.

■ The CD-P-TS actively promotes voluntary non-remunerated blood donation, mutual assistance, the optimal use of blood and blood components and the protection of donors and recipients.

WHO CAN BENEFIT

■ 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 (BEs), hospital blood banks, and healthcare and regulatory professionals in the blood sector.

THE GUIDE IN BRIEF

■ The Blood Guide provides technical guidelines for the preparation, use and quality assurance of blood and blood components. It collates the most up-to-date scientific information to provide a comprehensive overview of the most recent advances in the field, as well as technical standards aimed at ensuring the quality, safety and efficacy of blood and blood components.

■ In addition, the Blood Guide provides guiding principles to be considered for the donation of blood and blood components and includes the Good Practice Guidelines (GPGs) which provide standards for the implementation of quality systems in blood establishments and, where applicable, hospital blood banks. In accordance with European Commission Directive (EU) 2016/1214, the GPG should be taken into account by EU member states in the implementation of quality systems in blood establishments.

■ As part of its revision, each new edition of the Blood Guide goes through an extensive consultation process, during which input is solicited from stakeholders involved in the various stages of the blood transfusion chain, regulatory oversight and in the collection and testing of plasma for fractionation.

NEW IN THE 21st EDITION

■ For the first time, all changes with respect to the previous edition have been documented in a change log, accompanied by background documents detailing the scientific rationale behind them. Both the change log and background documents are published alongside this 21st edition.

■ The terminology used has been standardised, harmonising in particular the use of the terms "must" and "should", and inclusive language has been introduced.

■ The guide also presents new and updated standards on data-processing systems in the GPGs, along with changes in donor selection criteria related to haemoglobin, iron stores, allergy and anaphylaxis, cancer and malignancies, interventions and treatments, acupuncture, tattooing, body piercing, and aesthetic medical procedures, surgery and dental treatment. With regard to plasmapheresis, evidence is provided to support an annual donation frequency, unchanged from the previous edition, although the recommended frequency for monitoring of donor IgG levels was reduced. With regard to blood components, glucose measurement is now recommended as a more appropriate quality indicator than pH for platelets in additive solution.

HOW TO OBTAIN A COPY

■ The *Guide to the preparation, use and quality assurance of blood components* is available in English, in print and electronic form. It can be downloaded in electronic format free of charge, and the print version can be purchased from the EDQM Store. For more details, visit the EDQM website: <https://go.edqm.eu/BTg> or scan the QR code overleaf.

ADDITIONAL GUIDANCE IN THE FIELD

■ The 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.

■ For more information and additional guidance documents, reports and information on activities in the blood transfusion field for governments, professionals and the general public, please visit <https://www.edqm.eu/en/blood>.

■ *Guide to the quality and safety of organs for transplantation* (8th Edition, 2022): <https://go.edqm.eu/OTg>.

■ *Guide to the quality and safety of tissues and cells for human application* (5th Edition, 2022): <https://go.edqm.eu/TCg>.