Why a European guide?

This guide is a compendium of harmonised requirements designed to ensure the safety and quality of blood components used in transfusion.

In the field of blood transfusion, co-operation among Council of Europe member states started back in the 1950s. From the outset, the activities were inspired by the following guiding principles: promotion of voluntary, non-remunerated blood donation, mutual assistance, optimal use of blood and blood products and protection of the donor and of the recipient.

Work on Recommendation No. R (95) 15 started in 1986, when the Select Committee of Experts on Quality Assurance in Blood Transfusion Services published proposals on quality assurance in blood transfusion services. Based on these proposals, the Select Committee produced a more comprehensive guide on blood components in 1995. The immediate success and acceptance of this document was such that the Committee of Ministers adopted the Guide to the Preparation, Use and Quality Assurance of Blood Components as a technical appendix to its Recommendation No. R (95) 15.

The Recommendation requires that the guide be updated to keep it in line with scientific progress and regulatory changes. Co-ordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM, Council of Europe), the European Committee on Blood Transfusion (CD-P-TS) acts as the Steering Committee in charge of blood transfusion activities for the Council of Europe. The CD-P-TS is entrusted with the regular update of the Guide.

This revision process includes a public consultation and comments are invited from national health authorities as well as all interested parties before a new edition is published.

What information does the guide contain?

The guide contains harmonised standards and recommendations on blood collection, preparation and use of blood and its components, and elements of quality management for blood establishments and hospital blood banks. It represents the basis for the establishment of national regulations and certain European Directives.

What is new in the 19th Edition of the Guide?

This edition contains an updated version of the Good Practice Guidelines (GPG) fully reflecting the most recent changes in good manufacturing practices relevant for blood establishments.

The GPG have been jointly developed by the EDQM and the European Commission. In the European Union, Directive (EU) 2016/1214, published in July 2016, requests member states to ensure that blood establishments comply with the Good Practice Guidelines for their quality system by 15 February 2018.

This edition includes a new monograph on Cryoprecipitate, Pathogen Reduced, a component that will contain a major portion of coagulation factor VIII, von Willebrand factor and fibrinogen present in freshly drawn and separated plasma.

Who is the guide designed for?

The guide is a tool specifically designed for all professionals working in the field of blood transfusion, including regulatory authorities, blood establishments and hospital blood banks.

Publication and purchase of the guide

The guide is available in English. Translations into other languages may be produced under the responsibility of external parties and with the agreement of the EDQM.

The Guide can be downloaded in electronic format free of charge: go.edqm.eu/dl

Paper copies are available for purchase at the EDQM Store: www.edqm.eu/store