



EDQM Quality Programmes for Blood Establishments



Improving Quality Systems in European Blood Establishments

BLOOD PROFICIENCY TESTING SCHEME (B-PTS) PROGRAMME

B-PTS studies aim at assessing the performance of European Blood Establishment laboratories



BACKGROUND AND OBJECTIVES

With a view to improving the safety of blood components and plasma-derived medicinal products, and of patients undergoing blood transfusion, the European Directorate for the Quality of Medicines and HealthCare (EDQM), a Directorate of the Council of Europe, has implemented a **Proficiency Testing Scheme (PTS)** programme dedicated to European Blood Establishments. This activity has been co-funded by the EDQM and the European Commission since 2010.

Participation in **External Quality Assessment (EQA)** programmes such as PTS programmes, is recognised as an important aspect of any Quality Management System (QMS) as required in **EU legislation**, in particular **Directive 2005/62/EC** and the **Good Practice Guidelines (GPG)** which are part of the Council of Europe's *Guide to the Preparation, Use and Quality Assurance of Blood Components*.

The EDQM designs and organises the Blood Proficiency Testing Scheme studies according to *ISO/IEC 17043:2010 Conformity assessment – General requirements for proficiency testing*.

ACTIVITIES ORGANISED

B-PTS studies

the B-PTS studies are specifically designed for use in **Blood Establishment laboratories**. Participants receive test panels, which consist of a combination of genuine samples that would typically be received by a blood transfusion laboratory.

Studies are organised in the following fields:

Nucleic Amplification Technique (NAT)

HBV, HCV, HIV, NAT

Serology

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

Immuno-Haematology

ABO, Rhesus, Kell, extended phenotyping and irregular antibodies

ADDED VALUE

Participation in B-PTS studies provides laboratories with an objective means to assess and demonstrate the reliability of their data. It enables them to evaluate the integrity of their entire testing process in order to identify sources of errors and to prevent erroneous results.

Participants can also compare their results with other peer European Blood Establishments and gain further insight into their testing practices and state-of-the-art assays used in Europe in the field of blood transfusion.

PARTICIPATION AND FEES

Participation in B-PTS studies is open to all European Blood Establishments.

Fees are charged for every study (inclusive of shipping costs).

For more information: visit <https://go.edqm.eu/BPTSfees>

BLOOD QUALITY MANAGEMENT (B-QM) PROGRAMME

A programme supporting the development & implementation of QMS in European Blood Establishments



BACKGROUND AND OBJECTIVES

■ With a view to supporting European Blood Establishments in developing, implementing and improving their **Quality Management System (QMS)**, the EDQM has developed a Quality Management programme.

■ Implementation of a QMS in Blood Establishments is required by EU legislation.

ACTIVITIES ORGANISED

On-site Training and Auditing Schemes

■ The EDQM offers different on-site schemes depending on the maturity of the QMS in the Blood Establishment.

■ **Blood Training Visits (B-TVs)** involve on-site visits at Blood Establishments and training sessions on technical and QMS issues, based on observations made during the on-site visit.

■ **Blood Mutual Joint Visits (B-MJVs)** involve on-site audits as a basis for advising and helping Blood Establishments in implementing and/or improving their QMS.

■ **Blood Mutual Joint Audits (B-MJAs)** involve on-site audits aimed at assessing whether the QMSs of Blood Establishments comply with applicable standards. These audits must be followed by a Corrective and Preventive Action (CAPA) plan.

■ The minimum standards against which these schemes are conducted are the **EU Blood Directives, the Good Practice Guidelines (GPG) for Blood Establishments** and the Council of Europe's *Guide to the Preparation, Use and Quality Assurance of Blood Components*.



Knowledge and Best Practices Sharing Events

■ In addition to these on-site schemes, the EDQM organises training courses, workshops and/or conferences once a year with the aim of sharing best practices in the field.

PRACTICAL GUIDANCE

■ The EDQM is currently developing a practical guidance document to support Blood Establishments to further improve their QMS. More information will be available in 2020.

ADDED VALUE

■ The B-QM Programme is an assistance and educational programme for European Blood Establishments that provides an opportunity to learn and exchange information with peers. European experts share their experience and knowledge, using a constructive and open approach, to help Blood Establishments implement the European standards and develop risk-based and cost-effective QMSs.

PARTICIPATION

■ Participation in B-QM schemes is open to all European Blood Establishments and is free of charge. Applications have to be submitted to the EDQM **before 30 September** of each year in order to be considered for the programme of the following year. To apply, please request an application form: EDQM_B_QM@edqm.eu.

If you are interested in participating in B-PTS studies, please visit our website

<https://go.edqm.eu/BPTS>

or contact us at

EDQM_B_PTS@edqm.eu

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The Council of Europe is the continent's leading human rights organisation. It comprises 47 member states, including all members of the European Union. All Council of Europe member states have signed up to the European Convention on Human Rights, a treaty designed to protect human rights, democracy and the rule of law. The European Court of Human Rights oversees the implementation of the Convention in the member states.