26 October 2017, Strasbourg, France

EDQM highlights importance of guiding Blood Establishments (BEs) in implementing quality standards

The EDQM has cast a light on the importance of supporting Blood Establishments (BEs) in implementing Quality Management (QM) elements such as risk management, change control and validation/qualification, as well as of delineating their practical implementation. This was the focus of a conference organised by the EDQM in Strasbourg from 17 to 19 October 2017 on *Sharing best practices: quality risk management, change control, validation and qualification in BEs*. As blood transfusion carries intrinsic and extrinsic risks, the implementation of Quality Management Systems (QMSs) is of the utmost importance to manage these risks and thus ensuring the safety and quality of human blood and blood components.

Changes in blood transfusion practices over the past 10 years, along with the complexity of current regulatory requirements, have made the implementation of QM requirements a challenge for many BEs. A number of issues have been observed by the EDQM in the day-to-day practices of BEs; in particular, requirements related to risk management, change control, qualification and validation are subject to interpretation, leading to differing expectations on their practical implementation between establishments and regulatory bodies. Additionally the responsibilities and duties of suppliers of equipment/devices and BEs when it comes to qualification and/or validation, particularly regarding acceptance testing, may need further definition. The EDQM also noticed that very little guidance is currently available on how these elements have to be followed and to what extent.

During the event, which was co-financed by the European Commission and attended by 134 participants from 33 countries, Dr Susanne Keitel, Director of the EDQM, said: "Discussions at this conference have confirmed that the EDQM can play a role in further supporting BEs across Europe in implementing QM requirements."

The EDQM Blood Quality Management (B-QM) Working Group will therefore continue to develop appropriate guidelines and organise training sessions on the key elements of QM for BEs across Europe. This contribution is essential considering that as of 15 February 2018, the implementation of these elements will become mandatory with the transposition of Commission Directive (EU) 2016/1214 into the national legislation of member states of the European Economic Area (EEA), which also requires the EDQM's Good Practice Guidelines (GPG) to be taken into account.

During the conference, national authorities – including inspection bodies, BEs and suppliers – had the opportunity to discuss current regulatory requirements and practical experiences in the areas of risk management, change management and qualification/validation. This promoted further clarification of these quality requirements, their practical implementation and the responsibilities of the different stakeholders in the field. Participants also stressed the importance of maintaining on-going dialogue and communication amongst all stakeholders concerned with the implementation of QM in blood transfusion.

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

B-QM Programme

Funded by the European Union and the Council of Europe

EUROPEAN UNION

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Implemented by the Council of Europe

In line with its mission of contributing to the basic human right of access to good quality medicines and healthcare, the EDQM is responsible for the Council of Europe's activities in the area of blood transfusion, which are built around three major principles: promoting voluntary and non-remunerated donations, making optimal use of blood and protecting both donors and recipients. The EDQM actively addresses the ethical, legal and organisational aspects of blood transfusion with a view to ensuring the safety, quality and optimal use of blood supplies, increasing their availability and avoiding wastage.

More information on the work of the EDQM in the field of blood quality and on Blood Quality Management (B-QM) activities can be found here: https://www.edqm.eu/en/blood-quality-management-programme-b-qm

Contact: Caroline Larsen Le Tarnec, Public Relations Division, EDQM, Council of Europe
Tel.: +33 (0) 3 88 41 28 15 - E-mail: caroline.letarnec@edqm.eu

Note for the Editor: Further information is available on the internet site **www.edqm.eu**
The EDQM is a leading organisation that protects public health by enabling development, supporting implementation and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states[1]. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

[1]There are thirty-nine members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom and the European Union.*

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.

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

B-QM Programme
Funded by the European Union and the Council of Europe
EUROPEAN UNION
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE
Implemented by the Council of Europe