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EDQM issues recommendations for sustainable, cost-effective quality management in Europe's blood sector

The EDQM has issued a set of recommendations for the development of cost-effective and sustainable Quality Management Systems (QMSs) in Blood Establishments (BEs) across Europe. The document follows on from the European Conference on "Sharing best practices: Quality Risk Management, Change Control, Validation and Qualification in Blood Establishments", held by the EDQM in October 2017 in Strasbourg. These recommendations provide clear guidance for the future technical and regulatory landscape of blood transfusion in Europe from a quality perspective.

With speakers representing the major stakeholders in the sector — competent authorities, inspection bodies, blood establishments and suppliers — the event attracted participants from all over Europe to reflect on current regulatory requirements and discuss QMS best practices, current and future. The 36 speakers presented their know-how and practical experience in the field of qualification, validation, change management and risk management followed by a series of dedicated, practical workshops. With 34 countries present at the event, precedence was given to clarifying these concepts and their interpretation, discussing their practical implementation and shedding light on the roles and responsibilities of the different interested parties. The set of recommendations that ensued from these exchanges constitute a best practices roadmap to assist all stakeholders, from the major influential organisations active in the field (the European Commission, EDQM and European Blood Alliance) to the national authorities, BEs and suppliers of equipment and devices, in their efforts to develop and implement cost-effective and sustainable QMSs.

The EDQM recommendations can be of support to policy makers in defining regulatory frameworks that are flexible and based on scientific evidence and can rapidly adapt to technical progress, encourage resource-sharing in the form of joint initiatives (suppliers' audits and procurement activities) and rationalise spending by proposing economies of scale wherever possible. Such initiatives should also be encouraged and enabled by European stakeholders but also accepted by authorities and suppliers. The development of a risk- and evidence-based approach within both national authorities and BEs themselves is also seen as crucial to the future of sustainable quality management in Europe.

Susanne Keitel, Director of the EDQM explained that: "On-going dialogue between blood establishments and other stakeholders involved in the field of blood transfusion has provided valuable information for regulatory activities in Europe. Evidence and risk-based approaches are key to ensuring the safety and quality of blood for the benefit of all patients in Europe".

Harmonised standards and the development of practical guidance and training courses focusing on know-how and including risk-based approaches are highlighted as a means of supporting the implementation of the regulatory framework. In this regard, the practical guidance that will be offered by the EDQM's emerging B-QM programme together with existing tools such as mutual joint audits and training courses constitute valuable sources of existing know-how and tried and tested approaches.

More than just a collection of individual proposals, these recommendations seek to iron out current disparities in the approach to quality management in European BEs and redefine the roles and responsibilities of the various stakeholders in the sector. They are issued in the wider context of a major exercise initiated by the European Commission to gather feedback from experts in the field of



blood and ensure that any potential future EU blood legislation is both evidence- and risk-based; it is also worthy of note that they find their echo in the outcomes of the "Blood, Tissues and Cells Stakeholder Event" held by the European Commission in September 2017.

More information on the EDQM's blood guide: <https://www.edqm.eu/en/blood-transfusion-guide>

More information on the EDQM's Blood Quality Management Programme (B-QM):
<https://www.edqm.eu/en/blood-quality-management-programme-b-qm>

More information on the Blood, Tissues and Cells Stakeholder Event held by the European Commission:

https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/ev_20170920_sr_en.pdf

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Note for the Editor: Further information is available on the internet site <https://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 states¹. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

¹There 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.