

THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



10 YEARS OF
CO-OPERATION

Concluding remarks *- From HIV epidemic to COVID 19 pandemic -*

*Keeping up with Reality and Quality: A challenge for
European Blood Establishments*

29 October 2020

Alex Aquilina
Chair of the B-QM Working Group

30 + years in Transfusion Medicine...

Events that have shaped transfusion practice

1980's ●
1990's ●

- **HIV epidemic**
 - Investment in Blood Banking
- **NAT testing**
 - Quality systems in Blood Banking (start)
 - **1992** - Blood guide '**Guide to the preparation, use and quality assurance of blood components**' (CoE), **1st Edition.**
 - **1995** - Principles of **Voluntary non remunerated blood donation (CoE)**



3 Marie-Laure Hecquet ©2020 EDQM, Council of Europe. All rights reserved



2000.....

2000 ●

-**vCJD, WNV, ZIKA, Dengue.....Covid-19**
- **2002** - EU Blood Directives
- Filtration (Leucodepletion)
- Pathogen Reduction/Inactivation
- Developed Quality Systems
- European Blood Alliance
- Closer collaboration Council of Europe and European Commission

4 Marie-Laure Hecquet ©2020 EDQM, Council of Europe. All rights reserved



What next?

- Till an **artificial substitute** for blood/products is available, which is safe, sustainable (affordable) and effective....
- Expect, '**new**' diseases,
- **Regulatory** issues,
- **Natural** events,
- **Economic** issues.....etc....etc.....
- **Working together**, blood establishments, regulatory authorities, industry problems can be overcome.

EDQM B-QM Working group (1)

- Coordination and lead by EDQM (CoE)
- Consists of a number of professionals with considerable experience in the field of Blood Transfusion and Quality Management,
- Cover all aspects of Blood Establishment operations,
- Professionals from different backgrounds with a broad range of expertise & complementarity between members,
- A mandate that covers Quality Management and which makes the B-QM WG activities as pivotal activities in blood transfusion – a enabler to decision making.

Though Quality Management is often seen as a burden “Quality Management is the process approach to the organisation challenges”

EDQM B-QM Working group (2)

Main activities

- Support **Blood Establishments** through:
 - Organised **audits**: educational, supporting, benchmarking and compliance,
 - Organised **training & conference** activities (also on BE site): sharing knowledge/expertise,
 - Guidance (ongoing): help BEs turn knowledge/requirements into practice,
- But also facilitate networking, share challenges.....

EDQM B-QM Working group (3)

So far, more than **30** audits (B-TVs/B-MJVs/B-MJAs), **5** training courses/conference

&

Many great moments/journeys
with the BEs and staff,
with peers
who require support or,
who want to benefit from others,
Who want to help patients
& who are very proud of their work

Concluding remarks

After these 3 days, if I would have one recommendation to share with you before I retire, It would be the following....

Thank you for your attention



Stay connected with the EDQM

EDQM Newsletter: <https://go.edqm.eu/Newsletter>
LinkedIn: <https://www.linkedin.com/company/edqm/>
Twitter: @edqm_news
Facebook: @EDQMCouncilofEurope