

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



**10** YEARS OF  
CO-OPERATION



**EDQM supporting initiatives to help European BEs to have more resilient and sustainable blood systems**

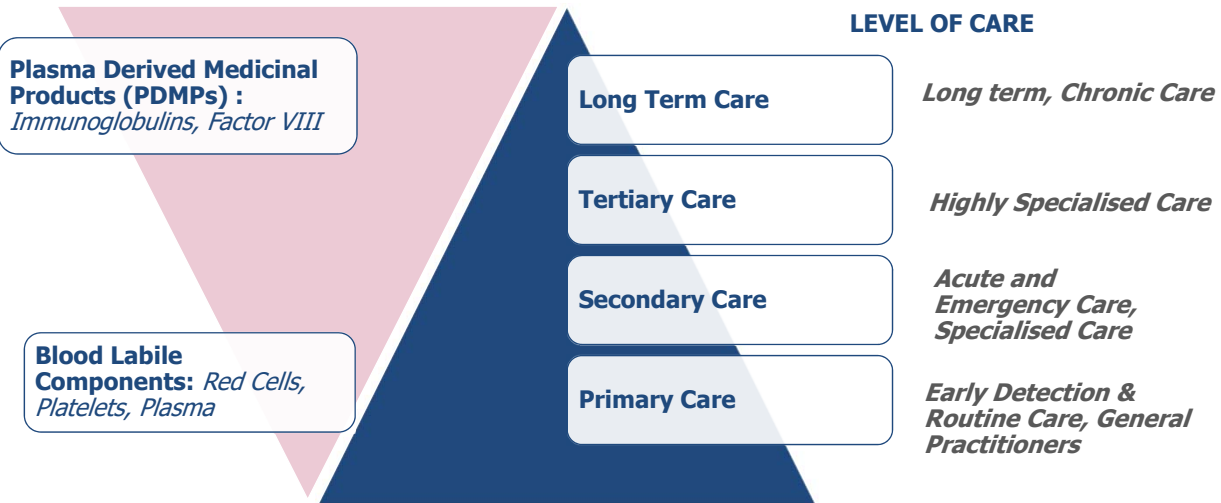
*Keeping up with Reality and Quality: A challenge for European Blood Establishments*

29 October 2020

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EDQM/Council of Europe



# BLOOD TRANSFUSION IN A HEALTHCARE SYSTEM

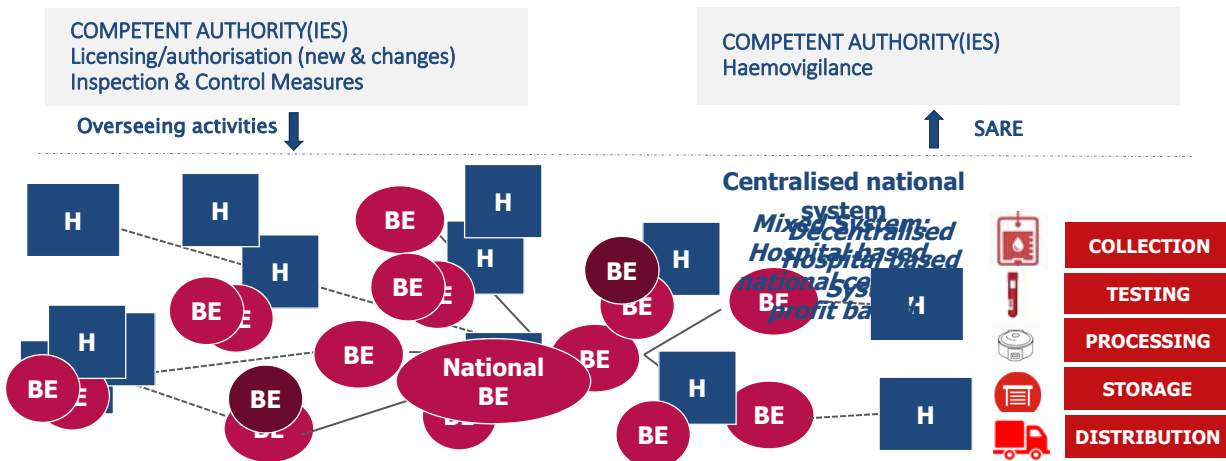


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# NATIONAL BLOOD SYSTEMS – A GREAT VARIABILITY OF SYSTEMS

>1400 Blood Establishments in Europe



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# A CHANGING ENVIRONMENT



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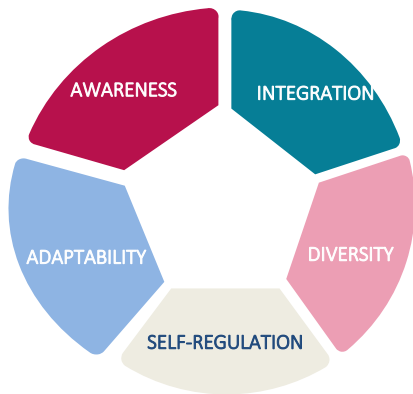
# EVOLUTION OF SYSTEMS - PAST DECADE



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# RESILIENCE MODEL – Adapted to Blood Systems



Model – Kruk & Co.

**ADAPTABILITY**  
 Be able to operate under changing conditions, rebounds from crisis  
 ▶ QMS & Contingency/Emergency planning ▶ EDQM

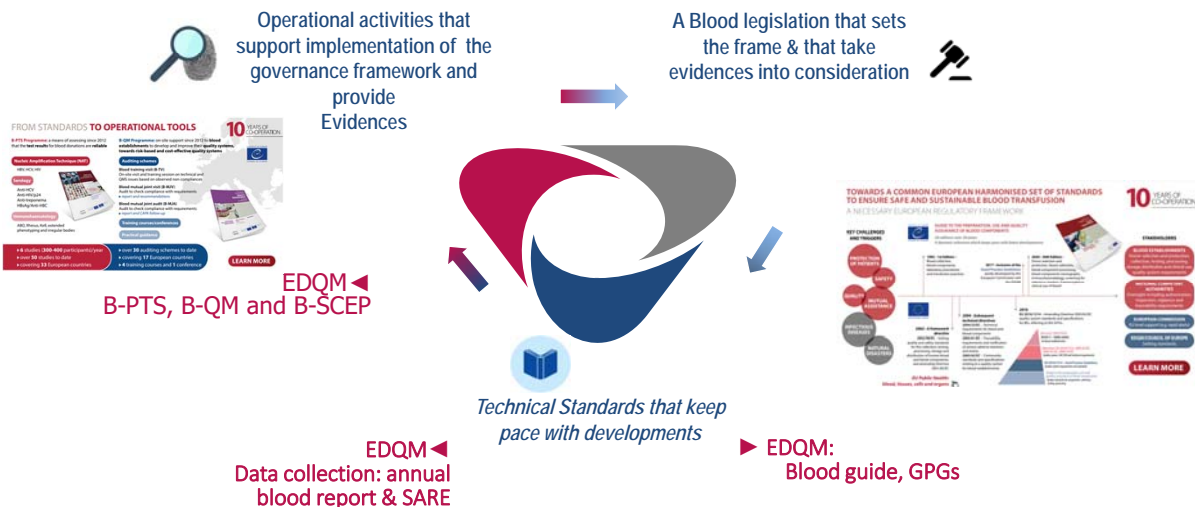
**AWARENESS**  
 Detect risks/threats before they arise.  
 Know its own capacity to react/own resources  
 ▶ QMS & Contingency/Emergency planning ▶ EDQM

**DIVERSITY**  
 Reliance on multiple suppliers, diverse health professionals  
 ▶ QMS ▶ EDQM

**SELF-REGULATION**  
 Capacity to have own policies to mitigate risks/contain crisis  
 Flexible regulatory framework ▶ EC & EDQM  
 ▶ QMS ▶ BEs

**INTEGRATION**  
 Regulatory framework  
 ▶ EC & EDQM  
 Collaborate/coordinate with others  
 ▶ European Blood Alliance

# EDQM ACTIVITIES COMPLEMENTARY TO EC ACTIVITIES



# AS IS THE BLOOD GUIDE & GPGs .....

## TOWARDS A COMMON EUROPEAN HARMONISED SET OF STANDARDS TO ENSURE SAFE AND SUSTAINABLE BLOOD TRANSFUSION A NECESSARY EUROPEAN REGULATORY FRAMEWORK

### KEY CHALLENGES AND TRIGGERS

- PROTECTION OF PATIENTS
- SAFETY
- QUALITY
- MUTUAL ASSISTANCE
- INFECTIOUS DISEASES
- NATURAL DISASTERS



**10 YEARS OF CO-OPERATION**

- STAKEHOLDERS**
- BLOOD ESTABLISHMENTS:** Donor selection and protection, collection, testing, processing, storage, distribution and clinical use, quality system requirements
  - NATIONAL COMPETENT AUTHORITIES:** Oversight including authorisation, inspection, vigilance and traceability requirements
  - EUROPEAN COMMISSION:** EU level support (e.g. rapid alerts)
  - EDQM/COUNCIL OF EUROPE:** Setting standards
- LEARN MORE**

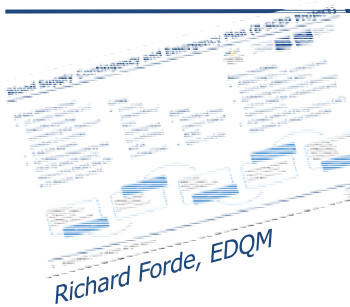
► That keeps pace with developments

► if referred to in the EU legislation  
► **Sustainable Regulatory framework**

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# ARE THE BLOOD QUALITY ACTIVITIES.....



## FROM STANDARDS TO OPERATIONAL TOOLS

**B-PTS Programme:** a means of assessing since 2012 that the **test results** for blood donations are **reliable**

### Nucleic Amplification Technique (NAT)

HBV, HCV, HIV

### Serology

Anti-HCV  
Anti-HIV/p24  
Anti-treponema  
HBSAg/Anti-HBC

### Immunohaematology

ABO, Rhesus, Kell, extended phenotyping and irregular bodies



**B-QM Programme:** on-site support since 2012 to **blood establishments** to develop and improve their **quality systems**, towards **risk-based and cost-effective quality systems**

### Auditing schemes

**Blood training visit (B-TV)**  
On-site visit and training session on technical and QMS issues based on observed non-compliances

**Blood mutual joint visit (B-MJV)**  
Audit to check compliance with requirements  
► report and recommendations

**Blood mutual joint audit (B-MJA)**  
Audit to check compliance with requirements  
► report and CAPA follow-up

### Training courses/conferences

### Practical guidance



- 6 studies (300-400 participants)/year
- over 50 studies to date
- covering 33 European countries

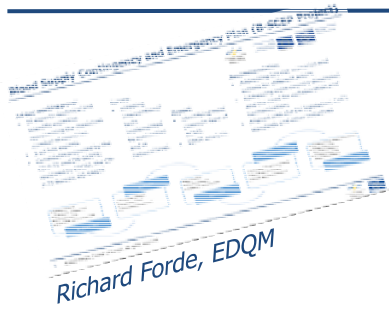
- over 30 auditing schemes to date
- covering 17 European countries
- 4 training courses and 1 conference

**LEARN MORE**

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# ARE THE BLOOD QUALITY ACTIVITIES.....



► While the EC provides the **framework**: Regulatory framework and funding instruments for EU & candidate, neighbouring & partner countries

► **EDQM Blood quality activities**: **continuous** support to BEs to **implement** requirements, **adapt their systems** to a changing environment and respond to **risks & crisis** ► **resilience and sustaining** results & systems



## THINKING BEYOND

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- Regulatory Framework
- Quality System driven by Risk Management & Change Control
- Resilience and Sustainability

**Cost-efficiency?**



FIGURE 1: Value in Healthcare

KS6



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## THANK YOU

**KS6** Replace Dollare by Euro...

KEITEL Susanne; 26/10/2020



# Thank you for your attention

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