

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



10 YEARS OF
CO-OPERATION



10 Years of Cooperation Between the **European Commission** & the **EDQM/Council of Europe** in the field of Blood

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

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EDQM & EC COLLABORATION – In a Nutshell

Legal & Technical cooperation

Mutual Representation

Medicinal products



60 years of
Collaboration (Legal &
technical)



Substances of Human Origin



10 years of Collaboration
Blood Transfusion

7 years of Collaboration
Tissues & Cells

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A WIDE PORTFOLIO OF ACTIVITIES.....

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EDQM & EC COLLABORATION – Medicinal products



The EDQM is in charge of:

► **European Pharmacopoeia (Ph.Eur):**

- Compendium of official standards, defining the quality of medicinal products and their components and the tests to be performed,
- Standards recognised as a scientific benchmark world-wide,
- referred into **the EU pharmaceutical legislation**

>>> **More than 2400 monographs, 350 general texts**

► **Certification of suitability to the monographs of the Ph. Eur. :**

- confirms Ph.Eur monograph adequately controls the quality of a substance, CEP certificates part of MA dossiers
- Risk-based inspection of manufacturing sites and brokers/distributors holding CEP certificates
- referred into **the EU pharmaceutical legislation**

>>> **5300 valid certificates & 70 sites covered by the annual programme /year worldwide**



EDQM & EC COLLABORATION – Medicinal products Cont.



The EDQM is in charge of:

► **Biological Standardisation Programme (BSP):**

- Standardisation of methods and reference standards for biological medicinal products *e.g. vaccines*
- Inclusion into the Ph.Eur

>>> **more 160 BSP projects since 1991**

► Network of **Official Medicinal Control laboratories (OMCL Network)**, independent control from the manufacturers:

- Work sharing and mutual recognition of test results
- Market surveillance testing programme for centrally authorized products

>>> **More than 600 Centrally Authorised Products, nearly 220 External Quality assessment scheme and more than 190 audits.**

► **Official Control Authority Batch Release (OCABR):** testing results for biological medicinal products of 1 MS are mutually recognized by **all** Member States

- Procedures and guidelines

>>> **more than 24500 lots released (Vaccines, plasma pool & PDMPs) by 15 OMCLs**

EDQM & EC COLLABORATION – Substances of Human Origin

The EDQM is in charge of:




**Technical
cooperation**

► **Development of Technical Standards** that reflect latest scientific and technical developments in the fields

- The Tissues & Cells Guide,
- The Good Practices Guidelines for Blood Establishments,



► **Monitoring data and practices**

- Harmonisation of data collection (Tissues & Cells)
- Analysis of biovigilance data in the EU (Blood and Tissues & Cells)
- Post mortem blood testing (Tissues & Cells)

► **Trainings**

- Biovigilance best reporting practices (Blood and Tissues & Cells)
- Quality Management (Tissues & Cells)

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EDQM & EC COLLABORATION – SoHO cont.

The EDQM is coordinating:




**Technical
cooperation**

► **Blood Quality Management (B-QM) programme for Blood Establishments**

- Auditing/assessment schemes
- Trainings/Conferences
- Practical Guidance

► **Blood Proficiency Testing (B-PTS) programme for Blood Establishments**

- Proficiency Testing scheme studies

► **Plasma Supply Management (PSM)**

- Ensuring plasma supply: Symposium & ensuing recommendations

► **Blood Supply Contingency Emergency Planning (B-SCEP)**

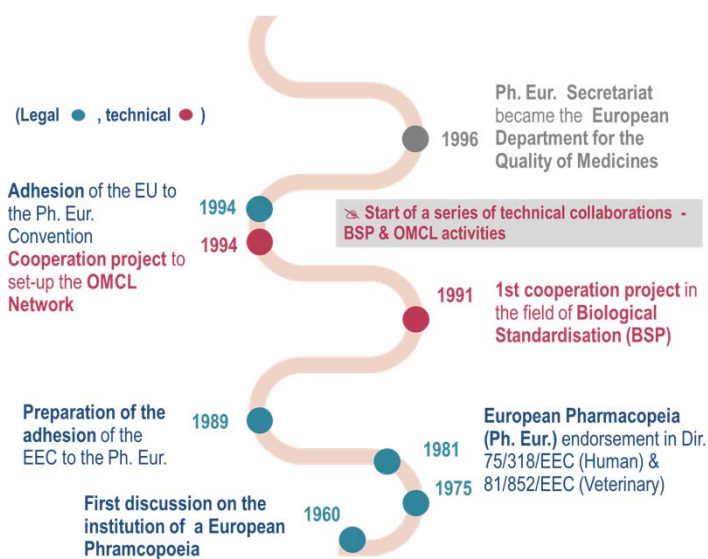
- Provide an overview of interventions implemented by authorities to strengthen national & EU-level plans for continuity of blood supply under emergency situations

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THE PATH TO GET THERE.....

EDQM & EC COLLABORATION – KEY MILESTONES



EDQM & EC COLLABORATION – KEY MILESTONES

(Legal ● , technical ●)

1st cooperation project in the field of Blood Transfusion

2010

Start of a series of technical collaborations - SoHO field

2007 - 2008

EDQM responsible for SoHO activities (transfer from the CoE)

Recognition of the EDQM certification & inspection schemes in the EU legislation

2004

2001

Dir. 2001/82/EC & 2001/83/EC codified the pharmaceutical legislation

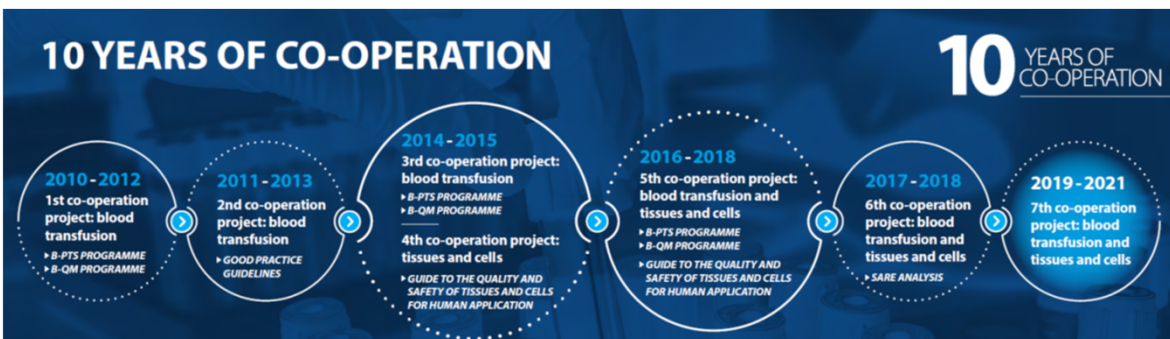


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IN SUM.....

- Overall, more than **35 technical cooperation** projects run successfully
- **7 technical cooperation projects in Blood Transfusion**



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ACHIEVEMENTS IN THE FIELD OF BLOOD

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BLOOD-PROFICIENCY TESTING SCHEME PROGRAMME

► **AIM: B-PTS** provides Blood Establishments (BEs) with an objective mean of assessing that the **testing results** for blood donations are **reliable**.



'Regular participation in a formal system of proficiency testing, such as an external quality-assurance programme'

*EU Directive 2005/62/EC; Good Practice Guidelines
,Guide to the Preparation, Use and Quality
Assurance of Blood Components*

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



► **Since 2010: 6** studies (300-400 participants)/year, over **50** studies to date covering **33** European countries

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BLOOD-QUALITY MANAGEMENT PROGRAMME

► **AIM: Assistance/Educational Programme** to help Blood Establishments in establishing, developing, improving comprehensive and integrated **Quality System**



'Quality System to be in place'

*EU Directive 2005/62/EC; Good Practice Guidelines
,Guide to the Preparation, Use and Quality Assurance
of Blood Components*

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



► **Since 2010:** over **30** auditing schemes to date covering **17** European countries **5** training courses/conferences

GOOD PRACTICE GUIDELINES FOR BLOOD ESTABLISHMENTS

► **Compendia of** *Quality system standards and specifications of Directive 2005/62/EC, Quality system standards and Principles derived from the Guide to the Preparation, Use and Quality Assurance of Blood Components (17th edition), Quality system elements derived from the detailed principles of GMP*

► **Since 2017, integral part of the Blood Guide**

► **Directive (EU) 2016/1214/EC:** Member States to take the GPG into account in implementing good practices based on the GMP

► Advantages:

- Dynamic reference (as is the European Pharmacopoeia in the EU Pharmaceutical legislation)>>> no need for regular update of the EU legislation;



PLASMA SUPPLY MANAGEMENT (PSM)

(1) ↘ Plasma supply

(2) ↗ Plasma need due to ↗ Plasma
Derived Medicinal Products (PDMPs)

(3) Highly dependent on **US**
paid plasma donors for PDMPs



Symposium, January 2019

- Quality & safety **standards for plasmapheresis**
& Protection of **intense plasmapheresis donors**
- Reducing **dependence** on US imported plasma &
use **plasma** to its full potential



Proceedings &

Consensus recommendations



**Revision of the Blood
Guide**

'Blood Donor protection'

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Concluding remarks

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RESULTING LEGAL & TECHNICAL FRAMEWORK

	SUBSTANCES OF HUMAN ORIGIN (SoHO)			MEDICINAL PRODUCTS
				
 Key EU legislation	2010/45/EU 2012/25/EC	2004/23/EC 2006/17/EC 2006/86/EC	2002/98/EC 2004/33/EC 2005/61/EC 2005/62/EC	2001/82/EC 2001/83/EC
 EDQM Standards	Organ Guide	Tissues & Cells Guide	Blood Guide Good Practice Guidelines	European Pharmacopoeia
EDQM activities supporting the implementation of EU legislation		Mapping practices, Trainings	Mapping practices, Quality management activities inc. auditing schemes, trainings, guidance and external quality assessment	Standardisation Marketing surveillance Mutual recognition

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