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

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EDQM Blood Establishments 2015

GENERAL INFORMATION

The European Directorate for the Quality of Medicines and Healthcare (EDQM) of the Council of Europe (CoE) is conducting a survey with the aim to assess various issues that Blood Establishments (BEs) in Europe might be facing.

Blood Establishments are key actors in the blood system. Therefore, it is important for the EDQM to evaluate your needs and constraints and hear your opinion on different aspects of blood transfusion.

This survey should help the EDQM to adapt its activities dedicated to Blood Establishments, and in particular the Blood Quality Management Programme (B-QM) (B-QM webpage).

It should also allow the EDQM in disseminating information to stakeholders on the obstacles blood establishments are facing.

Finally, it should help updating/harmonising quality management and regulatory policies in Europe and improve mutual confidence between blood establishments.

We would really be grateful if you, as Director or QA Manager of your Blood Establishment could take the time to reply to this questionnaire.

We recognise that this survey is substantial. However, a high participation rate in the survey might really support EDQM to voice Blood establishments' concerns.
We would also like to remind you that a similar survey was carried out in 2012, which enabled the EDQM to develop the B-QM activity.

Individual questionnaires will be kept confidential at the EDQM. If data is used from this survey outside of the EDQM or in reports, this will be done in anonymised form.

Many thanks in advance for your collaboration !

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1. CONTACT DETAILS

Contact details will only be used as means of contacting if further details are necessary. The results of this survey will be treated and presented in an anonymous way.

* 1.1. Your profile

First Name & Last Name

Email Address

* 1.2. Function

- ◯ Director of the blood establishment
- ◯ Quality Manager

* 1.3. Your Blood Establishment

Name of the Blood Establishment

Address (Street, City, Post Code)

Country

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2. ACTIVITY PROFILE OF YOUR BLOOD ESTABLISHMENT

* 2.1. Is your Blood Establishment part of another blood establishment/bigger entity ?

- ◯ Yes
- ◯ No

If yes,please specify :

* 2.2. Your blood establishment is :

- ◯ Public (or belonging to the Ministry of Health)
- ◯ Supranational (e.g. Red Cross)
- ◯ Private
- ◯ Hospital based
- ◯ Other, please specify :

* 2.3. How many (please enter numerical value e.g. 10500):

Whole blood donations do you have per year	
Apheresis donations do you have per year	
Donors do you have per year	
Full-time equivalent employees (FTEs) does your blood establishment have	

* 2.4. What is your activity profile :

- [ ] Blood Collection
- [ ] Blood Storage
- [ ] Blood Testing
- [ ] Blood Release and Distribution
- [ ] Blood Component Preparation/ Processing
- [ ] Blood Issuing (Issuing meaning compatibility testing)
- [ ] Apheresis Component Preparation/ Processing
- [ ] Immuno-hematology testing for blood recipients

Other, please specify :

2.5. Is one of the following activities delocalised (part of your Blood Establishment but not at the same location) or subcontracted (external service), if not please move to the next question ?

	Delocalised	Subcontracted
Blood Collection (e.g. external collection sites/mobile sites)	○	○
Blood Testing	○	○
Blood Component Preparation/ Processing	○	○
Apheresis Component Preparation/ Processing	○	○
Blood Storage	○	○
Blood Release and Distribution	○	○
Blood issuing (issuing meaning compatibility testing)	○	○
Immuno-haematology testing for blood recipients	○	○

* 2.6. Which tests do you perform in your laboratory to qualify individual blood donations, please specify if these are commercially available methods or in-house methods and whether the tests are mandatory in your country?

	Commercial Method	In-house Method	Mandatory
Anti-HIV-1/2	☐	☐	☐
Combo Ag/Ab HIV	☐	☐	☐
Anti-HCV	☐	☐	☐
Combo Ag/Ab HCV	☐	☐	☐
Anti-HBc	☐	☐	☐

	Commercial Method	In-house Method	Mandatory
Anti-HBs	☐	☐	☐
HBsAg	☐	☐	☐
Anti-CMV	☐	☐	☐
Anti-HTLV	☐	☐	☐
Anti-Treponema (Syphilis)	☐	☐	☐
Anti-Malaria	☐	☐	☐
NAT-HCV	☐	☐	☐
NAT-HIV	☐	☐	☐
NAT-HBV	☐	☐	☐
NAT-HAV	☐	☐	☐
NAT-B19	☐	☐	☐
Other NAT assays, please specify below (e.g. WNV)	☐	☐	☐
Blood grouping (ABO)	☐	☐	☐
Rhesus phenotyping	☐	☐	☐
Antibody screening	☐	☐	☐
Platelet count	☐	☐	☐
White cell count	☐	☐	☐
Red cell count	☐	☐	☐
F VIII assay	☐	☐	☐
Haemoglobin	☐	☐	☐
Hematocrit	☐	☐	☐
pH	☐	☐	☐
Total protein	☐	☐	☐

Other tests/assay, please specify:

2.7. Which tests do you perform in your laboratory for quality control of blood components ?

- [ ] Platelet count
- [ ] White cell count
- [ ] Red cell count
- [ ] F VIII assay
- [ ] Haematocrit
- [ ] Haemoglobin
- [ ] Residual leucocyte content
- [ ] Haemolysis at the end of storage
- [ ] Fibrogen

Other (please specify)

2.8. Which of these whole blood components do you prepare as transfusion products ?

- [ ] Whole blood
- [ ] Whole blood, Leucocyte-Depleted

2.9. Which of these plasma components do you prepare :

- [ ] Plasma, Fresh Frozen
- [ ] Plasma, Fresh Frozen, Pathogen Reduced
- [ ] Cryoprecipitate
- [ ] Plasma, Fresh Frozen, Cryoprecipitate-Depleted

2.10. Which of these Platelet components do you prepare :

- [ ] Platelets, Recovered, Single Unit
- [ ] Platelets, Recovered, Pooled
- [ ] Platelets, Recovered, Pooled, Leucocyte-Depleted
- [ ] Platelets, Recovered, Pooled, in Additive Solution
- [ ] Platelets, Recovered, Pooled, Leucocyte-Depleted,in Additive Solution
- [ ] Platelets, Pooled, Pathogen reduced
- [ ] Platelets, Apheresis
- [ ] Platelets, Apheresis, Leucocyte-Depleted
- [ ] Platelets, Apheresis, in Additive Solution
- [ ] Platelets, Apheresis, Leucocyte-Depleted, in Additive Solution
- [ ] Platelets, Apheresis, Pathogen-reduced
- [ ] Platelets, Cryoperserved

2.11. Which of these Red Cell components do you prepare :

- [ ] Red Cells
- [ ] Red Cells, Buffy Coat Removed
- [ ] Red Cells, in Additive Solution
- [ ] Red Cells, Buffy Coat Removed, in Additive Solution
- [ ] Red Cells, Leucocyte-Depleted
- [ ] Red Cells, Leucocyte-Depleted in Additive Solution
- [ ] Red Cells, Apheresis
- [ ] Red Cells, Washed
- [ ] Red Cells, Cryopreserved

2.12. Which of these blood components for intra-uterine neonatal and infant use do you prepare :

- [ ] Red Cells, Leucocyte-Depleted for Intrauterine Transfusion
- [ ] Platelets, Leucocyte-Depleted for Intra-uterine Transfusion
- [ ] Whole Blood, Leucocyte-Depleted for Exchange Transfusion
- [ ] Whole Blood, Leucocyte-Depleted, Plasma Reduced for Exchange Transfusion
- [ ] Red Cells, Leucocyte-Depleted, suspended in Fresh Frozen Plasma, for Exchange Transfusion
- [ ] Red Cells for Neonatal and Infant Small Volume Transfusion

2.13. Which of these other components do you prepare :

- [ ] Granulocytes, Apheresis
- [ ] Lymphocytes
- [ ] Autologous Blood Components
- [ ] Cord blood

2.14. If you provide plasma to fractionators please specify which type of plasma do you provide :

- [ ] Apheresis plasma
- [ ] Recovered plasma

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3. QUALITY MANAGEMENT SYSTEMS/STANDARDS & REGULATION

A Quality Management System (QMS) is a defined set of interacting processes & actions to direct and control an organisation towards quality. In a Blood Establishment a QMS should encompass quality, quality control, quality assurance & continuous improvement. It should cover the following elements :
***Donor Selection, Blood Collection/Testing/Processing/Issuing/Distribution; General Quality Management & Organisation; Management of Personnel; Contract Management; Management of Quality Documents; Equipment/Material/Premises; Change Control; Non-conformance(NC)/Corrective and Preventative Actions (CAPAs); Management Review; Internal auditing and Risk Management*.**

* 3.1. With this definition in mind how would you rate the current level of implementation of your Quality Management System?

- ◯ 1. No Quality Management System is currently implemented
- ◯ 2. A Quality Management System is partially implemented (please provide the areas where a QMS is implemented in the comment field below)
- ◯ 3. A Quality Management System is implemented but it needs to be further developed as it is
- ◯ 4. A Quality Management System is in place and is efficient

* 3.2. Which of the following Standards are used in your Blood Establishment and please specify whether they are used on a mandatory basis or on volontary basis or not used ?

	Mandatory basis	Volontary basis	Not used
EU Directive 2002/98/EC	☐	☐	☐
EU Directive 2004/33/EC	☐	☐	☐
EU Directive 2005/61/EC	☐	☐	☐
EU Directive 2005/62/EC	☐	☐	☐
ISO Standard 9001	☐	☐	☐

	Mandatory basis	Volontary basis	Not used
ISO Standard 17025	☐	☐	☐
ISO Standard 15189	☐	☐	☐
Guide to the Preparation, Use and Quality Assurance of Blood Components (**CoE Guide**)	☐	☐	☐
Good Practice Guidelines (GPGs) for blood establishments and hospital blood banks required to comply with the EU Directive 2005/62/EC (as a part of the 18th CoE Guide)	☐	☐	☐
WHO guidelines on GMP for Blood Establishments	☐	☐	☐
EU GMP (Medicinal Products for Human and Veterinary Use, Part I)	☐	☐	☐
EU GMP for Blood Derived Products (Annex 14)	☐	☐	☐
PIC/S Guidelines (Guide for Blood Establishments, PE 005-3)	☐	☐	☐
National standards/guidelines	☐	☐	☐

Other, please specify :

* 3.3. For which of the following ISO Standards are you certified/ accredited or on the way to be accredited ?

	Status	Reason
ISO Standards 9001		
ISO Standards 17025		
ISO Standards 15189		

Other, please specify :

* 3.4. In which of the following areas do you encounter difficulties in implementing/developing your QMS?

- [ ] Donor Selection
- [ ] Blood Collection
- [ ] Blood Testing
- [ ] Blood Processing
- [ ] Blood Storage
- [ ] Blood Issuing
- [ ] Blood Distribution
- [ ] General Quality Management
- [ ] Organisation (Policy, Objectives)
- [ ] Mangement of Personnel (recruitment, initial & continuous training)
- [ ] Management of Quality Documents
- [ ] Equipment/Material/Premises (e.g. qualification, validation, selection)
- [ ] Contract management
- [ ] NC/CAPA Management
- [ ] Internal Auditing
- [ ] Change Control
- [ ] Management Review
- [ ] Risk Management
- [ ] Other, please specify :

* 3.5. How do you rate the quality of the following standards in helping you develop/improve your QMS with regards to the following processes ?
A rating matrix is given below :

1 - Not useful at all
2 - Useful to a limited extent
3 - Useful to a moderate extent
4 - Significantly useful

	EU Blood Directives	CoE Guide and Good Practice Guidelines	ISO Standards
Donor Selection, Blood Collection/Testing/Storage/Distribution/Issuing			
Management of Quality Documents			
Equipment/Material/Premises			
Change Control Management			
NC/CAPA Management			
Management Review			
Management of Personnel			
Internal Auditing			
Risk Management			

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4. SELF EVALUATION OF THE LEVEL OF THE QUALITY MANAGEMENT SYSTEM IN YOUR BLOOD ESTABLISHMENT

The EDQM foresees the necessity to elaborate guidelines on specific matters to help Blood Establishments implementing their QMS. The aim of this part of the Survey is to allow to the EDQM to develop and adapt its activities to your needs (among other initiatives develop for example a manual or a guidance on how to qualify an automate etc..)

Evaluation levels :

Level 1

The stated requirement is false or the action is not done. There is no evidence of this action, the requirement is not implemented.

Level 2

The stated requirement is often false or the action is partially done. There is little evidence of the accomplished actions. The requirement is on an initial stage and there is a partial level of implementation.

Level 3

The stated requirement is true or the action is done. Evidence of a systematic approach of significant accomplishments is available.The requirement is defined, managed andimplemented.

Level 4

The requirement is systematically true or the action is systematically done and optimised. There is evidence of a complete and systematic actions. The requirement is optimised and systematically implemented and optimised.

4.1. Organisation

	Level 1	Level 2	Level 3	Level 4
A quality policy, objectives, and a quality manual are defined and communicated to the personnel.	○	○	○	○
An independent quality function (Quality Manager) is in place and is responsible for the oversight of all QMS issues.	○	○	○	○
An organisation chart/organigram is in place and, shows hierarchical structure and lines of responsibilities.	○	○	○	○
Resources (Personnel, material/equipment) are available in sufficient number and suit the activities to be carried out.	○	○	○	○
Quality Policy, Objectives, Quality Manual and resources are regularly reviewed and updated.	○	○	○	○

4.2. Management Review

	Level 1	Level 2	Level 3	Level 4
A procedure on management review is in place and is regularly updated.	○	○	○	○
Management review meetings take place regularly, involve key personnel and are documented.	○	○	○	○
Management review meetings monitor the effectiveness of the QMS (Any factors affecting the quality such as non-conformities, complaints are discussed and effectiveness of actions are monitored).	○	○	○	○
After management review meetings, actions (CAPA) are identified, planned and implemented.	○	○	○	○

4.3. Personnel

	Level 1	Level 2	Level 3	Level 4
Job descriptions, with clear tasks and responsibilities, are in place for all personnel.	○	○	○	○
Procedure(s) for recruitment, initial and continuous training of the personnel is/are in place. It covers approach to training, its contents and its evaluation and effectiveness.	○	○	○	○
Training plans are in place, training records are maintained for all personnel.	○	○	○	○
Training programmes are periodically assessed and competence of personnel evaluated regularly.	○	○	○	○
When non-conformities related to lack of training are found, actions (CAPA) are identified, planned and implemented.	○	○	○	○

4.4. Equipment, Material and Premises

	Level 1	Level 2	Level 3	Level 4
Procedures on qualification, validation, calibration, maintenance are in place and regularly updated.	○	○	○	○
All equipment, methods, premises are regularly validated, qualified, calibrated and maintained.	○	○	○	○
Qualification/validation comprises Design, Installation, Operational and Performance Qualification.	○	○	○	○
Validation master plans or equivalent are defined. Results of validation/qualification, maintenance, calibration are documented and reviewed.	○	○	○	○
When defect material , equipment malfunctions, failures are found, actions (CAPA) are identified, planned and implemented.	○	○	○	○

4.5. Quality Documentation Management

	Level 1	Level 2	Level 3	Level 4
A document control system, defined in a procedure is established for review, revision history and archiving of documents.	○	○	○	○
Quality documents are uniquely identifiable, approved, signed and dated by an authorised person. Non-controlled copies are prevented.	○	○	○	○
Training is performed against procedures and procedures are available on the effective date.	○	○	○	○
All significant changes to quality documents are acted upon promptly, are reviewed, dated and signed by an authorised person.	○	○	○	○

4.6. Supplier Qualification and Contract Management

	Level 1	Level 2	Level 3	Level 4
Procedures on Contract management and supplier management is in place and is regularly updated.	○	○	○	○
All tasks performed externally (e.g. purchasing of material, external testing, transport by hospitals) are defined in a contract. All duties and responsibilities of each party are defined.	○	○	○	○
Purchasing of equipment/material is documented. User Specifications Requirements (USR) are defined for all equipment/material.	○	○	○	○
All suppliers and subcontracted parties are evaluated and audited.	○	○	○	○
When problems related to contract, suppliers, subcontracted parties are found, actions (CAPA) are identified, planned and implemented.	○	○	○	○

4.7. Selection of donors and collection

	Level 1	Level 2	Level 3	Level 4
Procedures for safe identification of donors, suitability interview, and eligibility assessment are implemented and updated.	○	○	○	○
Procedures for blood collection ensure that the identity of the donor is checked, that link between donor and blood components is established, actions take place following unsuccessful donation, risk of misidentification and mix up is avoided.	○	○	○	○
Blood collection procedure minimise risk of microbial contamination; the disinfection procedure is validated.	○	○	○	○
When problems related to donor selections and blood collection are found, actions (CAPA) are identified, planned and implemented.	○	○	○	○

4.8. Testing

	Level 1	Level 2	Level 3	Level 4
Procedures describing testing activities, handling donors specimens, sampling, analysis and data processing are in place.	○	○	○	○
Screening algorithms are defined in procedures for all tests performed.	○	○	○	○
The performance of the laboratory is assessed regularly by participation in formal external quality assessment/proficiency testing programme for all tests carried out in the laboratory.	○	○	○	○
When problems related testing, discrepant results are found; actions (CAPA) are identified, planned and implemented.	○	○	○	○

4.9. Processing & Release

	Level 1	Level 2	Level 3	Level 4
Procedures describing processing and release of blood components are defined and regularly updated.	○	○	○	○
All processes related to processing are validated to ensure the quality of blood components.	○	○	○	○
Released and non-released components are physically and administratively segregated.	○	○	○	○
When non-conformities related processing and release are found, actions (CAPA) are identified, planned and implemented.	○	○	○	○

4.10. Storage & Distribution

	Level 1	Level 2	Level 3	Level 4
Procedures describing storage and distribution are defined and regularly updated.	○	○	○	○
All processes related to storage and distribution are validated to ensure the quality of blood components during the entire storage, distribution and exclude mix-up.	○	○	○	○
There are appropriate records of inventory and distribution and they are kept up to date.	○	○	○	○
When problems related to storage and distribution occur, actions (CAPA) are identified, planned and implemented.	○	○	○	○

4.11. Internal Auditing

	Level 1	Level 2	Level 3	Level 4
Procedures on internal audits/self-inspections are in place and regularly updated.	○	○	○	○
Internal audits/self-inspection are performed regularly by trained and competent persons, in an independent way.	○	○	○	○
Outcomes of internal audits/self-inspections are reviewed and documented.	○	○	○	○
When non-conformities are found during audits, actions (CAPA) are identified, planned and implemented.	○	○	○	○

4.12. Non-Conformities and CAPA Management

	Level 1	Level 2	Level 3	Level 4
Procedures on management of non-conformance and CAPA are in place and are regularly updated.	○	○	○	○
Non-conformities (e.g. deviation, adverse events,/reactions, complaint, out of specifications) are documented, investigated for causative factors and followed by corrective action to prevent recurrence.	○	○	○	○
Regular reviews of non-conformities are conducted, to verify the effectiveness of corrective and preventive actions.	○	○	○	○

4.13. Change Control

	Level 1	Level 2	Level 3	Level 4
There is a formal change control system in place to plan, evaluate and documents all changes that may affect processes and the quality and safety of blood components	○	○	○	○
Procedures for change control are in place and are regularly updated.	○	○	○	○

4.14. Risk management

	Level 1	Level 2	Level 3	Level 4
There is policy in place on risk quality management.	○	○	○	○
Risk based decision making is used in various area such as change control, validation/qualification and investigations of non-conformities.	○	○	○	○

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5. TARGETING THE NEEDS OF YOUR BLOOD ESTABLISHMENT

5.1. What are the main obstacles you are facing to implement regulatory requirements and a Quality Management System?

- [ ] Lack of financial resources
- [ ] Inappropriate financial resources
- [ ] Lack of Human resources
- [ ] Inappropriate Human resources
- [ ] Lack of equipment/material
- [ ] Inappropriate equipment/material
- [ ] Lack of educational support (e.g. guidelines, trainings…)
- [ ] Inappropriate educational support (e.g. guidelines, training)
- [ ] Difficulties to implement legislation (e.g. ambiguous, unclear requirements)
- [ ] Other, please specify :

5.2. Do you feel a lack of the following support from you competent authority?

- [ ] Financial resources
- [ ] Material/equipment
- [ ] Educational support
- [ ] Legislation
- [ ] Other, please specify :

5.3. What are the source of financing in your Blood Establishment?

- [ ] State financing (Competent Authority/Ministry)
- [ ] Self-financing by selling of blood components or blood products to hospitals
- [ ] Self-financing by selling of plasma to fractionators
- [ ] Other, please specify :

5.4. Which requirements of the EU Directives/Legislation are the most difficult to implement, is ambiguous or need to be further clarified?

Please specify and indicate the reason...

5.5. Are you able to meet the demands in components from the hospitals/clinics?

- ◯ Yes
- ◯ No
- ◯ If No, please specify :

5.6. If you throw away/discard unused plasma, what type of plasma do you throw away/discard ?

- [ ] Recovered plasma
- [ ] Apheresis plasma
- [ ] Please specify how many liters/year on average :

5.7. If you are unable to sell plasma to fractionators, what are the main reasons ?

- [ ] Lack or no acess to fractionation facilities
- [ ] Financial issues
- [ ] Level of QMS
- [ ] Safety issues (e.g. NAT testing, epidemiology issues) please specify below
- [ ] Other, please specify :

5.8. Which of the following do you provide to blood donors

	Whole Blood Donors	Apheresis Donors
Reimbursement of medical costs	☐	☐
Direct payment (e.g. money, cheques)	☐	☐
Compensation linked to loss of earnings/ salary	☐	☐
Food vouchers	☐	☐
Free physical check-up	☐	☐
Time off work, private sector	☐	☐
Small tokens (mugs, t-shirts etc..)	☐	☐
Refreshments	☐	☐
Other forms of compensation	☐	☐

Please specify :

5.9. Is there any national legislation in place, which harmonises the type and amount of incentives/compensations that are allowed ?

- ◯ Yes
- ◯ No

If yes, please specify :

5.10. Do you encounter a decrease in the usage of red cells?

- ◯ Yes
- ◯ No

If yes, would you be able to make an estimation in liters :

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6. THANKS !

Thank you very much for taking time in replying to this survey.
Do not hesitate to contact us (EDQM_B_QM@edqm.eu) if you would like to receive further information or provide us with additional information.
If you are interested in participating in B-QM activities please visit our webpage (B-QM webpage) this activity is free of costs and aims at supporting BEs .

By clicking on the "Submit" button below, you will definitely submit your answers.