DEFINITIONS UTILISED IN QUALITY MANAGEMENT OF BLOOD ESTABLISHMENTS

Prepared by the Working Group on Definitions

of the

International Society of Blood Transfusion (ISBT)

Quality Management Working Party

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Introduction

The Board of the ISBT Quality Management Working Party has initiated a project to harmonise the definitions commonly used in blood establishments around the world. A working group was established to work on this project with the aim of providing simple, unambiguous definitions that can be applied in a standardised way.

Common references available internationally have been consulted in drafting a list of definitions relating to quality management and these reference sources are quoted in the document. Criteria for selection of the optimal definition included clarity, simplicity, comprehensiveness and best applicability. Definitions have been adapted from the original sources in some instances. The resulting list of definitions is not prescriptive but is meant to serve as a recommendation for establishments that choose to use them. It is understood, however, that establishments in some countries are obliged to follow national legislation and terminology.

It is the intention of the ISBT Quality Management Working Party to periodically review the list of definitions and perform updates when required so feedback from interested parties is welcome.

ISBT Quality Working Party Board for this Project:

- Lesley Bust *(South Africa)*
- Christian Seidl *(Germany)*
- Tomislav Vuk *(Croatia)*

Additional Participants in Working Group on Definitions:

- Wade Atkins *(USA)*
- Sibel Eldemir *(Turkiye)*
- Nigar Ertuğrul Őrüç *(Turkiye)*
- Yan Qiu *(China)*
- Paul Strengers *(The Netherlands)*

Definitions for Quality Management of Blood Establishments

These definitions were first published on the ISBT website (www.isbtweb.org) [1] in July 2023 and the table was re-formatted in August 2025. A list of definitions is also available in Chinese.

TERM	DEFINITION	REFERENCE/ SOURCE
Accreditation	Process by which an independent and authorized agency certifies the quality and competence of an organization/ establishment on the basis of certain predefined standards.	WHO Guidance Implementation of a QS in BEs [2]
Agreement	A contract, order, or understanding between two or more parties, such as between a blood establishment and one of its customers.	AABB Standards for Blood Banks and Transfusion Services, 33rd ed [3] *(adapted)*
Apheresis	Method of obtaining one or more blood components by machine processing of whole blood, in which the residual components of the blood are returned to the donor during or at the end of the process.	EDQM Blood Guide, 21st ed 2023 [4]
Assessment	Evaluation of processes and systems to identify areas for improvement and to ensure that they are meeting the needs of stakeholders. Assessments may be conducted by internal staff or by external experts, and may involve a review of the quality management system, an analysis of customer feedback, and an examination of compliance with regulatory requirements or accreditation standards.	ISBT Quality Management - Working Party (ISBT QM-WP)
Audit	A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.	EDQM Blood Guide, 21st ed 2023 [4]
Batch /lot	A specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. In the case of continuous production, a batch may correspond to a defined fraction of the production. The batch size can be defined by a fixed quantity or by the amount produced in a fixed time interval.	PIC/S Guide to GMP for Medicinal Products: PE 009-16 (Part II), 2022 [5]
Batch /lot number	A unique combination of numbers, letters, and/or symbols that identifies a batch (or lot) from which the production or distribution history can be determined.	PIC/S Guide to GMP for Medicinal Products: PE 009-16 (Part II), 2022 [5]
Biovigilance	The science and activities relating to the detection, assessment, understanding and prevention of adverse events or any other problem related to biologicals. Biovigilance for biologicals is analogous to pharmacovigilance for pharmaceuticals,	Therapeutic Goods Administration, Australia (TGA) Guidance on Biovigilance [6]
Blood (whole blood)	Blood collected from a donor and processed either for transfusion or for further manufacturing.	Directive 2002/98/EC [7]

TERM	DEFINITION	REFERENCE/ SOURCE
Blood collection	The procedure whereby a donation of blood is collected in an anticoagulant and/or stabilizing solution, under conditions designed to minimize microbial contamination, cellular damage and/or coagulation activation of the resulting blood donation.	WHO Technical Report Series, No. 961, 2011 (Annex 4) [8]
Blood component	A therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by various methods. *Note: Methods may include centrifugation, freezing, filtration or irradiation, etc using established conventional blood processing methodology.*	Directive 2002/98/EC [7]
Blood establishment (BE)	Any structure, facility or body that is responsible for any aspect of the collection, testing, processing, storage, release or distribution of human blood or blood components (including source plasma) when intended for transfusion or further industrial manufacturing. BE includes hospital blood banks that are also engaged in blood collection, processing, testing, storage and distribution activities	WHO guidance on increasing supplies of PDMP [9] ISBT QM-WP
Blood product	Any therapeutic product derived from human blood or plasma.	Directive 2002/98/EC [7]
Calibration	The set of operations which establish, under specified conditions, the comparison of a measurement instrument or system of unverified accuracy to one of known accuracy to detect any variation from the required performance specification.	Eudralex Guidelines for GMP [10] ASQ quality glossary [11] ISBT QM-WP
Change control	A structured method of revising a policy, process, or procedure, including hardware or software design, transition planning, and revisions to all related documents.	AABB Standards, 33rd ed [3]
Clean area	An area with defined environmental control of particulate and microbial contamination constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area. *Note: The different degrees of environmental control are defined in the Supplementary Guidelines for the Manufacture of sterile medicinal products. Also see ISO 14644 series of standards.*	Eudralex Guidelines for GMP [10]
Clean contained area	An area constructed and operated in such a manner that will achieve the aims of both a clean area and a contained area at the same time.	Eudralex Guidelines for GMP [10]
Closed system	A system, the contents of which are not exposed to air or outside elements during collection, preparation, and separation of components.	AABB Standards, 33rd ed [3]

TERM	DEFINITION	REFERENCE/ SOURCE
Collection facility	An establishment that performs blood collection or apheresis, but does not test. *Note: Alternate names are blood donation facility or plasmapheresis facility.*	FDA form for blood establishment registration [12]
Competence	Demonstrated personnel attributes and demonstrated ability to apply knowledge and skills in performing tasks according to procedures.	ISBT QM-WP
Competent authority (CA)	The agency responsible under its national law for regulations applicable to blood establishments.	AABB Standards, 33rd ed [3] *(adapted)*
Compliance / conformance	Fulfilment of requirements that may be defined by regulatory agencies, customers, practice standards, or law.	AABB Standards, 33rd ed [3] *(adapted)*
Computerised system	A system including the input of data, electronic processing and the output of information to be used either for reporting, automatic control or documentation.	Directive 2005/62/EC [13]
Contained area	An area constructed and operated in such a manner (and equipped with appropriate air handling and filtration) so as to prevent contamination of the external environment by biological agents from within the area.	Eudralex Guidelines for GMP [10]
Controlled area	An area constructed and operated in such a manner that some attempt is made to control the introduction of potential contamination, and the consequences of accidental release of living organisms. At a minimum, the area should be maintained at a pressure negative to the immediate externa environment and allow for the efficient removal of small quantities of airborne contaminants.	Eudralex Guidelines for GMP [10]
Corrective and preventive action (CAPA)	Corrective action (CA): Action to eliminate the cause of a detected non-conformity or other undesirable situation in order to prevent a recurrence. Preventive action (PA): Action to eliminate the cause of a *potential* non-conformity or other undesirable situation.	ISO 9000:2015 [14] ISBT QM-WP
Critical	Potentially having an effect on the quality and/or safety of blood, blood components or blood products.	Directive 2006/86/EC [15]
Critical equipment/ material/ tasks	A piece of equipment, material, service, or task that can affect the quality of the establishment's products or services.	AABB Standards, 33rd ed [3]
Criticality	A term that implies the state of being extremely important and refers to how often a failure will occur, how easy it is to diagnose, and whether it can be fixed.	ISBT QM-WP
Cross- contamination	Contamination of a material or of a product with another material, product or pathogenic microorganism.	Eudralex Guidelines for GMP [10] *(adapted)*

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Customer	The receiver of a product or service as defined by the blood establishment. A customer may be internal (eg, another department within the same establishment) or external (eg, another organisation).	AABB Standards,33rd ed [3] *(adapted)*
Deferral (blood donor)	Suspension of the eligibility of an individual to donate blood or blood components, such suspension being either permanent or temporary.	Directive 2002/98/EC [7]
Deficiency	A lack, inadequacy or insufficiency in meeting a particular requirement or standard. Deficiencies can arise in various contexts, such as product features, processes, documentation, or performance. They represent areas where improvement or corrective action is needed to address the identified shortcomings.	ISBT QM-WP
Derivatives	Sterile solutions of a specific protein(s) derived from blood or by recombinant technology (eg, albumin, plasma protein fraction, immune globulin, and factor concentrates).	AABB Standards, 33rd ed [3]
Disaster	An event (internal, local or national) that can affect the safety and availability of the blood supply or the safety of staff, patients, volunteers, and donors.	AABB Standards, 33rd ed [3]
Distribution	The act of delivery of blood, blood components and blood products to other blood establishments and manufacturers of blood and plasma derived products. It does not include the issuing of blood or blood components for transfusion.	Directive 2002/98/EC [7]
Document/ documentation (noun)	Written or electronically generated policies, procedures, instructions and records involved in providing a product or service.	WHO Guidance Implementation of a QS in BEs [2] *(adapted)*
Document (verb)	To capture information through writing or electronic media.	AABB Standards, 33rd ed [3]
Donation	Blood and blood components collected from an individual and intended for transfusion to another individual (allogeneic) or to the same (autologous) individual.	EuBIS Manual & Guide for Quality Management & Inspection of BES, 2016 [16]
Donor adverse events	An unintended response in a donor associated with donation. *Note: Donor adverse events have been defined in an IHN/ISBT document and may be grouped into the following categories:* • *Local symptoms* • *Generalized symptoms - vasovagal reactions* • *Allergic reactions* • *Reactions related to apheresis* • *Other complications related to blood donation.*	Goldman M et al, Development of standard definitions for surveillance of complications related to blood donation. Vox Sang 2016;110: 185-188 [17]
Donor management	Measures taken in line with national and international regulatory requirements to ensure a safe, sufficient, stable and sustainable blood supply that incorporate; identifying,	ISBT QM-WP

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	selecting and recruiting eligible donors who meet the required criteria; screening and evaluation of donors to help identify any potential risks associated with blood donation; retention of donors; and public awareness and education to promote a culture of voluntary, regular blood donation.	
Donor, voluntary non-remunerated	A donor who has been motivated to donate blood without expectation of compensation or pursuant to third party pressure. Donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation.	Africa Society for Blood Transfusion (AfSBT) Standards, 4th ed 2021 [18] Council of Europe Recommend-ation No. R (95) 14 Art. 2 [19]
Donor, allogeneic	An individual from whom blood, or blood components, intended for another person are collected.	AABB Standards, 33rd ed [3] *(adapted)*
Donor, autologous	A person who acts as his or her own blood donor. A person who donates blood for his or her own use.	AABB Standards, 33rd ed [3] *(adapted)*
Donor, blood	A person in normal health with good medical history who voluntarily gives blood or plasma for therapeutic use.	PIC/S GP Guidelines for BEs, PE 005-4, 2021 [20]
Donor, designated/ dedicated	An individual who donates blood components intended for and used solely by a single identified recipient.	AABB Standards, 33rd ed [3]
Donor, first time	Someone who has never donated either blood, plasma or apheresis components before.	ISBT QM-WP
Donor, regular	Someone who routinely donates their blood or plasma (i.e. within the last two years), in accordance with minimum time intervals.	ISBT QM-WP
Donor, repeat	Someone who has donated before but not within the last two years.	ISBT QM-WP
Donor, replacement	A donor who has been asked by the family of a patient in need of a transfusion to give blood for a specific recipient, or to replace the blood transfused to a specific recipient.	AfSBT Standards, 4th ed 2021 [18]
External quality assessment (EQA)	The external assessment of a laboratory's performance using samples of known, but undisclosed, content and comparison with the performance of other laboratories.	WHO/EHT/ 04.09 [2]
External quality assessment scheme (EQA)	A recognized scheme for organizing EQA. This can be a local scheme or organized at national, regional or international level.	WHO/EHT/ 04.09 [2]

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Failure Mode Effects Analysis (FMEA)	A systematic, proactive method for evaluating a process to identify where and how it may fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change.	Institute for Healthcare Improvement (IHI) FMEA [21]
Familiarisation visit	An activity, that includes a visit to a blood establishment in order for a candidate inspector to become familiar with its overall processes, functions and operations.	EuBIS Manual & Guide for QM & Inspection, 2016 [16] *(adapted)*
Good manufacturing practice (GMP)	All elements in established practice that will collectively lead to final products or services that consistently meet appropriate specifications and compliance with defined regulations.	PIC/S GP Guidelines for BEs, PE 005-4, 2021 [20]
Good practice (GP)	All elements in established practice that collectively will lead to final blood or blood components/products that consistently meet predefined specifications and compliance with defined regulations.	Directive 2005/62/EC [13] *(adapted)*
Haemovigilance	A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the use of labile blood products, and to prevent their occurrence or recurrence.	Hemovigilance: An Effective Tool for Improving Transfusion Safety (eds R R P De Vries and J-C Faber), Wiley-Blackwell, Oxford, UK, 2012 [22]
Hospital blood bank	Hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within the hospital facilities, including hospital-based transfusion activities. *Note: Please refer also to definition of blood establishment*	PIC/S Good Practice Guidelines for BEs: PE 005-4, 2021 [20]
Imputability	The likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused or that a serious adverse reaction in a donor can be attributed to the donation process.	Directive 2005/61/EC [23]
Inspection	Formal and objective control according to adopted standards to assess compliance with relevant legislation and to identify problems.	EDQM Blood Guide, 21st ed 2023 [4] *(adapted)*
Inspector/ assessor, lead	The inspector responsible for leading and coordinating the activity of the inspection team and presenting the findings and outcomes of the inspection. *Note: In smaller BEs often the inspections are carried out by a single inspector.*	EuBIS Manual & Guide for QM & Inspection, 2016 [16] *(adapted)*
Inspectorate training programme	A training programme that covers general topics essential for inspectors, including principles of inspection techniques as well as specific and on-going training.	EuBIS Manual & Guide for QM & Inspection, 2016 [16] *(adapted)*

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ISBT 128	A standard for the identification, terminology, coding, and labelling for blood, cellular therapy and tissue products. When linear barcodes are used, Code 128 symbology is utilised.	AABB Standards, 33rd ed [3]
Issue	The provision of blood or blood components for transfusion to a recipient. *Note: Issuing relates to the prescription of blood for a patient based on a clinical indication.*	ISBT QM-WP
Label	An inscription affixed or attached to a unit of blood or a blood component, a tissue, a derivative, or a sample for identification.	AABB Standards, 33rd ed [3]
Labelling	Information that is required or selected to accompany a unit of blood or blood component, a tissue, a derivative, or a sample, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use.	AABB Standards, 33rd ed [3]
Mobile site	A temporary or movable place used for the collection of blood and blood components which is in a location outside of but under the control of the blood establishment.	Directive 2005/62/EC [13]
Near-miss event	An unexpected occurrence that did not adversely affect the outcome but could have resulted in a serious adverse event.	AABB Standards, 33rd ed [3]
Non-compliance	Failure to meet requirements or to adhere to applicable laws, regulations, or legal requirements. Non-compliance may arise from intentional or unintentional actions or omissions and can pose risks to patient safety and product quality.	ISBT QM-WP
Non-compliance, critical	Any non-compliance in a process or a written procedure which directly affects the safety of the donor or patient.	EuBIS Manual & Guide for QM & Inspection, 2016 [16]
Non-compliance, major	A serious non-compliance in a process or a written procedure but does not on its own affect the safety of the donor or patient.	EuBIS Manual & Guide for QM & Inspection, 2016 [16]
Non-compliance, other significant	A non-compliance in a system or process where there is insufficient information to classify it as a major or critical. *Note (EuBIS): There could be a combination of several other significant non-compliances, none of which on their own may be major or critical, but may together represent a major or critical non-compliance. These should be clearly explained and reported as such.*	EuBIS Manual & Guide for QM & Inspection, 2016 [16]
Non-conformance/ non-conformity	A deviation or departure from established standards, specifications, procedures, or requirements. Non-conformance can result in products, processes or systems that do not conform to the prescribed criteria or	ISBT QM-WP

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	established norms. Non-conformance requires investigation, root cause analysis, and appropriate corrective actions.	
Observation	An inadequacy in a system or process that is not a failure to comply with a standard.	EuBIS Manual & Guide for QM & Inspection, 2016 [16]
Pathogen reduction	Exposure of blood components to a system designed to reduce the risk of transfusion-transmitted infections.	AABB Standards, 33rd ed [3]
Preservation (of blood components)	The use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of blood or blood components.	EDQM Blood Guide, 21st ed 2023 [4]
Process/ in-process control	Checks performed during production in order to monitor and, if appropriate, to adjust the process and/or to ensure that the product conforms to its specification. *Note: The control of the environment or equipment may also be regarded as part of in-process control.*	EudraLex Guidelines for GMP [10]
Process parameter, critical	A process parameter, which is documented, whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality. A critical quality attribute is defined as a physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality.	ICH Harmonized Tripartite Guideline Q8 [24] ISBT QM-WP
Processing/ preparation	Any step in the preparation of a blood component that is carried out between the collection of blood and the issuing of a blood component.	Directive 2005/62/EC [13]
Proficiency testing	Structured evaluation of laboratory methods that assesses the suitability of processes, procedures, equipment, materials, and personnel.	AABB Standards, 33rd ed [3]
Qualification	As part of validation, qualification means the action of verifying that any personnel, premises, equipment or material works correctly and delivers expected results.	Directive 2005/62/EC [13]
Quality assurance	All the activities from blood collection to distribution made with the object of ensuring that blood and blood components are of the quality required for their intended use.	Directive 2005/62/EC [13]
Quality attributes, critical (CQA)	A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality. *Note: Critical Quality Attributes (CQA) link quality attributes to clinical safety and efficacy of a bioproduct.*	ICH Harmonized Tripartite Guideline Q8(R2) Annex [24]

TERM	DEFINITION	REFERENCE/ SOURCE
Quality control	Part of Good Practice that is concerned with sampling, specifications and testing, as well as with the organisation, documentation and release procedures which ensure that materials are not released for use in preparation, and blood and blood components are not released for distribution, until their quality has been judged to be satisfactory and that the necessary and relevant tests have been carried out.	PIC/S Good Practice Guidelines for BEs, PE 005-4, 2021 [20]
Quality control, internal (IQC)	Testing routinely performed on materials and equipment to ensure their proper function.	AABB Standards, 33rd ed [3]
Quality indicators (QI)	Objective quality measures of key system elements, used to identify potential quality concerns and risks, and to monitor the changes over time.	ISBT QM-WP
Quality monitoring	That part of a quality assurance programme concerned with maintenance and improvement of quality which deals with the identification and use of indicators to detect variations from standards or specifications.	PIC/S Good Practice Guidelines for BEs, PE 005-4, 2021 [20]
Quality system/ quality management system	The organizational structure, defined responsibilities, procedures, processes, and resources for implementing quality management. This includes all activities which contribute to quality, directly or indirectly.	Directive 2005/62/EC [13] *(adapted)*
Quarantine	Physical or other effective way, of isolation of blood components or products or incoming materials/reagents over a variable period of time while awaiting their acceptance, issuance or rejection.	Directive 2005/62/EC [13] Directive 2004/23/EC [25] *(adapted)*
Reagent	A substance used to perform an analytical procedure. A substance used (as in detecting or measuring a component or preparing a product) because of its biological or chemical activity.	AABB Standards, 33rd ed [3]
Recipient	Someone who has been transfused with blood or blood components.	Directive 2005/61/EC [23]
Record (noun)	Information captured in writing or through electronically generated media that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.	AABB Standards, 33rd ed [3]
Record (verb)	To capture information for use in records through writing or electronic media.	AABB Standards, 33rd ed [3]
Record of audit, assessment or inspection	Report indicating findings/results of an assessment, inspection or audit.	ISBT QM-WP

TERM	DEFINITION	REFERENCE/ SOURCE
Regulations	Rules promulgated by federal/national, state, regional or local authorities to implement laws enacted by legislative bodies.	AABB Standards, 33rd ed [3] *(adapted)*
Release - of blood component	Process which enables a blood component to be released from a quarantine status by the use of systems and procedures to ensure that the finished product meets its release specification.	Based on PIC/S GP Guidelines for BEs, PE 005-4, 2021 [20]
Responsible person	The person designated by a blood establishment who is responsible for: - ensuring that every unit of blood or blood components has been collected and tested, whatever its intended purpose, and processed, stored, and distributed, when intended for transfusion, in compliance with the laws in force - implementing quality management system to ensure the safety, purity, and potency of blood and blood products - providing information to the competent authority in the designation, authorisation, accreditation or licensing procedures - and the implementation of other requirements specified in respective legislation.	Directive 2002/98/EC [7] ISBT QM-WP
Risk assessment	Method to assess and characterise the critical parameters in all the activities of the quality system including functionality of equipment, systems or processes.	PIC/S Good Practice Guide for BEs PE 005-4, 2021 [20]
Risk management	The systematic application of quality management policies, procedures, and practices to the tasks of assessing, controlling, communicating, and reviewing risk. Risk management should include risk assessment and risk mitigation.	FDA Guidance Q9, Quality Risk Management [26]
Risk mitigation	Minimizing the effects of probable hazards by creating strategies to avoid, reduce, transfer or accept risk.	US National Institute of Standards and Technology. NIST SP 800-30 rev. 1 [27]
Sample/ specimen, blood	A small quantity of blood taken from a blood donor, donation or a patient for testing, retention or research purposes.	ISBT QM-WP
Self-audit, assessment or inspection	A process where a trained and competent individual or a team within an organization audits/assesses/inspects their own work or processes to ensure compliance with established standards, requirements, or procedures.	ISBT QM-WP
Serious adverse event (SAE) - for patient	Any untoward occurrence associated with the collection, testing, processing, storage and distribution, transfusion or administration, of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.	ISBT QM-WP adapted from Directive 2002/98/EC [7]
Serious adverse reaction (SAR) - for patient	An unintended response in donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling,	Directive 2002/98/EC [7]

TERM	DEFINITION	REFERENCE/ SOURCE
	incapacitating, or which results in, or prolongs, hospitalisation or morbidity	
Specification	A description of the criteria that must be fulfilled in order to achieve the required quality standard.	Directive 2005/62/EC [13]
Standard	The requirements that serve as the basis for comparison.	Directive 2005/62/EC [13]
Standard operating procedure (SOP)	A document describing a regularly recurring operation that affects the quality of the process. Its purpose is to ensure that the operations are carried out correctly and in a consistent way.	EU Blood SOP Manual [28]
Statistical process control (SPC)	The use of statistical techniques to control a process or production method.	ASQ, quality glossary [11]
Storage	Maintaining blood or blood products derived from human blood under appropriate controlled conditions until distribution.	ISBT QM-WP
Subcontractor	Any organisation that provides a service to a BE on the basis of a contract or written agreement.	ISBT QM-WP
Supplier/ vendor	An entity that provides an input material or service.	AABB Standards, 33rd ed [3]
Supplier /vendor qualification	An evaluation method designed to ensure that input materials and services (eg. materials, blood, blood components, tissue, derivatives, patient blood samples) obtained from a supplier meet specified requirements.	AABB Standards, 33rd ed [3]
Technical expert	Individual with appropriate qualifications and experience to provide technical advice to a blood establishment or to an inspector of a relevant competent authority.	ISBT QM-WP
Traceability	The ability to trace each individual unit of blood or blood component derived thereof from the donor to its final destination, whether this is a recipient, a manufacturer of medicinal products or disposal, and vice versa.	Directive 2005/61/EC [23]
Transfusion -autologous	Transfusion in which the donor and the recipient are the same person and in which pre-deposited blood and blood components are used.	Directive 2002/98/EC [7]
Validation	The establishment of documented and objective evidence that the pre-defined requirements for a specific procedure or process can be consistently fulfilled.	Directive 2005/62/EC [13]
Validation Plan	A description of the validation activities, responsibilities and procedures describing specifically how a certain validation is to be done.	ISBT WP- QM
Verification / confirmation	Confirmation by examination and provision of objective evidence that specified requirements have been met.	AABB Standards, 33rd ed [3]

References/ Source Documents

1. ISBT Quality Management Working Party. Definitions utilised in quality management of blood establishments. Available from: https://www.isbtweb.org/isbt-working-parties/quality-management/resources.html.
2. World Health Organization (WHO). Guidance on implementation of a quality system in blood establishments, 2023. Available from: https://iris.who.int/handle/10665/376096.
3. Association for the Advancement of Blood & Biotherapies (AABB). Standards for blood banks and transfusion services, 33rd ed.; 2022.
4. European Directorate for the Quality of Medicines & HealthCare (EDQM). Guide to the preparation, use and quality assurance of blood components, 21st ed., 2023. Available from: https://www.edqm.eu/en/-/edqm-publishes-21st-edition-of-the-blood-guide-providing-state-of-the-art-guidance-for-healthcare-professionals.
5. Secretariat of Pharmaceutical Inspection Convention (PIC/S). Guide to good manufacturing practice for medicinal products: PE 009-16 (Part II), 2022. Available from: https://www.tga.gov.au/sites/default/files/2024-03/pe-009-16-gmp-guide-part-ii-basic-requirements-apis.pdf.
6. Australian Government, Department of Health and Aged Care, Therapeutic Goods Administration. Biovigilance responsibilities of sponsors of biologicals, 2017. Available from: https://www.tga.gov.au/resources/guidance/biovigilance-responsibilities-sponsors-biologicals
7. European Commission. Commission Directive 2002/98/EC of European Parliament and of the Council, of 27 January 2003, setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending directive 2001/83/EC. Available from: https://eur-lex.europa.eu/eli/dir/2002/98/oj/eng.
8. World Health Organization (WHO). Guidelines on good manufacturing practices for blood establishments. Available from: https://www.who.int/publications/m/item/trs961-annex4.
9. World Health Organization (WHO). Guidance on increasing supplies of plasma derived medicinal products in low- and middle-income countries through fractionation of domestic plasma, 2021. Available from: https://iris.who.int/bitstream/handle/10665/340171/9789240021815-eng.pdf?sequence=1.
10. European Commission. EudraLex, Volume 4, Good Manufacturing (GMP) Guidelines. Available from: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en.
11. American Society for Quality (ASQ). ASQ quality glossary. Available from: https://asq.org/quality-resources/quality-glossary.
12. Food and Drug Administration (FDA). BER Instructions for completing the electronic blood establishment registration and product listing form. Available from: https://www.fda.gov/media/116432/download.
13. European Commission. Commission Directive 2005/62/EC of 30 September 2005 implementing directive 2002/98/EC of the European Parliament and of the Council as regards community standards and specifications relating to a quality system for blood establishments. Available from:

    https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32005L0062.
14. International Organization for Standardization (ISO). ISO 9000:2015 quality management systems - fundamentals and vocabulary. Available from: https://www.iso.org/standard/45481.html.
15. European Commission. Commission Directive 2006/86/EC of 24 October 2006 implementing directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notifications of serious adverse reactions and events. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32006L0086.
16. European Union. EuBIS Manual and Guide for Quality Management and Inspection of Blood Establishments reflecting European best practice within the area addressing the quality and safety of blood. Version 1.0.1 (2016) Available from: https://www.eubis-europe.eu/blood_manual_ordering.php.
17. Goldman M, Land K, Robillard P, Wiersum-Osselton J. Development of standard definitions for surveillance of complications related to blood donation. Vox Sang. 2016;110:185-8.
18. Africa Society for Blood Transfusion (AfSBT). AfSBT standards: step-wise accreditation programme, 4th edition 2021. Available from: https://afsbt.org/accreditation-standards/.
19. Council of Europe. Recommendation No. R (95) 14 of the Committee of Ministers on the protection of the health of donors and recipients in the area of blood transfusion. Available from: https://rm.coe.int/native/09000016804d35a0.
20. Secretariat of Pharmaceutical Inspection Convention (PIC/S). PIC/S good practice guidelines for blood establishments and hospital blood banks, PE 005-4, 2021. Available from: https://www.gmp-compliance.org/files/guidemgr/PE%20005-3%20PICS%20GMP%20Guide%20for%20Blood%20Establishments.pdf.

21. Institute for Healthcare Improvement. Patient safety essential toolkit: Failure Modes and Effects Analysis (FMEA). Available from: https://www.ihi.org/sites/default/files/SafetyToolkit_FailureModesandEffectsAnalysis.pdf.
22. De Vries R R P, Faber J-C. Hemovigilance: An effective tool for improving transfusion safety. Wiley-Blackwell, Oxford, UK, 2012.
23. European Commission. Commission Directive 2005/61/EC of 30 September 2005 implementing directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse events. Available from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32005L0061.
24. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). ICH harmonized tripartite guideline: Pharmaceutical development Q8 (R2). Available from: https://database.ich.org/sites/default/files/Q8_R2_Guideline.pdf.
25. European Commission. Commission Directive 2004/23/EC of the European Parliament and of the Council, of 31 March 2004, on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Available from: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:en:PDF.
26. U.S. Food and Drug Administration (FDA). Q9 (R1) Quality risk management: Guidance for industry. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q9r1-quality-risk-management.
27. U.S. National Institute of Standards and Technology (NIST). NIST SP 800-30 Rev. 1, Guide for conducting risk assessments. Available from: https://csrc.nist.gov/pubs/sp/800/30/r1/final.
28. European Union. Standard Operating Procedure (SOP) Manual: European standard operating procedure (SOP) methodology reflecting European best practice within the area addressing the quality and safety of blood. Available from: https://www.eubis-europe.eu/blood_manual_details.php.