AfSBT
Africa Society for Blood Transfusion
Société Africaine de Transfusion Sanguine
Sociedade Africana para Transfusão Sanguínea

Quality Management System

in Blood Services

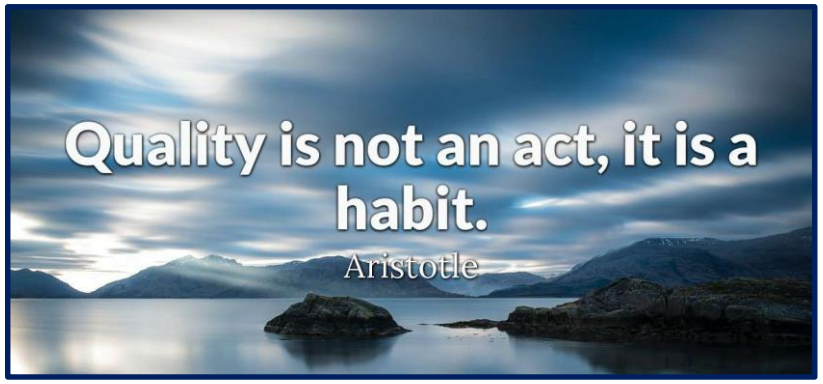
'AfSBT is making a Positive Difference to National Blood Programmes in Africa'

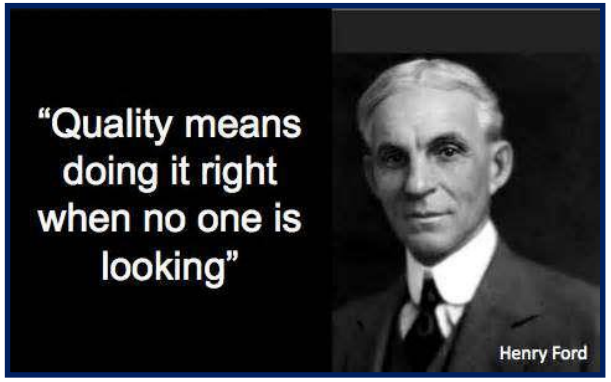
QSM-T11-0

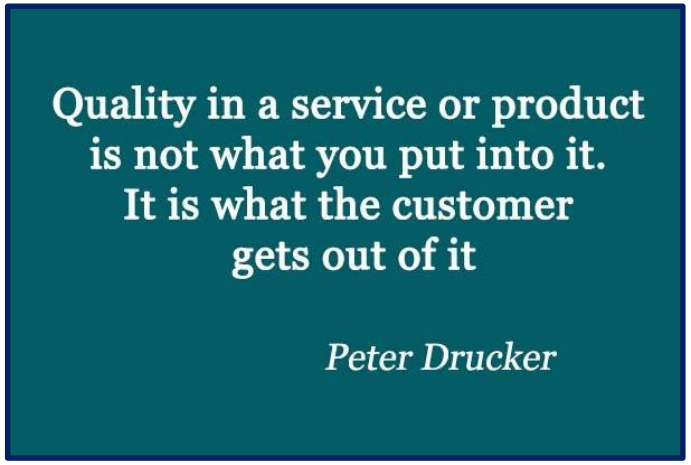
What is Quality?

- Standard of excellence
- Doing it right first time
- Fit for purpose
- Meets customer requirements
- Never having to say sorry to patient or donor
- A culture and way of life!

Opinions on Quality







Accreditation of AfSBT

- AfSBT working towards accreditation by international organisation
- ISQua - I*nternational Society for Quality in Healthcare*
- Steps required:
  - *Updating of AfSBT Standards to incorporate ISQua requirements* ✓
  - *Use of updated Standards in accreditation/ certification assessments* ✓
  - *Preparation of history of Standards development since 2009* ✓
  - *Revision of all AfSBT quality documentation* ✓
  - *Training and certification of AfSBT educators and assessors* ✓
  - *Submission of AfSBT Standards to ISQua* ✓

AfSBT Standards

AfSBT Standards originally based on:

- *AABB Standards*
- *WHO requirements*
- *ISO 9000, 17025, 15189*
- *Other countries*
- *Input from team of international experts*

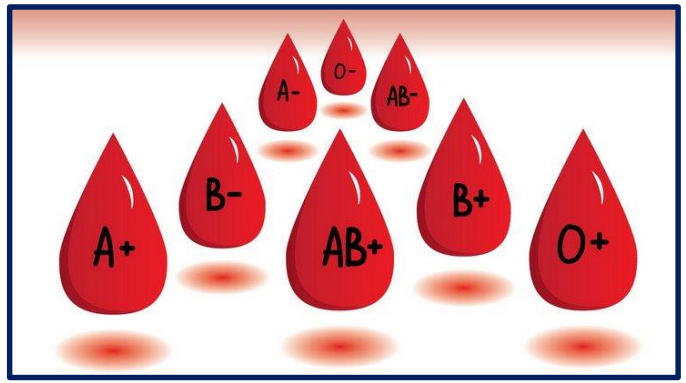
AfSBT Standards

AfSBT Standards consist of three sections:

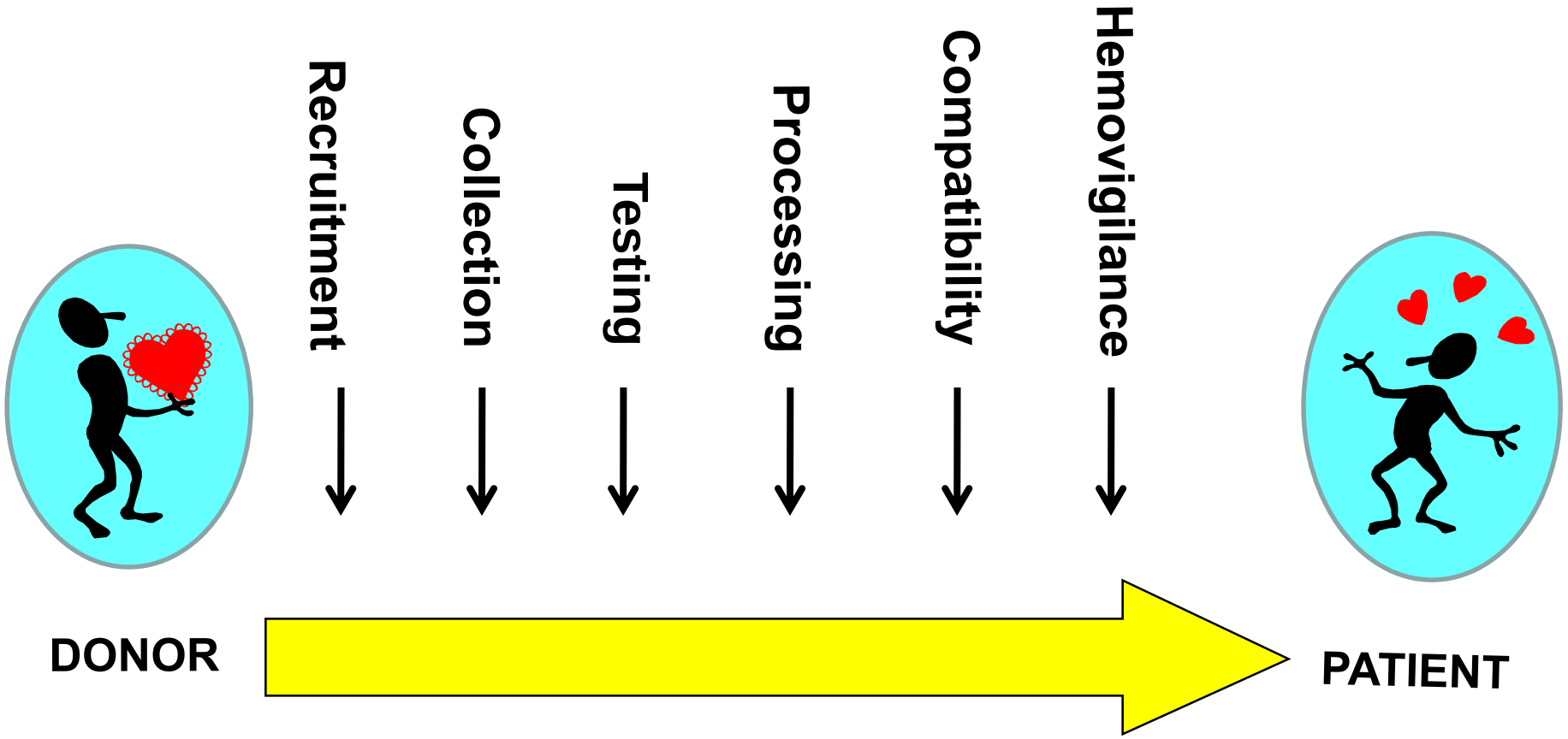
- *Section A: Quality Requirements*
- *Section B: Technical Requirements*
- *Section C: Requirements for Plasma for Fractionation*

Technical Requirements (Section B)

1. Blood donor management
2. Collection of blood
3. Handling, storage and transport
4. Testing of donated blood
5. Blood component production
6. Receipt, ordering & selection
7. Compatibility testing
8. Haemovigilance & clinical interface
9. Blood administration



Transfusion Chain



Quality Requirements (Section A)

1. Organization and Structure
2. The Quality Management System
3. Resources
4. Documents and Records
5. Suppliers and Service Providers
6. Incoming Receipt, Inspection and Testing
7. Equipment
8. Safety and Risk management
9. Internal and External Audits
10. Non-conformances
11. Continual Improvement
12. Process Control

Section A: Quality

This section of the AfSBT Standards:

- *Comprehensive*
- *Applies to all areas within a blood facility*
- *Challenging to implement*
- *Ensures efficient operation of organisation and supply of quality products and services*

A 1. Organization and Structure

- Mission statement defining organisation's core purpose and focus
- Code of ethics based on values and ethical standards
- Strategic plan detailing organisation's objectives
- Organisational structure outlining governance and management
- Organogram indicating responsibilities and inter-relationships

A 1. Organization and Structure

- Top Management responsible for ensuring operations carried out competently and in accordance with relevant laws, regulations and standards; responsible for quality policy and providing support for QMS implementation
- Medical Director qualified and licenced; responsible for all medical matters and for services relating to care and safety of donors and patients
- Quality Manager with authority and overall responsibility for quality and implementation of QMS

A 2. Quality Management System

- QMS requirements defined and communicated to staff
- Quality policy including quality objectives
- Quality manual covering all 12 sections of QMS
- Management review of quality system annually with improvements

A 3. Resources (Financial)

- Financial resources adequate to perform and manage the organisation's critical activities
- Budget developed to ensure ongoing operation

A 3. Resources (Human)

- Human resources adequate to perform activities
- Personnel trained, competent, registered, work under supervision
- Job descriptions for all personnel; correlate with organogram
- Training policy & programme to meet training needs
- Competency assessment performed every 12 months
- Personnel records maintained

A 4. Documents & Records

- Document control system to address document creation, identification, review, approval, revision, retention, final disposal
- Document requirements defined (current, dated, authorised, legible, uniquely identified, numbered, standardised)
- SOPs for all procedures, reviewed regularly
- Records maintained and retrievable
- Electronic records backed-up

A 4. Documents & Records (Principles)

- Confidentiality maintained
- Traceability of documents and signatures critical
- Changes to documents controlled and recorded
- Confirmation that staff have read and understood policies, SOPs

Do what you document and document what you do!

A 5. Suppliers & Service Providers

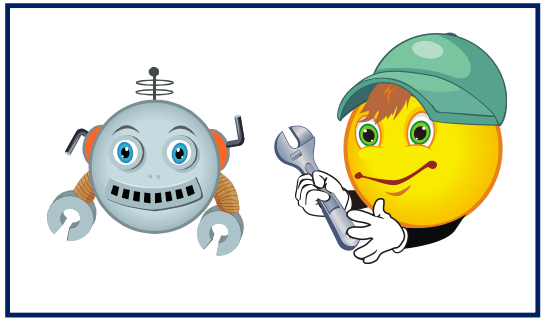
- Selection of suppliers before use
- Agreements that define customer and supplier expectations
- Evaluation of suppliers of critical materials, equipment, and services
- Records of supplier performance
- Inventory management system in place

A 6. Incoming Receipt, Inspection & Testing

- Incoming products & critical materials received, inspected and tested, as necessary, before acceptance or use
- Critical materials meet specified requirements and conform to international or national laws, regulations or standards

A 7. Equipment

- Selection criteria for critical equipment
- Identification of all equipment
- Equipment qualified for intended use (installation, operation & performance)
- Calibration performed to ensure accuracy
- Scheduled monitoring of equipment performed
- Preventive maintenance per manufacturer's instructions
- Malfunction procedures defined
- Electronic equipment correctly handled (hardware & software)



A 8. Safety & Risk Management

- Risk management plan and register for potential hazards
- Working environment suitable with orderly flow of work
- Working conditions safe with adequate protective equipment
- Safety programme to mitigate or prevent hazards
- Disaster recovery plan developed
- Protection of environment measures in place

A 9. Internal & External Audits

- Internal audits of operations and quality systems done annually
- Auditors independent of area being audited
- Reports generated; outcomes of all audits reviewed
- Corrective action taken for all non-conformances identified
- External audits performed by independent body

A 10. Non-Conformances

- Non-conformances arise from audits or during routine operations
- Procedures to detect, capture, assess, investigate and monitor NCs
- Root cause analysis done
- Corrective action taken and verified for effectiveness
- Preventive action taken to prevent non-conformances

A 10. Non-Conforming Products

- Authorized use in *exceptional circumstances,* at discretion of MD
- Recipient's doctor notified that all requirements cannot be met
- Authorisation by medical director & recipient's doctor fully documented
- Label on product indicates which tests have not been performed
- Testing continued after issue
- Non-conforming units recalled immediately and doctor notified

A 10. Non-Conformances

- Discard procedure for non-conforming blood or components defined
- Label indicates units not suitable for therapeutic use
- Units disposed of as biohazardous waste
- Recall procedure outlined for non-conforming blood or blood components determined after release not to meet specified requirements

A 11. Continual Improvement

- Quality improvement plan developed
- Feedback obtained from donors and customers/clinicians including complaints, compliments and suggestions
- Quality indicator data collected and evaluated
- M&E data used to improve operations of facility

A 12. Process Control

- Requirement that activities that affect quality of blood, blood components, and services are carried out under controlled conditions

A 12. Process Control

- Validation of new or changed procedures/ test methods prior to implementation
- Re-validation where changes occur or results indicate the need
- Change control for management of changes so that quality is maintained
- IQA/EQA for ensuring accuracy and reliability of tests
- Quality control testing on random blood components monthly
- QC results reviewed to monitor trends

A 12. Process Control

- Materials (including blood packs, reagents used for testing) stored and used in accordance with the manufacturer's written instructions and meet specified requirements
- Reagents prepared by facility standardized and meet specifications
- Identification at each critical step of who performed task, date and equipment used
- Traceability from source to final issue/disposition of blood, blood components, critical materials, laboratory specimens, donor and patient records

Champions of Quality

- Achieving accreditation is a journey that will not happen by itself
- Process needs to be driven by champions
- Dedicated personnel who are passionate about quality
- Quality Manager and MD/CEO are key champions
- Commitment from all senior management essential
- Personnel throughout the organisation to be aware and involved

Quality Department Functions

- Quality documentation system & document control
- Internal audit system
- Non-conformance system
- Management Review
- Monitoring & Evaluation Coordination
- Coordination of Validations
- Guidance and advice to all other departments
- Lead preparation for accreditation/ certification
- Compliance with legislation, interaction with regulatory bodies

Role of Quality Manager

- Quality Manager cannot achieve accreditation alone
- Must have adequate authority and responsibility
- Should report to highest level and receive support
- Must have training/ experience in quality systems
- Quality department should ideally consist of three people as a minimum:
  - *Manager*
  - *Deputy*
  - *Clerical officer*

Quality Ambassadors

- Aim to develop an ambassador/champion in each department
- Ambassadors to be trained and receive recognition
- Best at hands-on supervisory level
- Supervisors to be responsible for:
  - *Writing and timely updating of SOPs and forms*
  - *Addressing of non-conformances within time limits*
  - *Completion of validations*
  - *Mock audits in preparation for internal/ external audits*
  - *Monitoring of M & E indicators*
- Include in Job Descriptions, link to performance appraisals

Strong Foundation

- Quality pervades and influences all departments
- A good Quality Management System provides a strong foundation for the rest of the organisation
- Develop a quality culture for continual improvement
- Quality contributes towards ongoing sustainability of organisation

Good, better, best

Never let it rest

Till your good is better and your better best!

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Any questions?

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www.afsbt.org