ISO 9001 certification and AABB accreditation

1999 / 2010

2003 / 2012
Quality concepts
Quality Control

- Determine whether the product or service meets specifications
  - Tells the staff
    - Whether to continue
      - Everything is acceptable
    - Whether to stop until a problem has been resolved
      - Something is found to be out of control
  - Includes clerical checks, visual inspections and measurements such as
    - Temperature, cell counts, volume, etc
Quality Assurance

• Activities not tied to the actual performance of a process
• Includes
  • Documents development (SOPs, etc)
    • Ensure that processes are performed consistently and correctly
  • Training personnel
  • Qualification of materials and equipment
  • Retrospective review and analysis of operational performance
    • Determine if the overall process is in a state of control
    • Detect shifts or trends that require attention
    • E.g.: internal assessments, quality indicators
Quality Management System

• Organizational structure, responsibilities, polices, process, procedures and resources needed to implement and maintain a set of coordinated activities to direct and control an organization with regards to quality.

• Considers interrelated process in the context of the organization and its relations with customers and suppliers.
Quality System Essentials
Quality System Essentials

• Set of coordinated activities that serve as building blocks for quality management
  • Each one must be achieved!

• Organization and leadership
• Customer focus
• Facilities, work environment, and safety
• Human resources
• Suppliers and materials management
• Equipment management

• Process management
• Documents and records
• Information management
• Management of nonconforming events
• Monitoring and assessment
• Process improvement
Organization and leadership

- Responsibilities, Authorities
- Quality Policy
- Communication
- Provision of resources

Diagram: Venn diagram showing the intersection of responsibilities, authorities, quality policy, communication, and provision of resources.
Human resources

- Selection
  - Qualifications requirements
  - Job responsibilities
- Orientation
- Training
- Competency assessment
- Staffing
  - Adequate number
  - Professional development
  - Continuing education
Suppliers and materials management

- Critical materials, supplies and services
  - Affect the quality of products and services
  - E.g.: cryopreservation bags, drugs, etc
- Vendor qualifications
  - Agreements
  - Receipt, inspection and testing
    - Incoming supplies
- Inventory management
Documents and records

• Documents
  • Describes how process are intended to work and how they interact
    • Creation, revisions and review
    • Control and distribution

• Records
  • Provide evidence that the process was performed as intended and the information needed to access the quality
    • Collection, review
    • Storage, retention
Monitoring and assessment

• Internal
  • Quality indicators
  • Audit program
  • Audit review

• External
  • Proficiency testing
  • Inspections
  • Accreditations
Why implement it?

• Promote
  • Consistency and reproducibility
    • The process on Thursday is the same on Saturday
    • Minimize errors and improve patient care
  • The observed nonconformance will help to identify the problem cause
    • Process improvement
  • More credibility to the institution
    • Better patient outcomes
When implement it?

• As soon as possible!

It is easier to start our program with quality essentials in mind then to implement it retrospectively!
Summary and conclusions
Summary

- Transplant facilities and cord blood banks are complex systems and all aspects must function properly to achieve quality.
- Approaches to implementation will vary with the local situation.
- Start with changes that can be easily accomplished and have the biggest impact.
- Implement in a stepwise process but ultimately, all quality essentials must be addressed.
Conclusions

- Main goal
  - SAFETY
  - Improved patient outcomes
- Implementation of Quality Plan Process
  - Paradigm change
  - Staff compromised
- It is possible!
  - It is not easy!
- It was worth it!
Bibliography and interesting sites
Bibliography and interesting sites

• Books
  • AABB Technical Manual 17\textsuperscript{ed}, AABB, 2011
  • Cellular therapy: principles, methods and regulations, AABB, 2009
  • Laboratory Quality Management System: handbook, WHO, 2011

• Sites
  • www.who.int/ihr/training/laboratory_quality/en/index.html
  • www.aabb.org/resources/bct/ct/Pages/default.aspx
  • www.factwebsite.org/Inner.aspx?id=198
Thanks!