

Hemocentro RP



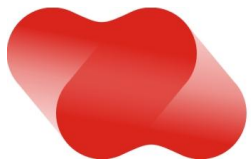
Overview and Principles of Quality System Essentials

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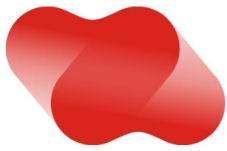
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Ribeirão Preto





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ISO 9001 certification and AABB accreditation

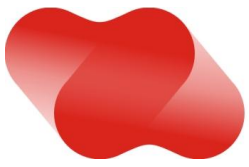


1999 / 2010



2003 / 2012

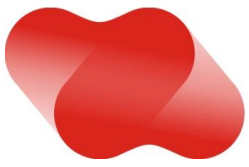
Quality concepts



Quality Control

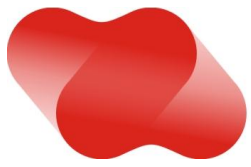
- **Determine whether the product or service meets specifications**
 - **Tells the staff**
 - **Whether to continue**
 - Everything is acceptable
 - **Whether to stop until a problem has been resolved**
 - Something is found to be out of control
 - **Includes clerical checks, visual inspections and measurements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





Quality Assurance

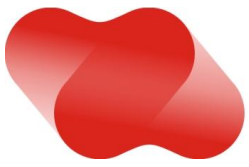
- **Activities not tied to the actual performance of a process**
- **Includes**
 - **Documents development (SOPs, etc)**
 - **Ensure that processes are performed consistently and correctly**
 - **Training personnel**
 - **Qualification of materials and equipment**
 - **Retrospective review and analysis 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

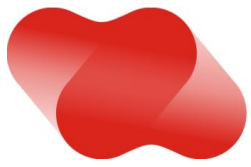
- **Organizational structure, responsibilities, policies, process, procedures and resources needed to implement and maintain a set of coordinated activities to direct and control an organization with regards to quality.**
- **Considers interrelated process in the context of the organization and its relations with customers and suppliers.**

Quality System Essentials



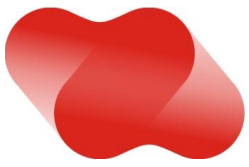
Quality System Essentials

- **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

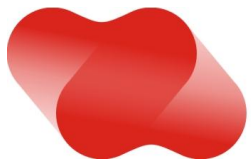




Human resources

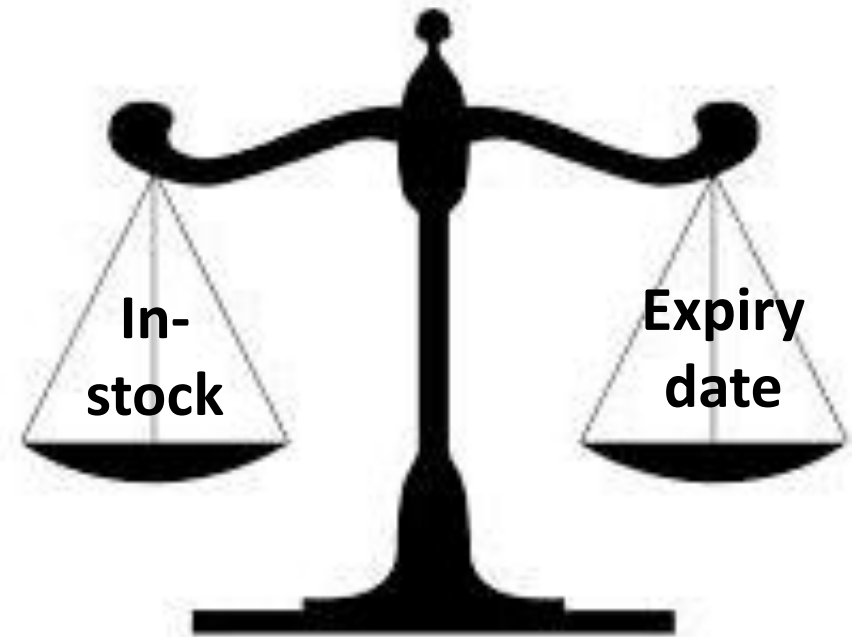
- **Selection**
 - Qualifications requirements
 - Job responsibilities
- **Orientation**
- **Training**
- **Competency assessment**
- **Staffing**
 - Adequate number
 - Professional development
 - Continuing education

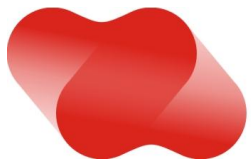




Suppliers and materials management

- **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**

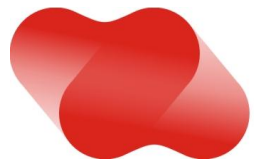




Documents and records



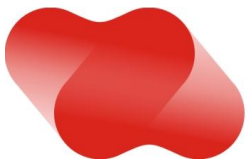
- **Documents**
 - Describes how process are intended to work and how they interact
 - Creation, revisions and review
 - Control and distribution
- **Records**
 - Provide evidence that the process was performed as intended and the information needed to access the quality
 - Collection, review
 - Storage, retention



Monitoring and assessment

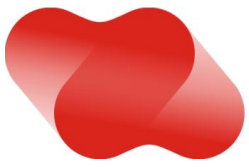
- **Internal**
 - Quality indicators
 - Audit program
 - Audit review
- **External**
 - Proficiency testing
 - Inspections
 - Accreditations





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

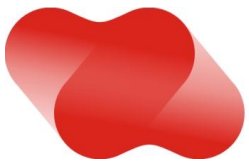


When implement it?

- **As soon as possible!**

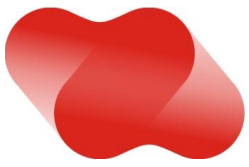
It is easier to start our program with quality essentials in mind then to implement it retrospectively!

Summary and conclusions



Summary

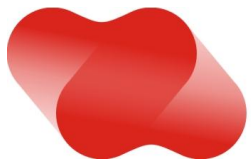
- **Transplant facilities and cord blood banks are complex systems and all aspects must function properly to achieve quality.**
- **Approaches to implementation will vary with the local situation.**
- **Start with changes that can be easily accomplished and have the biggest impact.**
- **Implement in 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



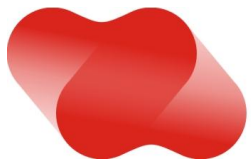
Bibliography and interesting sites

- **Books**

- **AABB Technical Manual 17^{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!

