Essential Elements:

A Guide For Establishing a Complete Quality Program. Cells & Tissues for Administration

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ahcta alliance for harmonisation of cellular therapy accreditation

Purpose

- List essential elements of quality required for a BMT program
  - Explain intent
  - Describe Quality Element
  - Provide Examples
- Preparatory to attaining accreditation
- Best to apply essential elements from time of initiation to full accreditation

Background

- Assigned by Worldwide Network for Blood and Marrow Transplantation (WBMT) to its' Accreditation Committee, the Alliance for the Harmonization of Cellular Therapy Accreditation (AHCTA) as a draft Aide-Memoire in 2010 with instruction to complete as a freely available resource
- Developed and reviewed by AHCTA subcommittee
- Reviewed by AHCTA Donor Committee
- Finalized and posted to AHCTA website May 2013
- Links established from WBMT participating organizations
- Dynamic document subject to periodic review and updating

Content

- Based on common elements found in existing standards
- Major focus on the establishment of a Quality Program
- Meant to apply to the entire transplant program
- Explanation meant to help program understand the intent of the element
- Examples are to show how the element applies
- Program may have other equally good ways to comply

Main Headers

1. Education and promotion
2. Program organization
3. Facility and staffing requirements
4. Quality Management
5. Policies and Procedures
6. Donor Issues
7. Process Control
8. Coding and Labeling
9. Product release/distribution
10. Product storage
11. Product transportation
12. Product disposal
13. Data management, registry reporting, outcomes assessment
14. Records

Sections 1-3

- **Education and promotion**
  - Healthcare professionals
  - Public campaigns
- **Program organization**
  - Identify regulatory requirements
  - Program structure
  - Program Leadership
- **Facility requirements and staffing**
  - Clinical
    - Clinical treatment facilities
    - Clinical requirements for physicians, mid-level practitioners, nurses, consultants
  - Collection
    - Collection facility requirements
    - Collection Staff
  - Laboratory
    - Processing facility requirements
    - Processing Staff

Sections 4-6

- **Quality Management**
  - Organization and responsible individuals
  - Quality Plan
  - Personnel
    - Training
    - Competency
    - Continuing education
  - Define critical processes, policies, and procedures
  - Document control
  - Agreements
  - Audits and assessments
  - Errors, accidents, biological product deviations, adverse events
  - Process improvement plan
  - Interruption of operations and disaster plan
- **Policies and Procedures**
  - Creation, Approval, Implementation
  - Required procedures
- **Donor Issues**
  - Donor recruitment
  - Donor selection and evaluation
    - Suitability and eligibility
    - HLA matching for allogeneic donors
  - Consents and confidentiality
  - Donor safety and follow-up

Sections 7-9

- **Process Controls**
  - Process and procedure validation
  - Materials Management
  - Product collection and processing
    - Physician orders
    - Prevention of contamination and cross-contamination
    - Product sampling and testing
    - Records, including lot records
  - Equipment use & maintenance
  - Therapy Administration
    - Preparative regimens
    - Patient consent
    - Physician orders
    - Product administration
    - Patient Safety
- **Coding and Labeling**
  - Naming systems & product identification
  - Labeling operations
  - Label Content
- **Product release/Distribution**
  - Release criteria
  - Exceptional release, urgent medical care
  - Accompanying documents

Sections 10-14

- **Product storage**
  - Temperature and duration
  - Safety and security
  - Monitoring and alarms
  - Inventory control
- **Product transportation, shipping, and receipt**
  - Within program facilities
  - Between facilities
- **Product disposal**
- **Data Management, registry reporting, outcomes assessment**
- **Records**
  - General requirements for all records
  - Electronic records

Format Example

1. Education and promotion

1.1. Healthcare professionals

Explanation	Process Elements	Examples
In order to promote optimal use of cells and tissues (cellular therapy), which are a true national resource, healthcare professionals must first be educated as to need.	Develop policies and procedures for education and training of healthcare professionals in optimal use of cells and tissues for administration and how to encourage donors.	• Plan educational activities for healthcare professionals and clinicians in use of cells and tissues for cellular therapy • Liaise with clinical programs treating patients that might benefit from cellular therapy • Collect data to monitor progress in use of the national resource of cell and tissue donation • Collect data to monitor success of educational programs in increasing donations

1.2. Public campaigns

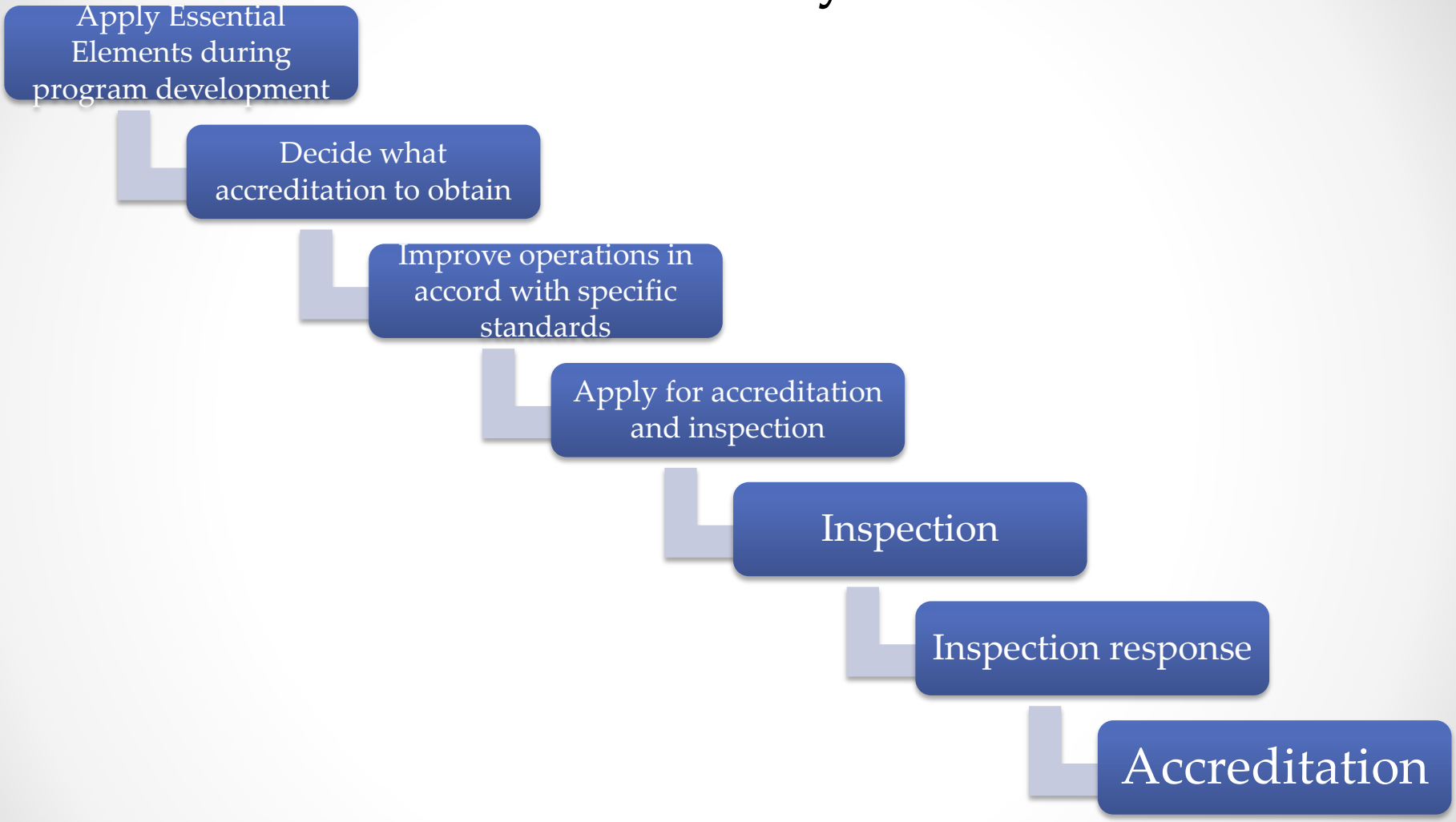
Explanation	Process Elements	Examples
The public must be made aware of the value of cell and tissue donation to overall public health and the importance that such donations be voluntary without expectation for remuneration	Establish campaigns to promote voluntary non- remunerated cell and tissue donation as an act of altruism.	• Ensure policies and procedures indicate voluntary and non-remunerated donation • Hold public educational seminars (e.g. schools, colleges, universities, other professional bodies) • Use social media such as Facebook, YouTube, or Twitter, to create population awareness

Example #2

- Laboratory
  - Processing facility requirements
  - Processing staff

Explanation	Process Elements	Examples
Facility Requirements The processing facility may be part of the clinical program, may be housed in the same institution as the clinical program but under different management (e.g. transfusion medicine or clinical laboratory) or may be a contracted facility. Regardless of management specification of basic requirements for the physical facility are needed.	Define requirements for the cellular therapy product processing laboratory. Ensure that facility design minimizes potential for contamination and cross-contamination and that space and equipment is adequate for the number of types of procedures performed.	1. Indicate on facility floor plans location(s) at which processing will occur and the relationship of the processing facility to the entire program 2. Require that the facility be accessible only to authorized personnel. 3. Identify space within the facility for controlled storage of processing supplies and reagents 4. Designate defined areas in the processing facility where products are received, processed, labeled and stored 5. Require that laboratory space includes or that the laboratory has ready access to all equipment required for product processing, testing, and storage 6. Define, monitor, and control environmental conditions that may affect viability, integrity, contamination, sterility, or cross-contamination of the cellular therapy product

Pathway to Accreditation



AHCTA Link

- http://www.ahcta.org/documents.html

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Documents

Title	Updated	Link
Mission statement		
Towards a Global Standard for Donation, Procurement, Testing, and Distribution of HSC and Related Cellular Therapies Position Paper (revised 27 May 2008)	27-05-2008	
Essential Elements - Cells & Tissues for Administration This document is intended for use as a resource for new or developing programs. It does not contain the full requirements of standards but seeks to provide clear examples of compliance and additional detail to support basic quality system elements.	14-05-2013	