AABB Standards and Accreditation Program:

International Components

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Advancing Transfusion and Cellular Therapies Worldwide

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AABB Mission

To advance the practice and standards of transfusion medicine and related biological therapies

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AABB Profile

- Established in 1947
- Institutional members
- Individual members
- International organization
- Standards and Accreditation Programs since 1957

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HCT/P Accreditations

- AABB has accredited 147 HPC and UCB facilities
  - 17 are outside US
  - Additionally, 11 in early stages of accreditation application (all international)

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AABB Standards Program

- Well defined infrastructure
- Process includes experts in field, ethicists, public, FDA and other organizations
- Established timelines for updates
- Allows for interim and emergent standards
- Requires member and public comment period
- Standards developed in FDA regulated climate

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Standards

- Incorporate Quality Management System and Technical Requirements
- Internationally accepted
  - Compatible with ISO
- Cellular Therapy Standards also compatible with GTPs (effective May 25, 2005)

AABB Accreditation Program

- Well established program - 50 yrs.
- Designed to operate in a regulated climate
- Policies guide program
- Operates under internationally accepted standards for accrediting bodies
- Accreditation based on assessment of conformance to standards

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International Accreditation

- Process is the same for all facilities
- International variances
  - Applies to US specific details which other countries cannot meet (usually testing)
  - NOT routinely granted

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Language Variations

- Accreditation manual requires all plans, policies and procedures to be in English
- When possible, assessor who speaks that language is sent
- Lead assessor on all HPC and UCB assessments
  - Accompanies volunteer with content expertise
  - Provides Consistency

Accreditation Program Policy Manual

- Well-defined infrastructure
- Policies consistent with internationally accepted standards for accrediting bodies, ISO Guide 58

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ISO Guide 58

- Addresses issues:
  - Requires the accrediting body to operate under a quality management system
  - Resolves conflict of interest issues
  - Ensures impartiality
  - Requires technical expertise
  - Addresses organization of accrediting body
  - Addresses confidentiality of information

Validation of Accreditation Program

- **External: CMS performs validation surveys based on volume**
  - Approved by CMS as equivalent to, or more stringent than, the CLIA condition
  - AABB has not had any disparities in >10 years
- **Internal: Random selection of 1% of assessments**
  - New: continuous improvement
  - Different team sent out
  - Thus far, consistent with original findings

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Assessments: Systems Approach

- Reviews objective evidence
- Demonstrates operations over a period of time, not a point in time
- Beginning Jan 2007 – unannounced

Imported Products

- AABB standards apply:
  - Supplier qualification and product acceptance specifications
  - Agreements (includes scope of service; responsibilities of each)
  - Vendor qualification
  - Receipt and shipping criteria

AABB Requirements: Supplier Qualification

- Must evaluate supplier
- Must establish and maintain policies, processes and procedures to ensure materials and services conform to requirements
  - FDA Guidance, Sept 2006 “Compliance with 21 CFRR Part 1271.150(c)(1)-Manufacturing Arrangements
- Define type of control and qualifications; risk based on potential impact on product quality

New Standard: Procurement Activities

- There shall be a process to ensure the quality of the procurement activities when these are performed by a supplier
  - Further clarifies the intent that all agreement and supplier requirements apply to collection/procurement/import of products and other materials

AABB Requirements: Agreements

- Must have policies, processes and procedures for developing, approving and reviewing agreements
- Before acceptance – review agreement
  - Confirm scope of service
  - Can meet requirements
  - Addresses medical services
    - Requires medical order for procurement, processing and storage
    - Obtain and share data for outcomes and adverse events
- Define process for changes

AABB Requirements: Agreements for Collection

- Procedures for receipt, handling and administration
- Reporting adverse events
- Access to records (both infusion and registry)
- Informed consent
- Physician order
  - Procurement
  - Processing and storage
  - Administration

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AABB Requirements: Informed Consent

- Rights as research subject (if applicable)
- Explanation of procedure and risks
- Sample procurement, testing and storage
- Infectious disease testing and notification of positive results
- Review of medical history and records
- Discussion of confidentiality and product ownership (including loss or damage)
- Additional requirements for UCB donors

AABB Requirements: Upon Receipt of Material/Product

- Inspected and/or tested as appropriate
  - FDA approved/cleared test kits
- Qualification of facilities providing test or services:
  - Lab certified by CMS and registered with FDA if indicated by 21 CFR 610.40(f).
- System to notify shipper and manufacturer of unacceptable condition(s)

During assessment

- AABB accredits activities, not facilities
- Assessor looks for documentation of:
  - Sample agreement
  - Documentation of agreement review
  - Vendor qualification (ex certificates, SOP review, audits)
  - Donor eligibility determination
  - Ongoing monitoring and reporting
  - Deviation management of incoming materials/products

Summary

- AABB Standards comply with FDA GTPs and apply to imported products
- EU struggling with similar issues
  - "Agreements between tissue establishments and third parties….must comply with Directive…specify terms…protocols to be followed to meet required specification"
  - "Must be a documented system for ratifying that tissues and/or cells meet appropriate specifications"
- Alliance for Harmonization of Cellular Therapy Accreditation (AHCTA)
  - Beginning with Import/export requirements