Production Assistance for Cellular Therapies

Educational Web Seminar

Vendor Qualification

Tuesday, 10 September 2019

12:00 PM – 1:00 PM ET

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Objectives

- Outline the requirements of vendor qualification as it relates to GMP regulations.
- Discuss how to develop appropriate forms, procedures and processes for qualifying vendors based on a review of case studies.
- Describe how concepts on vendor qualification differ for cord blood banking facilities and cell therapy facilities overall.

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Vendor Qualification

An Overview of The Process, Some Practical Advise and The Model from a Large Cell Therapy Laboratory with a Busy GMP Facility

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Objectives of The Presentation

- Define Vendor Qualification (VQ) and the reasons it is needed
- Discuss Benefits and Challenges of VQ
- Points To Consider when establishing a VQ program
- Compare VQ program tools
- Discuss the VQ Program at MDACC as an example for a large facility

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Vendor Qualification Overview

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Introduction to Vendor Qualification

FACT *"An integrated process for planning and controlling all steps in the acquisition and use of goods or supply items (materials) used for the collection or processing of cellular therapy products to ensure these materials are of adequate quality and quantity and available when needed.*

AABB *"The facility shall establish and maintain policies, processes, and procedures to ensure that purchased, donated, or otherwise acquired materials or services conform to specified requirements."*

21 CFR 1271 *"Before entering into a contract, agreement, or other arrangement with another establishment to perform any step in manufacture for you, you must ensure that the establishment complies with applicable cGTP requirements."*

21 CFR 820.50 "Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements."

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Why is it Needed?

- Regulatory Requirements
  - Code of Federal Regulations: cGMPs (21 CFR 210, 211), Quality Systems Regulation (21 CFR 820), HCT/Ps Good Tissue Practices (21 CFR 1271), FDA Guidelines to Industry, Center for Medicare/Medicaid Services (CMS Conditions of Participation/CLIA - 42 CFR 493)
- Accreditation Standards
  - Foundation for the Accreditation of Cellular Therapy (FACT), AABB (Formerly known as The American Association of Blood Banks), College of American Pathologists (CAP), The Joint Commission (TJC), American Society for Histocompatibility and Immunogenetics (ASHI)
- Industry Benchmarks
  - US Pharmacopeia
  - ISO-9001 (Quality management), 13485 (Medical Devices), 14001 (Environmental Monitoring)

It Just Makes Sense – Best Practices

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Benefits of Vendor Qualification

- Risk Management and Mitigation
- Avoid Supply Chain Issues and Disruptions
- Increase Communications and Strengthen Relationships
- Reduce Costs and Optimize Performance
- Minimized Product Quality and Compliance Issues
- Increase Administrative Efficiencies
- Increase Accreditation/Regulatory Compliance

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Classic Barriers to Vendor Qualification

- Cost – Expensive, Resource Intensive
- Apathy – Lack of Compliance, Useless, Annoying
- Perceived Privacy Issues – Intellectual Property, Trade Secrets
- Lack of Human and Technical Resources – No SME
- Lack of Trust – Confidentiality Issues
- Differing Business Cultures – Perceived Importance

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Elements of a GMP-Compliant VQ Program

1. Develop List of Supply/Service Requirements
2. Gather a List of Potential Vendors to meet requirements
3. Evaluate Vendors Using a Risk-Based Selection Method/Matrix
4. Assess (Audit) Selected Vendors/Suppliers
5. Develop a Collaborative Quality Agreement, as needed
6. Periodically Monitor Vendor Compliance

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Establish The Requirements

- Identify Equipment, Supplies or Services Needed
- Define specifications of the product or services
- Establish conditions of usage and terms of provision
- Evaluate feasibility within your organization
- Assess the level of vendor support required
- Identify any additional challenges (Customs, permits, local laws)

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Organizational Impact

- Leverage institutional contracts if possible
- Evaluate the need for staff training/availability of SMEs
- Assess facility resources (staff, facility, technology, budget)
- Determine the need for SOP/Policy creation or revision
- Are Information Technology resources available?
- Define budgetary specifications and limits

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Risk Assessment

- Define acceptable endpoints or critical limits
- Evaluate safety requirements for the particular item/services
- Establish “Critical” and “Non-Critical” criteria for product/services
- Assess Product Disposal / Waste Management needs
- Develop Materials Specification Sheets (Non-Critical)
- Define an Alternate (Backup) Provision Plan (Critical)

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Basic Qualification Tool Characteristics?

- Should be concise (short), pertinent (direct) and focused (targeted).
- Tool must be based on defined criteria with set frequency
- Tool based on risk to the operation (Spec Sheet, Audit, On-Site)
- First-time qualification or re-qualification of current vendor
- Design should facilitate (encourage) completion by the vendor
- Request basic summary documentation/certifications
- Not intrusive or redundant to increase compliance

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Define Qualification By Supplier Type

- Equipment – Approved (BLA) vs. Research (IDE)
- Reagents – Research (IND) vs. Licensed (BLA), GMP-grade
- Supplies – Sold Only Under IND vs. Commercially Available
- Services – External (Third Party) vs Internal (Institutional)

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Vendor Qualification Tool Comparison

Tool	Pros	Cons
On-Site Visit/Inspection	First Hand, Personal, Detailed, used for high risk vendors	Costly, Time Consuming, Needs SME, vendor resistance, resource intensive
Desk Audit	Easy to complete, email return, high rate of compliance, economical, No Need for SME, Fillable pdf	Does not fit all levels of risk, Requires development of a audit tool, Not always actionable
Phone Call	Expedient, economical, practical	Limited use and scope, provides no evidence, tedious
Third Party	Less overhead, No need for SME, may piggyback on institutional or multi-facility (pooled) resources	Costly, Additional Contract, focus on document review, middleman effect
Re-Qualification	Use with established vendors, may use a shortened format, economical	May not cover significant changes, vendor resistance, Reduced scope, low compliance rate

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Vendor Qualification at MDACC

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MDACC Stem Cell Transplantation Program

- One of the largest transplant programs in the world
- 850 - 950 Transplants per year
- All transplants are done under
  - Standard of Care (SOC)
  - Research Protocol (including IND/IDEs)
  - Compassionate (CIND), Single Patient (SIND) or Emergency IND (EIND)
- Not associated with the Division of Pathology and Laboratory Medicine (Clinical Diagnostic Labs) at MDACC

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MDACC Cell Therapy Laboratory Statistics

- Core Laboratory (Standard of Care Processing)
  - Product Collections/Acquisitions = 1850+
  - Infused Products = 1100+
  - Processing = 2900+
- GMP Facility (IND Products)
  - Active MDA Protocols Accruing Patients = 40
  - Industry Sponsored (External Sponsor Protocols) Trials = 62
  - Investigational New Drug (IND) Products Infused = 200+
  - Immune Effector Cell (IEC) Products Infused = 150
  - Research Protocols Pending Activation = 12

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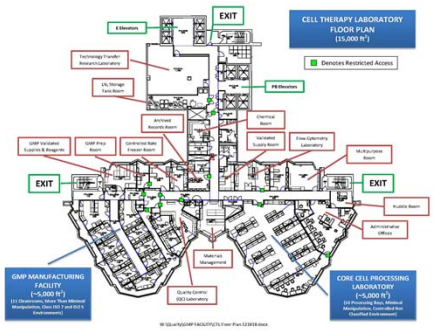

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MDACC CTL Staffing Model

- Laboratory Director – 1
- Laboratory Medical Director – 1
- Technical Director – SCT/GMP Labs –1
- Assistant Director, Quality Assurance and Regulatory Compliance – 1
- Department Administrator – 1
- Laboratory Manager – 1
- Laboratory Supervisors – 6
- Cell Therapy Laboratory Trainers – 3
- Quality Assurance Unit – 5
- Quality Control Lab – 4
- Sr. Clinical Cell Therapy Specialists – 12
- Clinical Cell Therapy Specialists – 12
- Clinical Cell Therapy Associates – 16
- Flow Cytometry Lab – 2
- Clean Room Techs – 2
- Inventory Planners – 2
- Office Manager – 1
- Administrative Assistant – 1
- Sr. Financial Analyst – 1

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MDACC CTL Certifications and Accreditations

FDA - Food and Drug Administration
Registered as a Human Cell and Tissue Establishment (FDA Form 3356) since 2001

CLIA - Centers for Medicare and Medicaid Services
Certificate of Accreditation

CAP - College of American Pathologists
Certificate of Accreditation (1997 – Present)

FACT - Foundation for the Accreditation of Cellular Therapy
Autologous and Allogeneic Transplantation, Pediatric and Adults
Cell Therapy Facility (Minimal and More Than Minimal Manipulation)
Immune Effector Cell (IEC) Products
Off-Site Storage Facility (CryoGene Lab)

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MDACC CTL Vendor Qualification Statistics

- Over 65 Vendors Listed (Supplies, Equipment, Services)
- 85% Response Rate (Increased from a previous 20-25%)
- Completed every 2 years
- Includes Internal Service Providers (MDACC Blood Bank, Microbiology, HLA Lab, Flow Cytometry Lab, Molecular DX)
- Very Cost Effective (Email documentation, 1 FTE, No budgetary impact)
- Trivia Note - Previous audit tool was 10 pages long ☹

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Vendor Qualification Cover Letter

- Short and To The Point
- Explain What you need
- Define Why you need it
- Pledge Confidentiality, except for accreditation/regulatory inquiries
- Explain tool's Ease-of-Use (Fillable pdf)
- Offer multiple ways to return
- Thank them for their participation

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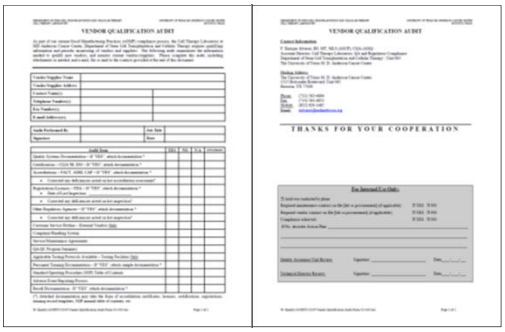

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Vendor Qualification Audit (MDACC CTL)

Shorter version of the Cover Letter

Specific Vendor information and contact in multiple formats

VENDOR QUALIFICATION AUDIT

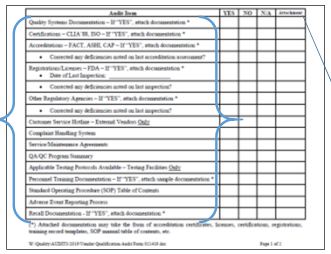
As part of our current Good Manufacturing Practices (cGMP) compliance process, the Cell Therapy Laboratory at MD Anderson Cancer Center, Department of Stem Cell Transplantation and Cellular Therapy requires qualifying information and periodic monitoring of vendors and suppliers. The following audit summarizes the information needed to qualify new vendors, and monitor current vendors/suppliers. Please complete this audit, including attachments as needed, mail e-mail, fax or mail to the contacts provided at the end of this document.

Vendor/Supplier Name			
Vendor/Supplier Address			
Contact Name(s)			
Telephone Number(s)			
Fax Number(s)			
E-mail Address(es)			

Audit Performed By		Job Title	
Signature		Date	

Vendor Qualification Audit (MDACC CTL)

A listing of items that include elements of the Quality Systems regulation, GTP/GMP requirements, Accreditation standards, registrations and licenses that can be used to establish the vendors qualifications to meet your required specifications



Audit Item	YES	NO	N/A	Attachment
Quality Systems Documentation – If "YES", attach documentation *				
Certifications – CLIA '88, ISO – If "YES", attach documentation *				
Accreditations – FACT, AABB, CAP – If "YES", attach documentation *				
• Corrected any deficiencies noted on last accreditation assessment?				
Registration/Licenses – FDA – If "YES", attach documentation *				
• Date of Last Inspection:				
• Corrected any deficiencies noted on last inspection?				
Other Regulatory Agencies – If "YES", attach documentation *				
• Corrected any deficiencies noted on last inspection?				
Customer Service Hotline – External Vendors Only				
Complaint Handling System				
Service/Maintenance Agreements				
QA/QC Program Summary				
Applicable Testing Protocols Available – Testing Facilities Only				
Personnel Training Documentation – If "YES", attach sample documentation *				
Standard Operating Procedure (SOP) Table of Contents				
Adverse Event Reporting Process				
Recall Documentation - If "YES", attach documentation *				

(*) Attached documentation may take the form of accreditation certificates, licenses, certifications, registrations, training record templates, SOP manual table of contents, etc.

W:\Quality\AUDITS\2019\Vendor Qualification Audit Form 012418.doc Page 1 of 2

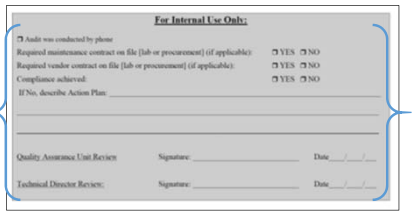
Specific documentation submitted in support of the vendor responses.

This may include SOP Manual TOC, Accreditation Certificates, Licenses, Registrations, Training records template, Organizational Charts, Vendor informational Brochures, etc.

Vendor Qualification Audit (MDACC CTL)

The final section includes additional internal information important to have on hand such as:

- Existence of a contract for services or maintenance
- A documented decision regarding compliance
- CAPA as needed
- Approval signatures



For Internal Use Only:

❒ Audit was conducted by phone

Required maintenance contract on file [lab or procurement] (if applicable): ❒ YES ❒ NO

Required vendor contract on file [lab or procurement] (if applicable): ❒ YES ❒ NO

Compliance achieved: ❒ YES ❒ NO

If No, describe Action Plan: _____

_____

_____

Quality Assurance Unit Review: Signature: _____ Date ___/___/___

Technical Director Review: Signature: _____ Date ___/___/___

Summary

- Vendor Qualification (VQ) is an essential element of quality systems
- A VQ program can increase accreditation and regulatory compliance
- Vendor prioritization should be risk-based (Critical/Non-Critical)
- A well-designed VQ audit tool can overcome the common barriers
- Should qualify more than 1 vendor for critical supplies and services
- Consider the need for a Quality Agreement with some suppliers

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Questions

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Establishment of an Unrelated Cord Blood Bank Qualification Program a Transplant Center/Cell Therapy Manufacturing Perspective

Fran Rabe
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University of Minnesota
Molecular and Cellular Therapeutics (MCT)

Objectives of Presentation

- The importance of a strong cord blood bank qualification program
- Quality versus regulatory qualification criteria
- Retrospective versus Prospective qualification
- Advantages and limitations with the qualification system

Abbreviations/Terminology in This Presentation

Unrelated Umbilical Cord Blood Bank, also synonymous with the frequently used term Public Cord Blood Bank = CBB

Unrelated Umbilical Cord Blood Unit = CBU

Driving Forces of Qualification Program

- May, 2005 US Food and Drug Administration (FDA) regulation of unrelated cord blood manufacture - 21 CFR Part 1271
- October, 2011 FDA regulatory requirement: Cord Blood Bank must have IND or License to manufacture and distribute
- Provides systematic process to evaluate the quality of cord blood banks necessary prior to the need for a CBU arises

Limitations of CBB Qualification

The qualification process is not fool-proof.

Therefore, monitoring of quality indices related to CBUs received and transplanted is critical as a supplement to the vendor qualification process.

Cord Blood Bank Qualification Possibilities

- In person audit
  - Yikes

- Remote audit review of paper-work
- Rely on professional accreditations
- Rely on government licensure or (non-US) government endorsement
- Rely on past CBU experience (quality indices)
- Combination or hybrid of above

Our CBB Vendor Qualification Experience

- Implemented a hybrid approach
- Developed an algorithm to define our process:
  - Retrospective qualification
  - Prospective qualification

Basis of Our Algorithm

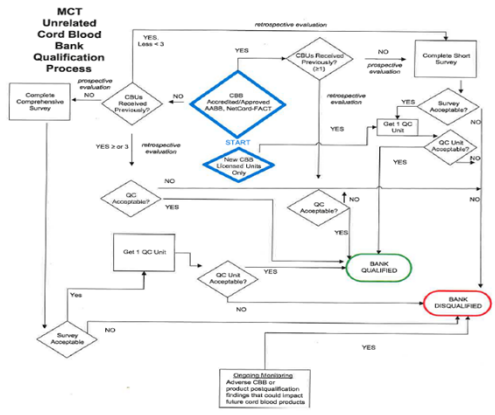
Risk based approach intended to capture the elements that we consider **critical** related to the cord blood bank:

- Ensure FDA requirements, 21 CFR 1271, 210 and 211 are met (US CBBs)
- Ensure adequate approach to donor screening and testing to eliminate/reduce disease transmission risk (US and Non-US CBBs Banks)
- Quality systems in place to ensure consistent quality practices (US and Non-US CBBs)
- Demonstrated product quality (US and Non-US CBBs)

Basis of Our Algorithm

Includes all of the following components

- Review of QC indices from previously received CBUs (retrospective qualification only)
- Review of QC indices from newly ordered CBUs (prospective qualification only)
- Review to ensure US FDA regulatory compliance (US CBB only)
- Review to ensure infectious disease transmission donor screening/testing is performed (Non-US CBB)
- Review of standard QA systems
- Confirming US FDA registered establishment
- Review and of professional accreditation
- FDA 481s and Warning Letters



RETROSPECTIVE QUALIFICATION

Cord Blood Banks that had been used as a source for cord blood for a short period or a number of years before a qualification process was developed, were retrospectively qualified.

Retrospective Qualification Evaluation Tools

Consideration of a Combination of Criteria:

1) FDA Establishment Registration (*FDA Form 3356*): Must be registered
2) The number of CBUs received during period of evaluation: Must have received at least 1
3) Results of historical post-thaw cell count(s): Must meet our internal requirement
4) The professional accreditation status of the Cord Blood Bank: AABB or NetCord-FACT
5) Short survey

Short Survey

The Short Survey is only used in cases where the Cord Blood Bank has accreditation from:

- NetCord Foundation for the Accreditation of Cellular Therapy (NetCord-FACT)

  Or

- AABB

The assumption is that the quality systems have been evaluated by the professional accrediting group; therefore the Short Survey looks at non-quality system criteria

Short Survey Content- Major Components

Quality/Regulatory Administrative
Collection Program
Donor Qualification
Product processing and testing

Retrospective Qualification of the Cord Blood Bank
University of Minnesota, MCT Algorithm

Previously Received CBUs from the CBB	QC Result(s)	CBB Accredited?	Short Survey	Comp-rehensive Survey	Qualification Result
1 or 2 CBUs	Failed	STOP	STOP	N/A	**FAILED**
1 or 2 CBUs	Yes-OK	Yes	N/A	N/A	**PASS**
1 or 2 CBUs	Yes-OK	No	N/A	Yes-OK	**PASS**
1 or 2 CBUs	Yes-OK	No	Yes-Failed	N/A	**FAILED**
≥3 CBUs	Failed	STOP	STOP	N/A	**FAILED**
≥3 CBUs	Yes-OK	N/A	N/A	N/A	**PASS**

Retrospective Qualification Results

1172 CBUs were evaluated
- Represented 41 CBB
  - US CBBs = 19 (46%)
  - Non-US CBBs = 22 (54%)
  - The 2 primary US CBB = 26% and 21% of total

7 CBBs were disqualified based on QC results
- US CBBs = 4 (57%)
- Non-US = 3 (43%)

8 CBBs moved to the prospective category

Unique Category

Retrospective qualification found 8 CBBs where we had only received 1 unit.

The 8 CBBs were not accredited.

We chose not to proceed with retrospective qualification (did not ask them to complete short survey)

These CBBs could be prospectively qualified.

Prospective Qualification

New Cord Blood Banks that have never been used by the transplant center/manufacturing facility are qualified prospectively.

Prospection Qualification "Tools"

- FDA Establishment Registration
- Accreditation status (NetCord-FACT or AABB)
- Short or Comprehensive Survey
- CBU requested QC result

Survey Category Comparison

Comprehensive Survey Major Categories

- Quality/Regulatory and Administrative
- Staff
- Equipment
- Collection Program
- Donor Qualification
- Product Processing, Storage and Testing

Short Survey Major Categories

- Quality/Regulatory and Administrative
- Collection Program
- Donor Qualification
- Product Processing, Storage and Testing

Prospective Qualification of the Cord Blood Bank University of Minnesota Algorithm

Received CBUs From the CBB	Accredited	Short Survey	Comp-rehensive Survey	QC Result	CBB Qualification
0	Yes	Yes-OK	N/A	Yes-OK	PASS
0	Yes	Yes-Failed	N/A	STOP	FAILED
0	Yes	Yes-OK	N/A	Yes-Failed	FAILED
0	No	N/A	Yes-OK	Yes-OK	PASS
0	No	N/A	Yes-Failed	STOP	FAILED
0	No	N/A	Yes-OK	Yes-Failed	FAILED
0-licensed	N/A	N/A	N/A	Yes-OK	Pass
0 -licensed	N/A	N/A	N/A	Yes-Failed	FAILED

Prospective Qualification Results

Qualified

3 US CBBs

1 Non-US CBB

Failed

1 CBB did not pass due to poor QC unit results

1 CBB failed due to survey results

Disqualification (after qualification)

A qualified CBB can be disqualified as an approved vendor at any time. Disqualification may be a result of, but not limited to:

- Failure of QC results or engraftment of a CBU
- Removal of accreditation by FACT-NetCord or AABB
- Voluntary or involuntary (FDA initiated) recalls
- FDA (or other government for non-US CBBs) actions such as FDA 483s, warning letters or other actions
- Other quality/regulatory issues associated with the CBB
- Patient adverse events
- Other

Additional Cautions and Considerations

Varied levels of approval:

1-2 banks have passed the approval process but not all subsequent CBUs received were of optimal quality.

- Bank remains on qualified list, but a notation is made that the bank is only utilized if an alternate "better" unit from a different qualified bank can not be sourced.

Challenges Faced in the Process

- Retrospective qualification: The CBBs practices have evolved over time. We may pick a "starting date" for CBUs we will accept.
- Prospective qualification:
  - The CBBs practices have evolved over time
  - Low compliance rate with participation of international centers when requests for survey completion
  - Some CBBs not thrilled with assuming expense of providing and shipping a CBU for testing

Summary

The qualification of unrelated CBBs by the user is an important and necessary process.

A center that has been in operation for some time may use both a retrospective and prospective qualification process.

The prospective qualification process should include the consideration of donor screening and testing, manufacturing and other criteria.

The CBB vendor qualification process should be supplemented by on-going monitoring of CBU quality indices and transplant events and outcomes.

References

Code of federal regulations. Federal Register, Volume 70, No. 100/Wednesday, May 25, 2005. Washington, DC:US Government Printing Office

Rabe F, McKenna DH, Kadidlo DM. Establishment of an unrelated umbilical cord blood bank qualification program: Transfusion.

Questions ????

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Vendor Qualification

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