Production Assistance for Cellular Therapies

Welcome to the

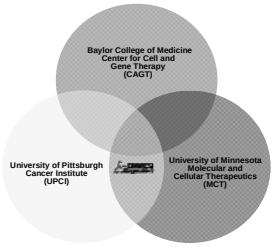
Educational Web Seminar

Qualification:
Vendor, Equipment, and Supplies

Thursday January 29, 2009
12:00 Noon - 1:00 PM ET

PACT

A National Heart Lung and Blood Institute-funded initiative



- PACT manufactures quality cell therapy products on behalf of investigators with funded clinical trials requiring support in product development
- PACT's educational training focuses on three general areas: translational development/scale-up and manufacture of cell therapy products, quality assurance, and regulatory issues
  - Workshops (onsite)
  - Web Seminars

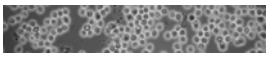
National **Heart Lung and Blood** Institute

NHLBI PACT Workshop
April 23-24, 2009

Converging Concepts in Cell Therapy

Location:
Natcher Conference Center
National Institutes of Health
Bethesda, Maryland

Intended Audience:
Clinical Investigators, Scientists, Researchers, and Technologists specializing in cell therapy



Program overview…
Discussions of Cell Processing and Treatment Indications Involving:

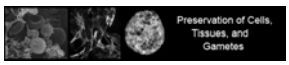
T-Regulatory Cells
Mesenchymal Stem Cells
Antigen Specific T Cells
Engineered T Cells
Natural Killer Cells
Dendritic Cells
Cell Trafficking & Imaging Techniques

Visit www.pactgroup.net to register

No charge for attendance*

*Travel and hotel accommodations not included

May 18-20, 2009 Professional Short Course: "Preservation of Cells, Tissues, and Gametes"



Hosted by: The Center for Translational Medicine and the Department of Mechanical Engineering
Location: University of Minnesota, Mechanical Engineering Building
111 Church Street SE. Minneapolis, Minnesota 55455

The course is offered both via the web and for in class attendance.
A brochure for the course and more information can be found at:
http://www.me.umn.edu/education/shortcourses/preservation/index.htm

On-line registration for the course is now open.
Early bird registration deadline for the course is April 17,2009.

Registration
http://www.me.umn.edu/education/shortcourses/preservation/registration.htm

For more information
Dr. Allison Hubel
Course Coordinator Dept. of Mechanical Engineering
Phone: 612.626.4451
Email: hubel001@umn.edu

Today's Education Web Seminar

"Qualification: Vendor, Equipment and Supplies"

Adrian P. Gee, MI Biol., PhD
CAGT - Baylor College of Medicine

Fran Rabe, BA
University of Minnesota

Chris Chun, MT(ASCP)HP
American Red Cross - Salt Lake City, Utah

The presentation slides for this web seminar are available publicly on the main page at:
www.pactgroup.net

Web Seminar

Description
The web seminar will provide an overview of the processes used at different centers to qualify vendors, equipment and supplies. Regulatory requirements and approaches to compliance will be discussed.

Objectives
- Apply approaches to compliance that have been used to the qualification process
- Develop appropriate procedures for qualifying vendors, equipment, and supplies
- Interpret the requirements of regulatory agencies and other standards regarding vendor, equipment, and supply qualification procedures

Faculty Disclosure

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of AABB and PACT. AABB is accredited by the ACCME to provide continuing medical education for physicians. In accordance with the ACCME Standards for Commercial Support[sm], all faculty for this event have signed a conflict of interest form in which they have disclosed any significant financial interests or other relationships with the industry relative to the topics they will discuss during this program.

Faculty Disclosure Information

Faculty	Disclosure	Nature of Relationship	Manufacturer/Provider
Chris Chun	None	non-PACT member	ARC, Salt Lake City, Utah
Fran Rabe	None	non-PACT member	University of Minnesota
Adrian P. Gee	None	PACT member	Baylor College of Medicine
Lisa Davis	None	PACT member	The EMMES Corporation
Nathan Kassalow	None	PACT member	The EMMES Corporation
Karin Quinnan	None	PACT member	The EMMES Corporation
David Styers	None	PACT member	The EMMES Corporation
Debbie Wood	None	PACT member	The EMMES Corporation

VENDOR QUALIFICATION

Fran Rabe
Manager Quality Assurance
University of Minnesota
Molecular and Cellular Therapeutics

Vendor Qualification - Why

- Provides security to ensure product and service consistently meet requirements
- Required by FDA to ensure raw materials are of acceptable identity, quality and purity

Vendor Qualification – How?

- Define how, per <u>your</u> Standard Operating Procedures (SOPs)

Vendor Selection Preparation

- Determine material requirements (specifications)
- Evaluate regulatory requirements of manufacturer of the supply
  - Is FDA licensure of this type of vendor required?
- Define fee restrictions
- Determine service requirements
- Soft requirements
  - Use “green” manufacturing processes
  - Good steward of the community

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Vendor Qualification- How Thorough?

If the material fails:

- How would you quantify the risk to the patient?
  - low
  - medium
  - high
- How likely is the material supplied by this vendor to fail?
  - low
  - medium
  - high
- How likely are you to detect a material failure prior to use and after use?

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Risk Matrix

Likelihood of Vendor Material Failure, which Would Not be Readily Detected					
	4	B	C	D	D
	3	B	C	C	D
	2	A	B	C	C
	1	A	A	B	B
	low	1	2	3	4

Patient Impact

A= Very good situation
B = Good situation
C = Critical situation
D = Catastrophic situation

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Risk Matrix

Patient risk grading is fairly straightforward
- Failure scale (one product/patient versus many)
- Detection of failure

Likelihood of Vendor Material Failure More Complex- Factors to Consider:
- Material's complexity
- Vendor longevity
- Vendor size
- Material is vendor's core business
- Word-of-mouth within the industry related to vendor performance
- Implemented quality systems
- ISO certified
- Good standing with FDA
- Supply historical integrity issues, not specific to this vendor, but across all vendors

Vendor Qualification Options

- On site audit
- Qualification by checklist
- Qualification by past performance
  - retrospective qualification
- No audit or checklist - Minimal impact material

Application of Risk Assessment

Define in your SOPs:
- D grade: require on-site vendor audit
- C grade: vendor checklist (comprehensive)
- B grade: vendor checklist
- A grade: no audit or vendor checklist

Define frequency within your SOP; (e.g., initially perform prior to vendor agreement and periodically)

Vendor Qualification – Case Scenario 1

Case Scenario 1 – Media Supplier

- Started using Media XYZ in 1999
- Manufacturing regulated our industry in 2005. Need documentation of vendor qualification
- Risk to patient is high if material fails
- Ability to detect failure is high
  - perform lot endotoxin and sterility before release of materials
- Retrospective qualification shows risk of material failure is low
  - Used this supplier for 6 years
  - Product quality and service record are flawless
  - Industry colleagues report favorable experiences

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Risk Matrix

Likelihood of Vendor Material Failure, or which Would Not be Readily Detected					
	4	B	C	D	D
	3	B	C	C	D
	2	A	B	C	C
	1	A	A	B	B
	low	1	2	3	4
		Patient Impact			

A= Very good situation C = Critical situation

B = Good situation D = Catastrophic situation

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Risk Matrix- Scenario 1

Likelihood of Vendor Material Failure or which Would Not be Readily Detected					
	4				
	3				
	2				
	1			B	B
	low	1	2	3	4
		Patient Impact			

A= Very good situation C = Critical situation

B = Good situation D = Catastrophic situation

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Case Scenario 1 Conclusion

Conclusion: This falls into B category

- B grade: vendor checklist

Provide continuity between products. If other similar medias fall into B, you may want guide your decision in this manner

Vendor Qualification – Case Scenario 2

Current vendor that performs donor infectious testing is doubling your fee. You are going to switch to another vendor 7/1/2009

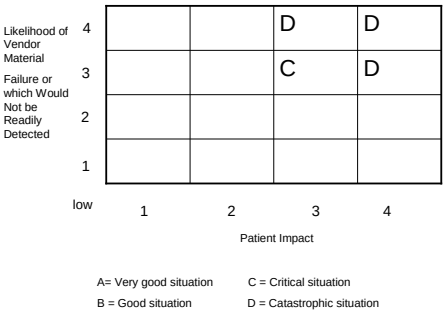
How are you going to qualify the new vendor?

Vendor Qualification – Case Scenario 2

Criteria to consider:

- Vendor failure can have negative patient impact (across many products). Failure could be “catastrophic”; category D
- Vendor failure would be difficult to detect (could go years before a patient infectious disease transmission is detected and reported)
- Failure could negatively impact my organizations’ reputation
- Failure could jeopardize standing with FDA
- Vendor has a good track record by word-of-mouth

Risk Matrix – Scenario 2



A= Very good situation
B = Good situation
C = Critical situation
D = Catastrophic situation

Case Scenario 2 Conclusion

Conclusion: This falls into D or C category

- D grade: require on-site vendor audit
- C grade: vendor checklist (comprehensive)

On-Site Audit

Audit against your user product specifications our “user requirements”

In this case, the FDA regulations specifically state the requirements for this vendor

On-Site Infectious Disease Testing Facility

Audit against user/regulatory requirements

- CLIA certified or meets CMS requirements
- Registered as a FDA establishment (FDA Form 3356)
- Screening tests used, which have been cleared/approved by the FDA. Not diagnostic tests
- Time constraints of sample testing maintained
- Temperature constraints of samples maintained
- Pooled versus singlet used where appropriate

Audit against our service requirements

- Reports meet requirements
- Results provided in timely fashion

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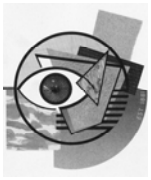
Equipment Qualification

Production Assistance for Cellular Therapies
National Heart Lung and Blood Program

PACT Webinar
January 29, 2009



Equipment Qualification

- What is It?
- When is it Done?
- What is Involved?
- Summary

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Qualification

- Performed to

  "Establish confidence that process equipment & ancillary systems are capable of consistently operating within established limits & tolerances"

3

Validation

- The purpose of validation is "to ensure that user needs and intended uses can be fulfilled on a consistent basis"
- It is "confirmation by examination and provision of objective evidence that specified requirements for a particular device or activity have been met"

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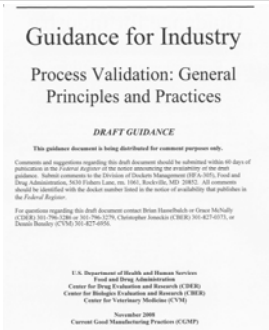
Validation
Helpful Information



Guidance for Industry

Process Validation: General Principles and Practices

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Brian Hasselbalch or Grace McNally (CDER) 301-796-3280 or 301-796-3279, Christopher Joneckis (CBER) 301-827-0373, or Dennis Beasley (CVM) 301-827-6956.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)

November 2008
Current Good Manufacturing Practices (CGMP)

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Components of Qualification

- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Requalification (RQ)

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Production Assistance for Cellular Therapies
National Heart Lung and Blood Program

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Design Qualification

- Pre-sets the specifications required for equipment
  - Performed prior to purchase
  - Describes the features required for the equipment
  - Outlines the decision process used to select the equipment

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Design Qualification Considerations

- Capabilities (e.g. speed, capacity & temperature for a centrifuge)
- Requirements (e.g. voltage, size limitations, operational specifications, requirement to work with existing instruments)
- Features (e.g. ease of cleaning PC interface, self calibrating, service contracts)
- May result in sole source availability – usually requires justification

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Design Qualification CAGT

- Indicate the requirements the equipment must meet
  - Equipment description *e.g. Centrifuge*
  - Specifications
    - Electrical
    - Tolerances/Performance
    - Maintenance/Cleaning
    - Other
  - Reasons for selection of this Model
  - Individual responsible for this selection

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Installation Qualification

Documents

- When and where received
- Condition upon receipt
- Complete order received?
- Transportation to site of use
- Unpacking

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Installation Qualification

Documents

- Installation (by whom, where, when)
- Start up (self check etc.)
- Calibration and cleaning
- SOP for maintenance and use?

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Installation Qualification CAGT

- Date of Delivery
- Order complete?
- Manual received? (hardcopy/electronic)
- Location for Installation
  - Meets manufacturer's specifications (Temp/Voltage etc.)
- Name of Installer
- Power up worked (Yes/No/N/A)
- Self check passed (Yes/No/N/A)
- Service/Calibration plan established (Details)
- Other
- Individual completing this section

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Operational Qualification oQ

- Does the equipment function as described by manufacturer?
- Confused with Validation
- OQ for a centrifuge
  - Does the centrifuge turn on and off
  - Spin at programmed speed & temperature
  - Brake as set
  - Retain programming

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Operational Qualification CAGT oQ

- Describe specifications to be tested
  - Accuracy of settings, maintenance of temperature etc.
- Has the equipment been calibrated
  - By whom (Attach calibration documents)
- Has an SOP been written
  - If no, then must be done before equipment put into use
- Individual completing this section

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Performance Qualification pQ

- Does the equipment function correctly and consistently for the intended application
- Analogous to Validation but here the emphasis is on whether a piece of equipment rather than a process is working appropriately

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Performance Qualification CAGT

pQ

For critical pieces of equipment it may be necessary to perform a Performance Qualification to ensure that it will function properly when used in a specific manufacturing procedure.

Does this equipment require Performance Qualification (Check with Quality Assurance)

If No, turn in completed forms and attachments to Quality Assurance for review

If Yes, proceed to Section 6, Performance Qualification page of the worksheet

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Performance Qualification CAGT

pQ

Provide evidence that the equipment is performing as expected when used in a manufacturing procedure.

The PQ will be performed using

- Mock product(s)
- Clinical materials intended for therapeutic use.
  *This requires **pre**-approval from QA, the patient's physician and a Laboratory Medical Director.*

Describe safeguards to be taken to protect patient in case of a manufacturing failure.

The proposed Performance Qualification is pre-approved for use on clinical materials

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Performance Qualification CAGT

pQ

- Centrifuge performance qualification
  - Does the use of this centrifuge in this procedure (e.g. density gradient separation) produce the expected results based on:
    - Previous results with other centrifuges
    - Published results on the same procedure
    - Results using same procedure at other sites
    - Results from the manufacturer

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Performance Qualification pQ

- PQ plan submitted to QA for pre-approval
- Describes
  - Procedure to be performed
  - Parameters for determining success
  - Allowable tolerances
  - Data to be collected
  - Analysis of data to be performed
- The results are submitted to QA to determine if acceptable for final qualification of equipment

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Requalification rQ

- Determine necessity in consultation with QA
  - After any incident that may affect equipment performance
    - After equipment repair
    - After equipment upgrade or service
    - After equipment is moved
    - After facility incident – power surge, closure etc.
    - If equipment is to be used in new way

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Qualification Summary

- Evidence that equipment operates consistently within established limits
- Performed in stages
  - Design
  - Installation
  - Operation
  - Performance
  - Requalification
- Information evaluated independently by Quality Assurance

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Supplies/Reagent Qualification

Christopher Chun, MT(ASCP)HP
Clinical Services Manager,
American Red Cross Blood Services
Lewis & Clark Region
Salt Lake City, Utah

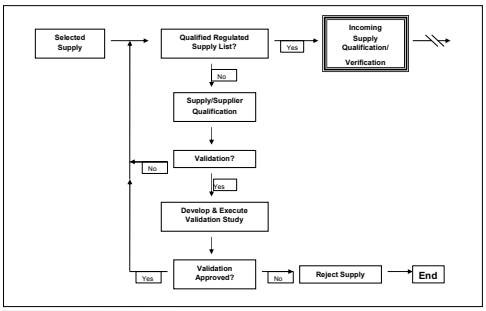
Supply Qualification

- Establish Supplier Qualification
- Define Supply/Reagent Qualification Process in SOPs
- Receive and Verify Supplies

Supplier Qualification at ARC

- Regulated or Non-Regulated Supply/Material?
- Is Supply/Material on the Approved Regulated Supplies List?
- Does the New Supply/Material Meet Approval Requirements?

Supply Qualification Flowchart:



The need is constant.
The gratification is instant.
Give blood. ™

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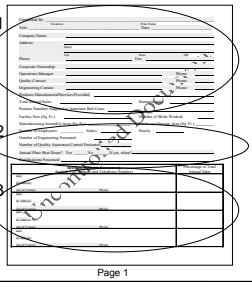
Example of Supplier Qualification:

Supplier Questionnaire

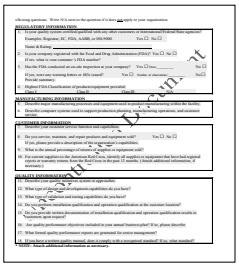
S-1

S-2

S-3



Page 1



Page 2

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Example of Supplier Qualification:

Supplier Questionnaire: Page 1, Section 1

Completed By: _____
Signature Print Name
Title: _____ Date: _____

Company Name: _____

Address: _____
Street
City State ZIP

Phone: _____ Fax: _____

Corporate Ownership: _____

Operations Manager: _____ Phone: _____

Quality Contact: _____ Phone: _____

Engineering Contact: _____ Phone: _____

Products Manufactured/Services Provided: _____

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Example of Supplier Qualification:

Supplier Questionnaire: Page 1, Section 2

Number of Quality Assurance/Control Personnel:_____

Annual Plant Shut Down? Yes ___ No ____ If yes, when?_____

Certifications Possessed: _____

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Example of Supplier Qualification:

Supplier Questionnaire: Page 1, Section 3

Reference (Major Customers) (Include Full Address and Telephone Number)	Percentage of Total Annual Sales
Name: Full Address: Point of Contact: Phone:	
Name: Full Address: Point of Contact: Phone:	
Full Name: Address: Point of Contact: Phone:	
Name: Full Address: Point of Contact: Phone:	

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Example of Supplier Qualification:

Supplier Questionnaire: Page 2

REGULATORY INFORMATION

1. Is your quality system certified/qualified with any other customers or International/Federal/State agencies?
   Examples: Registrar, EC, FDA, AABB, or IS0-9000. Yes ☐ No ☐
   Name & Rating: _____
2. Is your company registered with the Food and Drug Administration (FDA)? Yes ☐ No ☐
   If yes, what is your company's FDA number? _____
3. Has the FDA conducted an on-site inspection at your company? Yes ☐ Date:_____ No ☐
   If yes, were any warning letters or 483s issued? Yes ☐ Number of observations:_____ No☐
   Provide summary.
4. Highest FDA Classification of products/equipment provided:
   Class I:_____ Class II:_____ Class III:_____ N/A:_____

MANUFACTURING INFORMATION

5. Describe major manufacturing processes and equipment used in product manufacturing within the facility.
6. Describe computer systems used to support production planning, manufacturing operations, and customer service.

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Example of Supplier Qualification:

Supplier Questionnaire: Page 2

CUSTOMER INFORMATION

7. Describe your customer service function and capabilities.
8. Do you service, maintain, and repair products and equipment sold? Yes ☐ No ☐
   If yes, please provide a description of the organization's capabilities.
9. What is the annual percentage of returns of supplies or equipment sold?
10. For current suppliers to the American Red Cross, identify all supplies or equipment that have had regional rejects or warranty returns from the Red Cross in the past 12 months. (Attach additional information, if necessary.)

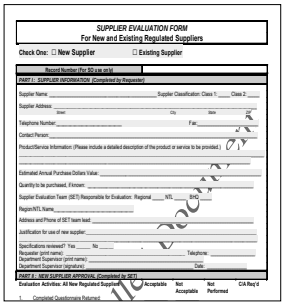
QUALITY INFORMATION

11. Describe your quality initiatives system or approaches.
12. What type of design and development capabilities do you have?
13. What type of validation and testing capabilities do you have?
14. Do you perform installation qualification and operation qualification at the customer location?
15. Do you provide written documentation of installation qualification and operation qualification results to customers upon request?
16. Are quality performance objectives included in your annual business plan? If so, please describe.
17. What formal quality performance reports are generated for senior management?
18. If you have a written quality manual, does it comply with a recognized standard? If so, what standard?

*** NOTE: Attach additional information as necessary.**

Example of Supplier Qualification:

Supplier Evaluation Form



SUPPLIER EVALUATION FORM
For New and Existing Regulated Suppliers

Check One: ☐ New Supplier ☐ Existing Supplier

Record Number (For SQ use only)

PART I - SUPPLIER INFORMATION (Completed by Requester)

Supplier Name: _____ Supplier Classification: Class 1 ____ Class 2 ____

Supplier Address: _____
Street City State Zip

Telephone Number: _____ Fax: _____

Contact Person: _____

Product/Service Information: (Please include a detailed description of the product or service to be provided.)

Estimated Annual Purchase Dollars Value: _____

Quantity to be purchased, if known: _____

Supplier Evaluation Team (SET) Responsible for Evaluation: Regional ____ NTL ____ BHD ____

Region/NTL Name: _____

Address and Phone of SET team lead: _____

Justification for use of new supplier: _____

Specifications reviewed? Yes ____ No ____

Requester (print name): _____ Telephone: _____
Department Supervisor (print name): _____
Department Supervisor (signature): _____ Date: _____

PART II - NEW SUPPLIER APPROVAL (Completed by SET)

Evaluation Activities: All New Regulated Suppliers	Acceptable	Not Acceptable	Not Performed	CA Req'd
1. Completed Questionnaire Returned				

Applicable Standards for Supplies:

- Supplies shall not be used until they have been inspected and verified to meet specifications.
- Supplies shall be sterile and of appropriate grade.
- Each supply/reagent shall be examined visually, upon receipt, for damage or evidence of contamination.

Example of Supply/Reagent Qualification Criteria

- The type of qualifying records is dependant on the type of supply/reagent, and its intended use
- Items coded **U** are classified as USP (United States Pharmacopoeia) grade and are typically reagents/solutions that are universally administered throughout the healthcare institution, thus generally requiring only visual inspection upon arrival. The same is the case for supplies coded **NA** (not applicable), which are inert, sterile packaged supplies (i.e. transfer packs, flasks, syringes).
- Items coded **C** are supplies/reagents that the vendor has supplied a "Certificate of Analysis" for the specific batch or lot. According to the FDA's cGTP regulations, this document is an acceptable means of verification upon receipt.

[continued next slide]

Supply/Reagent Qualification Criteria, Cont.

- Reagents, media or solutions that are used "off-label" or not directly for its intended purpose shall, generally, require validation prior to putting into use. The Laboratory Director shall determine which items shall undergo validation.
  - **IMPORTANT: Even though items may initially require only visual inspection upon receipt, they may be subject to more extensive qualification if there is concern of its safety, purity or potency in its application to Cell Therapy products.**
- All supplies/reagents shall be visually inspected upon receipt.

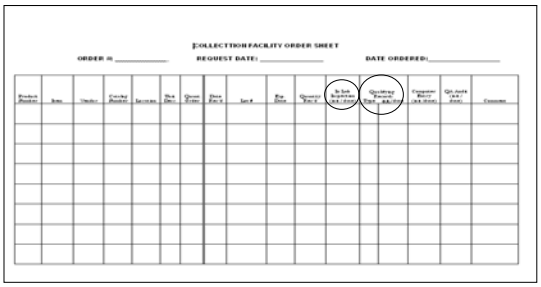
[continued next slide]

Supply/Reagent Qualification Criteria, Cont.

- The Laboratory Director is ultimately responsible for determining the extent of qualification to be undertaken in order to meet acceptance or release criteria.
- Whenever available, qualifying records (i.e. Certificate of Analysis) shall be requested from the "vendor" of supplies or reagents to verify the contents and/or sterility of items that are used in the collection, manufacturing and storage of Cell Therapy products.

[end]

SUPPLY/INVENTORY RECEIPT SHEET


[COLLECTION FACILITY ORDER SHEET

ORDER #: _____ REQUEST DATE: _____ DATE ORDERED: _____

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Labels?

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Applicable Standard for Labels:

Labels shall be held upon receipt from the manufacturer or upon on demand printing pending review and proofing against a copy or template to ensure accuracy.

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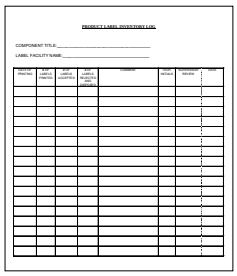
Example of In-House Label Qualification

- Check and verify labels for acceptability
- Establish Criteria for Acceptability
  - Must possess the same information as the Master Label Template
  - Must be legible and free of smudges
  - All printed information must fit within the borders of the label
- If labels meet the acceptance criteria, write initials and date on the sheet of confirmed labels, or on a blank index card secured to the batch of confirmed labels (i.e tie tags).
- Note the number of unacceptable labels, if any.
- Make an entry on the PRODUCT LABEL INVENTORY LOG. If any labels are rejected, indicate the reason in the "COMMENT" box.

Product Label Inventory Log



Product Label Inventory Log

PRODUCT LABEL INVENTORY LOG

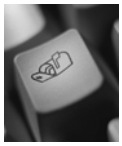
COMPONENT TITLE:_____

LABEL FACILITY NAME:_____

DATE OF PRINTING	# OF LABELS PRINTED	# OF LABELS ACCEPTED	# OF LABELS REJECTED AND DISPOSED	COMMENT	TECH. INITIALS	SUPERVISOR REVIEW	DATE

“Qualification: Vendor, Equipment, and Supplies”

Speaker Contact E-mail



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Web Seminar Presentation Slides

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CME Information

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of AABB and PACT. AABB is accredited by the ACCME to provide continuing medical education for physicians.

Physicians

AABB is approved by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians (Provider number 0000381). AABB designates this education activity for a maximum of 1 category 1 credit toward the AMA Physicians Recognition Award. Each physician should claim those credits that he/she actually spends in those activities.

California Clinical Laboratory Personnel

AABB is an approved, accredited provider (Provider number 0011) by the California Board of Clinical Laboratory Personnel as a provider of continuing education for California-licensed clinical laboratory personnel. AABB designates this education activity for a maximum of **1 credit**. California clinical laboratory personnel must provide a personal signature and other required information on the attendance log.

Florida Clinical Laboratory Personnel

AABB is an approved, accredited provider (Provider number 50-4261) by the Florida Board of Clinical Laboratory Personnel as a provider of continuing education programs for Florida-licensed clinical laboratory personnel. AABB designates this education activity for a maximum of **1 credit**.

CME Credit

If you are interested in obtaining CME credit for attending this web seminar, please note that each attendee must:

~Sign and fax roster to 240-306-2527~

~Complete the online survey~

PACT Web Seminar #13 Survey

(Survey link above embedded in the reminder email sent Wednesday 28th)

Note: Please complete within 48 hrs of the web seminar

AABB Live Learning Center

After the rosters have been processed, you will receive an email from AABB with instructions on how to print your CME/CE certificates for this web seminar

Thank you for attending!

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