Supplies/Reagent Qualification

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

American Red Cross

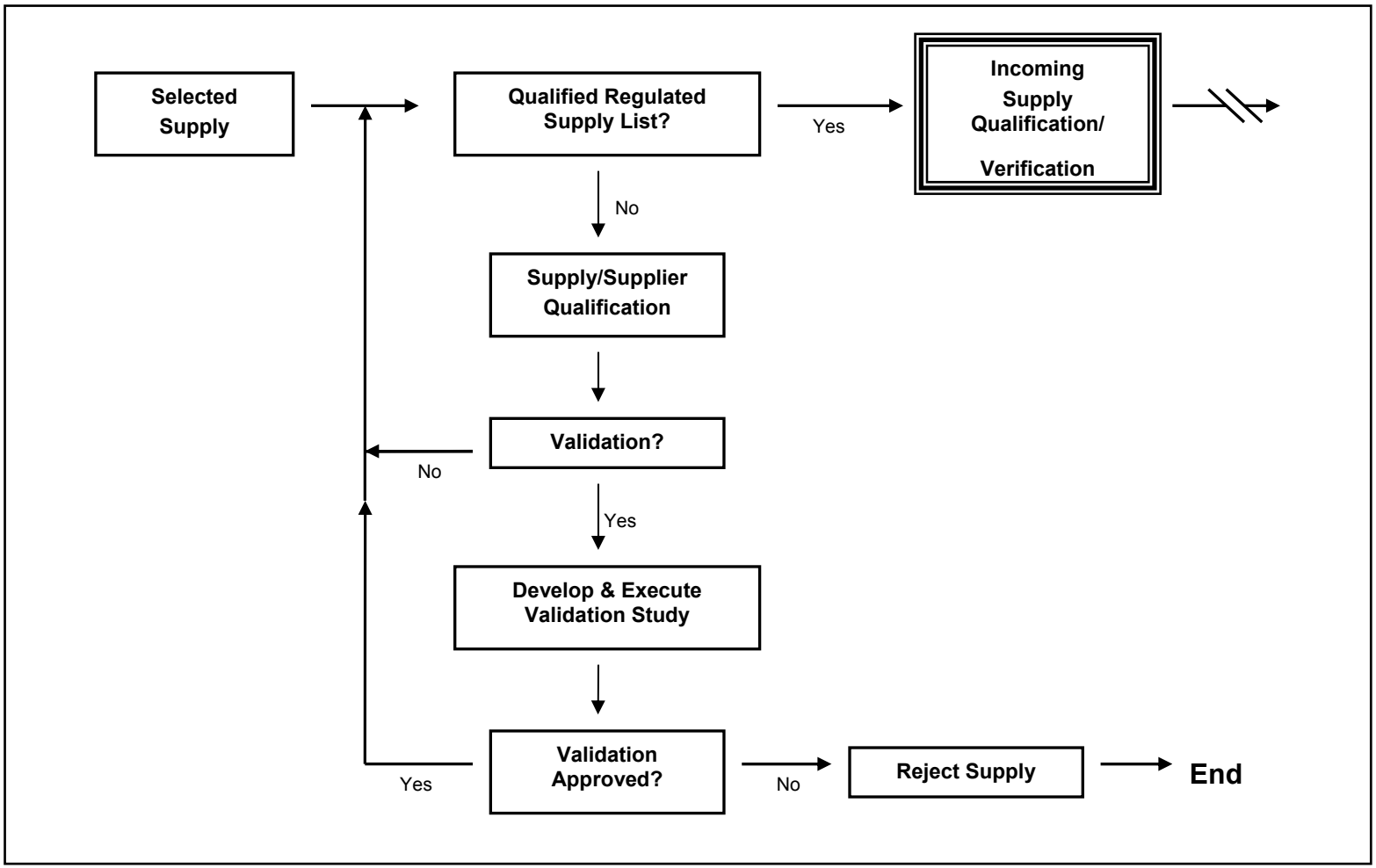
Supply Qualification

- 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:



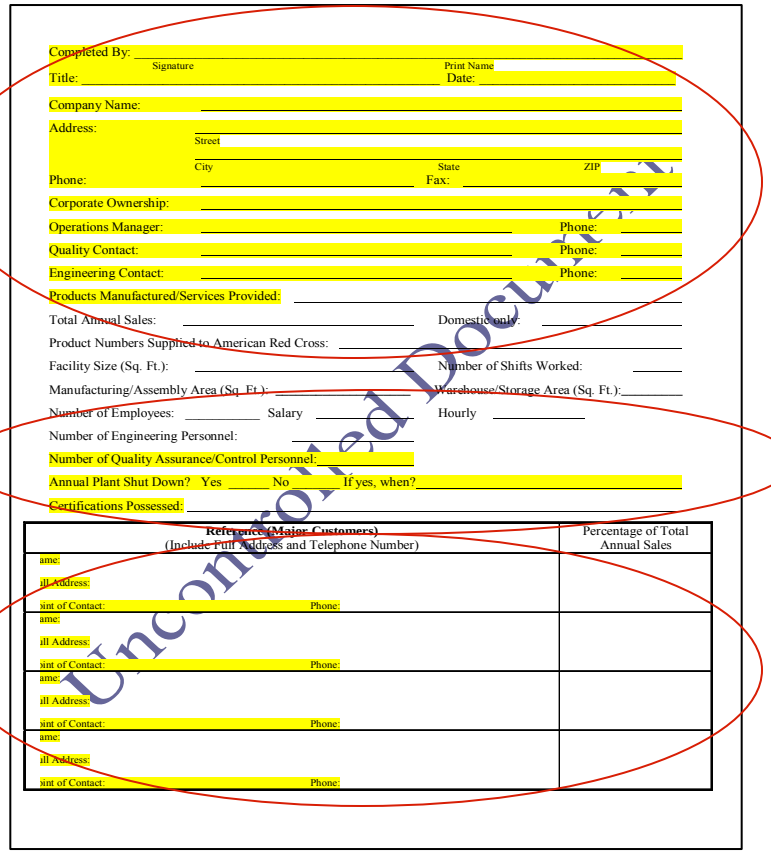
Example of Supplier Qualification:

Supplier Questionnaire

S-1

S-2

S-3



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: _____

Total Annual Sales: _____ Domestic only: _____

Product Numbers Supplied to American Red Cross: _____

Facility Size (Sq. Ft.): _____ Number of Shifts Worked: _____

Manufacturing/Assembly Area (Sq. Ft.): _____ Warehouse/Storage Area (Sq. Ft.): _____

Number of Employees: _____ Salary _____ Hourly _____

Number of Engineering Personnel: _____

Number of Quality Assurance/Control Personnel: _____

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

Certifications Possessed: _____

References (Major Customers) (Include Full Address and Telephone Number)	Percentage of Total Annual Sales
ame: ll Address: oint of Contact: Phone:	
ame: ll Address: oint of Contact: Phone:	
ame: ll Address: oint of Contact: Phone:	
ame: ll Address: oint of Contact: Phone:	

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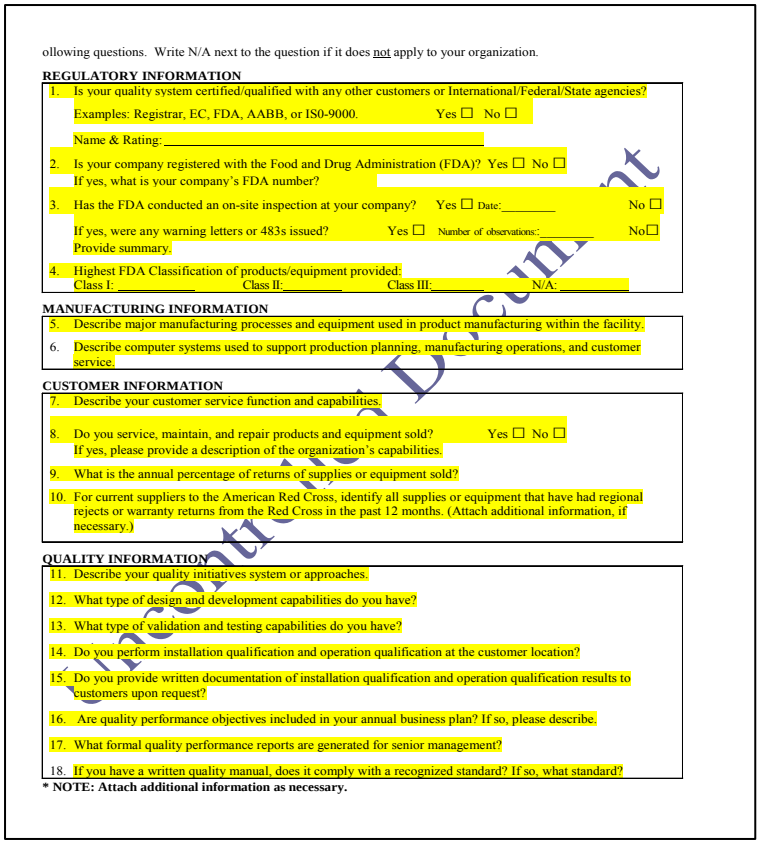
Page 1



ollowing questions. Write N/A next to the question if it does not apply to your organization.

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.

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.**

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Page 2

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: _____

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: _____

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:	

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.

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?

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16. Are quality performance objectives included in your annual business plan? If so, please describe.

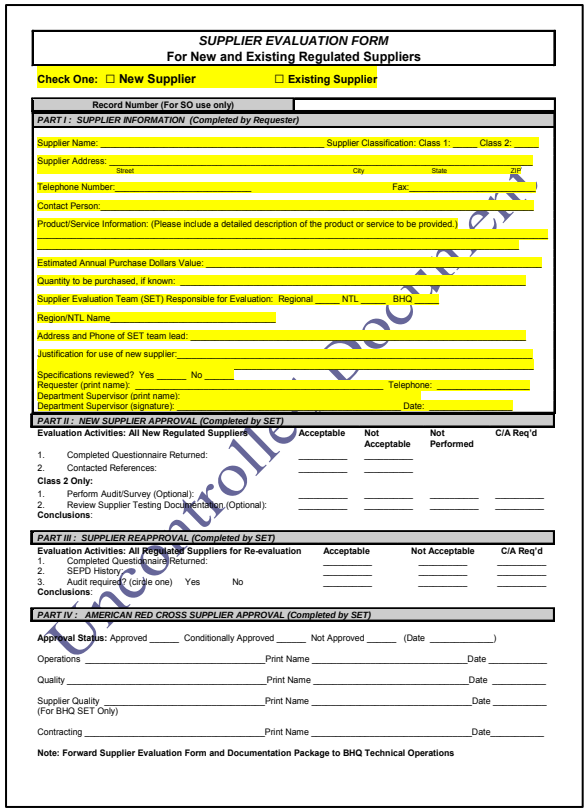
17. What formal quality performance reports are generated for senior management?

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 SO 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 ____ BHQ ____

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	C/A Req'd
1. Completed Questionnaire Returned:				
2. Contacted References:				
Class 2 Only:				
1. Perform Audit/Survey (Optional):				
2. Review Supplier Testing Documentation (Optional):				

Conclusions:

PART III : SUPPLIER REAPPROVAL (Completed by SET)

Evaluation Activities: All Regulated Suppliers for Re-evaluation	Acceptable	Not Acceptable	C/A Req'd
1. Completed Questionnaire Returned:			
2. SEPD History			
3. Audit required? (circle one) Yes No			

Conclusions:

PART IV : AMERICAN RED CROSS SUPPLIER APPROVAL (Completed by SET)

Approval Status: Approved _____ Conditionally Approved _____ Not Approved _____ (Date _____)

Operations _____ Print Name _____ Date _____

Quality _____ Print Name _____ Date _____

Supplier Quality _____ Print Name _____ Date _____
(For BHQ SET Only)

Contracting _____ Print Name _____ Date _____

Note: Forward Supplier Evaluation Form and Documentation Package to BHQ Technical Operations

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SUPPLIER EVALUATION FORM
For New and Existing Regulated Suppliers

Check One: ☐ New Supplier ☐ Existing Supplier

Record Number (For SO 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 ____ BHQ ____

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	C/A 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.

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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

COLLECTTION FACILITY ORDER SHEET

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

Product Number	Item	Vendor	Catalog Number	Location	Unit Desc.	Quant. Order	Date Rec'd	Lot #	Exp. Date	Quantity Rec'd	In Lab Inspection (init./date)	Qualifying Records: Type	Qualifying Records: init./date	Computer Entry (init./date)	QA Audit (init./date)	Comment

Labels?

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.

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

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

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