EXAMPLE OF VENDOR QUALIFICATION FOR IMMUNE EFFECTOR CELL PRODUCT MANUFACTURER

Disclaimer: This example is just one potential example of a vendor qualification form to verify the adequacy of the internal quality infrastructure of a cellular therapy product manufacturer. Potentially relevant aspects to verify include production scheduling; oversight of raw materials and supply chain; quality management and training in customer service, production, labeling, and record-keeping; and communication plans with clinical sites.

The general expectation is that the immune effector cell (IEC) program administering IEC products from an external manufacturer confirms basic quality metrics are in place at a given manufacturing site. Manufacturing under an Investigational New Drug (IND) application, FDA license, or state license may have already been reviewed and audited by one of those independent agencies for these metrics. Note that many IEC trial sponsors and manufacturers will ask similar questions of apheresis collection sites and downstream clinical administration sites. Thus, each entity in the IEC chain is expected to verify the quality infrastructure and resources at each step in the collaboration. If this example is used, the program is responsible for updating it as new information becomes available.
EXAMPLE QUALIFICATION FORM FOR MANUFACTURER OR VENDOR RELATED TO CELLULAR PRODUCT

The Cell Therapy department at XXX Institution requires qualifying information and vendor and manufacturer monitoring under FACT Common and IEC Standards. The following information is required to qualify all new and existing vendors and manufacturers. Please complete this audit with the relevant attachments and email/fax/mail the form to the contact provided in this document.

SECTION I

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Company Address</th>
<th>City, State, Zip Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Assurance Contact</td>
<td>Regulatory Contact</td>
<td></td>
</tr>
<tr>
<td>Telephone number</td>
<td>Telephone number</td>
<td></td>
</tr>
<tr>
<td>Email Address</td>
<td>Email</td>
<td></td>
</tr>
</tbody>
</table>

Is the product:  
☐ Cells  
☐ Drug  
☐ Other____________

Name of product(s) provided:   ___________________________________________

IND Number(s) of Study Material: _________________

INSTRUCTIONS

Section II must be completed by ONLY those personnel knowledgeable in organization processes.

Please provide answers to all questions as completely as possible.

• Explanations to all answers marked NO or N/A must be provided in the comment section or with an attached document.

• If a brief process overview or a written procedure is required please attach these to the form with the relevant question number identified on the document covers.

• For any items which this company distributes, but does NOT manufacture, please provide the vendor/manufacturer qualification procedures.

Once completed please send this form and all supporting material to:

XXX Institution
EXAMPLE QUALIFICATION FORM FOR MANUFACTURER OR VENDOR RELATED TO CELLULAR PRODUCT

SECTION II

BUSINESS INFORMATION

Do you employ the following in your business process? YES NO N/A

1. A production planning/scheduling system: ☐ ☐ ☐
2. Formal supplier/supply management and qualification system: ☐ ☐ ☐

Comments:

TECHNICAL/CUSTOMER SUPPORT

3. Support personnel have the required training, skills and background adequate for your product/process: ☐ ☐ ☐
4. Contingency disaster plans: ☐ ☐ ☐

Comments:

QUALITY

5. Formal Quality Manual/Quality Plan in place: ☐ ☐ ☐
6. Compliance with current Good Manufacturing Practices: ☐ ☐ ☐
7. FDA Licensed or Registered: (Please provide certificate) ☐ ☐ ☐
8. Certified under CLIA: (Please provide certificate) ☐ ☐ ☐
9. Accredited: (Please provide certificate(s))
   FACT: ☐ ☐ ☐
   AABB: ☐ ☐ ☐
   CAP: ☐ ☐ ☐
   Joint Commission: ☐ ☐ ☐
10. State Licensed: State License Number: ____________________________ ☐ ☐ ☐
11. ISO Certified since _________________: (Please provide certificate) ☐ ☐ ☐
12. Documented process control procedure: ☐ ☐ ☐
13. Documented label control procedure: ☐ ☐ ☐

On a separate piece of paper please provide details of the issues found during the last audit of each accrediting organization including corrective action.

Comments:
## EXAMPLE QUALIFICATION FORM FOR MANUFACTURER OR VENDOR RELATED TO CELLULAR PRODUCT

### RECORDS & DOCUMENT CONTROL

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>20. System in place to control product specification and labeling:</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>21. Process for notifying customers regarding process modifications:</td>
<td></td>
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<tr>
<td>22. Procedures written and executed in a manner to prevent microbial contamination:</td>
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</tbody>
</table>

Comments:

### STAFF/TRAINING

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>23. Formal documented training programs for all personnel involved in manufacturing and distribution:</td>
<td></td>
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</tbody>
</table>

Comments:

### PROCESS CONTROL

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
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</thead>
<tbody>
<tr>
<td>24. Procedure for identification, segregation and the control of non-conforming products</td>
<td></td>
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<tr>
<td>25. Procedures for process control:</td>
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<tr>
<td>26. Formal process for deviations:</td>
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</tbody>
</table>

Comments:

### FINAL PRODUCT RELEASE

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
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</thead>
<tbody>
<tr>
<td>27. Final testing and inspection of the product is performed, documented and reviewed prior to shipment:</td>
<td></td>
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<tr>
<td>28. Review of the Certificate of Analysis by an independent Quality Unit:</td>
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<tr>
<td>29. Study drug labels meet FDA requirements:</td>
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<tr>
<td>30. Study drug labels are ISBT 128 compliant:</td>
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</tbody>
</table>

Comments:
EXAMPLE QUALIFICATION FORM FOR MANUFACTURER OR VENDOR RELATED TO CELLULAR PRODUCT

STORAGE/SHPIPPING

31. Material is stored in a temperature controlled, restricted facility:
   YES  NO  N/A
   
32. Shipment methods are validated to assure the proper storage temperature is maintained during shipment and designed to prevent damage to product during shipping and handling:
   YES  NO  N/A

Comments:

THANK YOU