**DOCUMENT NUMBER:** COMM-QA-002

**DOCUMENT TITLE:**
Supplier Qualifications

**DOCUMENT NOTES:**

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**Document Information**

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COMM-QA-002
SUPPLIER QUALIFICATIONS

1 PURPOSE
1.1 To define the procedure for selection, qualification and monitoring of suppliers and contractors.
1.2 To assure that suppliers provide materials/services that comply with applicable quality requirements.

2 INTRODUCTION
2.1 Suppliers should be selected according to their ability to reliably provide high-quality materials/products that meet manufacturer’s defined requirements and expectations. Supplier qualification is based on a Quality Management System (QMS) that ensures that any goods, materials, services or components coming from a supplier are produced and delivered under a set of controls that ensure their predetermined standards are met.
2.2 A quality agreement will be established and retained by QSU for critical suppliers with the objective of preempting quality problems, preventing defects, and facilitating consistent quality through effective management and monitoring.
2.3 Suppliers providing critical materials/services that have the potential to affect quality should be qualified before use. Once qualified, periodic evaluation of performance helps to ensure the supplier is continuing to meet requirements.
2.4 A Quality Agreement is used to define the responsibilities of a service provider and prompts communication of changes, complaints, deviations/investigations, and out of specifications that may impact procedures and testing performed.

3 SCOPE AND RESPONSIBILITIES
3.1 This procedure applies to supplier qualifications conducted by the Quality Systems Unit (QSU).
3.2 Throughout this document, supplier may refer to vendor, manufacturer, laboratory, facility, or supplier. The manufacturer of the material is the preferred provider to be qualified rather than the vendor or distributor.
3.3 The Program/Medical Director, administrators, facility/laboratory managers and QSU are responsible for ensuring the requirements of this procedure are successfully met. The Program/Medical Director may designate staff to evaluate vendors.
3.4 Retention of supplier contracts will be retained by the Program Operations Director or designee.
3.5 QSU will retain documentation of supplier qualifications and quality agreements as applicable.
3.6 The QSU in collaboration with Program/Medical Director is responsible for determining if an audit is necessary when a qualifying service provider that does not return a signed Quality Agreement.

4 DEFINITIONS/ACRONYMS

4.1 Critical Materials/Components: A material or component that directly affects the quality, safety, and/or efficacy of the product being produced. If there is a reasonable expectation that failure of the material or component obtained will result in failure of the finished product then that material or component can be considered critical. A material or component may also be considered critical if it comes from a sole source provider for which a replacement would be difficult or impossible to locate.

4.2 Critical Service Provider: A qualified service provider (e.g., laboratory, facility, supplier/vendor) that provides testing, a critical material or component, or a service (including a computer service) that directly affects the quality, safety, and/or efficacy of the product being produced or a sole source service provider for which a replacement would be difficult or impossible to locate.

4.3 Critical Supplier: A supplier who supplies a critical material or component.

4.4 Critical Contracted Services: Any service provider providing a critical service.

4.5 cGMP: Current Good Manufacturing Practices

4.6 FDA: Food and Drug Administration

4.7 SDS: Safety Data Sheets

4.8 MC3: Marcus Center for Cellular Cures. Includes Carolinas Cord Blood Bank and Robertson GMP Laboratory

4.9 Non-critical Materials/Components: A material or component that assists and supports the quality of the product but does not affect the quality of the product or service being produced. A material or component may also be considered non-critical if it can be easily produced or provided by other supplier(s).

4.10 Non-critical Supplier: A vendor who supplies a non-critical material or component.

4.11 Supplier Audit: An independent examination (on-site audit, desk audit, or questionnaire/survey) to assess compliance to a specific process or procedure outlined in the contract, appropriate regulations, and guidance documents.

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 N/A
7 SAFETY

7.1 Universal precautions should be taken when auditing facilities or laboratories, as unknown biological agents may be present. This includes appropriate clothing and footwear.

8 PROCEDURE

8.1 Supplier Selection (Based on ability to meet specified requirements, including quality requirements.)

8.1.1 Considerations

8.1.1.1 Regulatory risk
8.1.1.2 Frequency of use
8.1.1.3 Type of supplier, e.g. critical versus non-critical supplies
8.1.1.4 Prior experience with supplier and/or audit history
8.1.1.5 Management request

8.1.2 Methods of Qualification

8.1.2.1 Following notification of a new supplier by Program/Medical Directors, administrators, or facility/laboratory managers, qualification of the supplier laboratory/contractor will be the responsibility of QSU.

8.1.2.2 Supplier Impact Assessment

8.1.2.2.1 The Supplier Impact Assessment, COMM-QA-002 FRM2 Supplier Impact Assessment, is completed for each supplier and dictates whether further qualification is required based on an assigned supplier risk grade.

8.1.2.2.2 All supplier impact assessments and applicable associated documentation (certifications, licensure, etc.) will be reviewed at a frequency dependent on the assigned risk grade. Supplier Impact Assessments and the applicable associated documentation will also be reviewed if and when QSU becomes aware of any significant changes to the material or manufacturing process.

8.1.2.3 Supplier Questionnaire

8.1.2.3.1 The Supplier Questionnaire, COMM-QA-002 FRM2 Supplier Questionnaire, is sent to any supplier receiving a grade of ‘A’ or higher on the Supplier Impact Assessment, COMM-QA-002 FRM2 Supplier Impact Assessment.

8.1.2.3.2 Upon receipt, the responses are reviewed by the QSU.
8.1.2.3.3 If approved, the method and frequency of requalification will be documented under the “Internal Use Only” section of the form if deemed necessary based on the assigned risk grade.

8.1.2.3.4 If the supplier does not agree to sign and return the Questionnaire, the QSU may work with the service provider to determine alternative methods for qualification, or will document rationale for why the service provider is currently acceptable. QSU will assess the documentation at the next qualification review to determine if the supplier should be contacted again.

8.1.2.3.5 Standardized Quality Responses developed by the supplier can be substituted for COMM-QA-002 FRM1 Supplier Questionnaire at the discretion of QSU after a thorough review of the document. The “Internal Use Only” section of COMM-QA-002 FRM1 Supplier Questionnaire will be filled out documenting the review of all documentation and risk grade will be reassessed.

8.1.2.4 Audit

8.1.2.4.1 Refer to sections 8.2-8.3.

8.1.2.4.2 If the service provider does not agree to an audit, the QSU may work with the service provider to determine alternative methods for qualification, or will document rationale for why the service provider is currently acceptable.

8.1.2.5 Qualification by Past Performance (Refer to Section 8.1.1 Considerations)

8.1.2.5.1 Consider past service, supply history/records, and industry/colleague report of experience.

8.1.3 Frequency of Qualification and/or Audit

8.1.3.1 The QSU (with Medical/Program Director input, as needed) will make the final decision as to which supplier require an audit.

8.1.3.1.1 Refer to COMM-QA-002 JA1 Supplier Risk Assessment for risk assessment guidance.

8.1.3.2 Monitoring of critical suppliers and service providers will include ongoing review of problems associated with the product or service including availability, delivery and
support, review of complaints, reports, and changes that may impact contractual expectations.

8.1.3.3 Re-qualification and/or audits will be repeated based on the schedule established in collaboration with the program, performance history, organizational change(s), and documentation suggesting supplier product quality issues.

8.1.3.3.1 External facilities performing critical contracted services will minimally be assigned a risk grade of C, and thus requalified on an annual basis to ensure that they continually meet the requirements of written agreements.

8.1.3.3.2 If new supplies are ordered from an existing supplier, no requalification is necessary beyond the established schedule unless the new supply increases the risk grade assigned to that supplier.

8.1.3.3.3 Documented failures by suppliers/service providers in meeting defined requirements should be promptly reported to the QSU, affected personnel/departments, and the supplier. A plan of action will be devised in coordination with the program, and if necessary, will be documented per the procedures outlined in COMM-QA-042 Deviations and Investigations. In the event that issues persist or ongoing concerns are present, additional options will be considered, including qualification of back-up suppliers and/or complete removal of the supplier from the approved supplier list. A new supplier will be qualified, and documentation will be retained.

8.1.4 Documentation of supplier qualifications, noting critical versus non-critical, will be recorded and retained by QSU.

8.1.4.1 Suitable alternatives for supplies and services will be maintained for contingency planning, as feasible.

8.1.5 At the time of re-qualification of all suppliers and service providers, at the frequency dictated by the risk grade assigned, QSU will review all current qualifications on file to ensure that all documentation is up-to-date and accurate. This review will include:

- Supplier Impact Assessment
- Supplier Questionnaire, if applicable
- Quality Agreement, if applicable
• Memo to File, if applicable
• Any other qualifications on file including certificates, processing methods, etc.

8.1.5.1 This review will be documented on COMM-QA-002 FRM3 Qualifications Review Form. The person completing the form will record the supplier name, criticality, and risk grade and will check the boxes for all applicable documentation on file. At the time of each required review, the review date, name and title of person completing the review, and the signature of the reviewer will be documented on this form.

8.1.5.2 Should any updates to the qualifications on file be required, the actions taken to retrieve any updated documentation will be noted in the ‘Notes’ column.

8.1.5.3 A new risk grade may be assigned at the time of review based off of the documentation on file or any significant changes since the last assessment.

8.1.5.4 For any supplier requiring only a biennial COMM-QA-002 FRM2 Supplier Impact Assessment for requalification (Risk grades Z and A), review of qualifications negates the need to complete a new Supplier Impact Assessment biennially. Documentation of Supplier Impact Assessment review on this form is sufficient for requalification and will be recorded in the supplier database as such, with the review date being the date of requalification.

8.2 Conducting the Supplier Audit

8.2.1 Ensure that past supplier questionnaires and qualifications have been reviewed and are thus considered current. Although a remote/paper audit can be substituted in some cases for an onsite audit, an in person visit should be conducted a minimum of every 3-5 years if the supplier is classified of that risk grade unless rationale can be provide in writing by Quality and/or the Medical/Program Director.

8.2.1.1 Contact suppliers in advance to schedule the audit and to provide ample time to negotiate any required agreements, if applicable.

8.2.1.2 Request the following documentation, as needed:
• standard operating procedure (SOP) table of contents
• copies of accreditation/certification
• contract
• scope of work
• timelines and schedules
• list of contracted or proposed contracted activities
• organizational chart
8.2.1.3 Identify key personnel who will need to be available if an on-site audit is performed.

8.2.1.4 In order to meet EU GMP regulations, a physical, on site audit must be performed.

8.2.2 The auditor conducts the opening meeting with appropriate personnel for introductions, to review objectives and scope of the visit, and to answer any questions.

8.2.3 The auditor conducts the audit which may include:

8.2.3.1 Interviews with key personnel

8.2.3.2 Tour of the facility

8.2.3.3 Review of Mission Statement, Company Brochure/History, Organizational Chart

8.2.3.4 Review Regulatory Authority Inspectational history

8.2.3.5 Review SOPs including SOP systems, database and methods for training on SOPs

8.2.3.6 Training and development database/curriculum for key positions

8.2.3.7 Equipment validation

8.2.3.8 Review of Quality Management System

8.2.3.9 Storage and archival of records

8.2.3.10 Security and protection systems (e.g., fire, disaster recovery procedures and facility/server/network security)

8.2.4 Upon completion of the audit, the auditor conducts a closing meeting with applicable personnel to summarize observations and clarify any outstanding issues.

8.3 Audit Observations, Classifications, and Scoring

8.3.1 Audit reports will be written in accordance with COMM-QA-039 Quality Systems Unit Audit.

8.3.2 A supplier report summarizing the key observations of the audit will be provided to the supplier in a timely manner following completion of the audit.

8.3.3 If the report reflects areas of concern regarding the capabilities and regulatory compliance of a supplier currently in use or about to be used, applicable personnel will be notified and collectively reach a decision regarding the appropriateness of utilizing the supplier.

8.3.4 All observations must be discussed with the supplier/vendor and a remediation plan documented in consultation with the supplier/vendor prior to approval. In situations where a supplier/vendor provides written responses and a remediation plan that is in process, the
vendor/supplier may still be utilized by MC3, with continued follow-up by MC3 QSU deemed as necessary.

8.3.5 Documentation pertaining to the audit report will be filed and retained.

8.3.6 The supplier risk grade will be re-assessed following the audit to determine if a change in grade or audit frequency is required based on observations. This re-assessment will be documented on COMM-QA-039 JA5 Supplier Qualification Audit Report.

8.4 Service Providers Requiring Documentation of a Quality Agreement

8.4.1 QSU evaluates each laboratory, facility, and supplier/vendor performing testing or providing a material, component, or service to determine if that service is deemed critical and the service directly affects the quality, safety, and efficacy of the product being produced.

8.4.2 Critical service providers for the Carolinas Cord Blood Bank and the Robertson GMP Laboratory require a Quality Agreement.

8.5 Completing the Quality Agreement

8.5.1 QSU provides COMM-QA-002 FRM4 Service Provider Quality Agreement (or another draft quality agreement if deemed more appropriate for that specific situation), to critical service and material providers for review of responsibilities, terms of agreement and dispute resolution. A service provider’s internal quality agreement template, if available, may also be used.

8.5.1.1 QSU completes the service provider section, including contact information and description of product/service prior to providing to the service provider.

8.5.1.2 The Quality Agreement may be customized as necessary to document specific responsibilities associated with the service provider.

8.5.2 QSU reviews and approves the signed service provider Quality Agreement.

8.5.3 QSU retains the completed Quality Agreements.

8.5.4 If the service provider does not agree to sign and return the Quality Agreement, the QSU may work with the service provider to determine alternative methods for qualification, or will document rationale for why the service provider is currently acceptable. QSU will assess the documentation at the next qualification review to determine if the service provider will need to be contacted again.

8.6 Responsibilities as a Service Provider for MC3, include, but are not limited to:

8.6.1 Maintain current documentation of training for employees involved in procedures performed for MC3.

8.6.2 Maintain an independent quality unit that fulfills quality assurance (QA) and quality control (QC) functions.
8.6.3 Follow applicable current Good Manufacturing Practices (cGMPs), current Good Laboratory Practices (cGLP), current Good Tissue Practices (cGTP) and locally imposed requirements, as applicable for the applicable material/service.

8.6.4 Maintain an audit program that includes routine internal/external audits for compliance.

8.6.5 Allow MC3 to audit applicable facilities, systems, and documents as they pertain to the service being provided to MC3.

8.6.6 Maintain a change control and revision system to initiate, review, revise, approve, obsolete, and archive standard operating procedures.

8.6.7 Obtain prior approval from the QSU for any change in procedure or method that affects the product/service being provided to MC3.

8.6.8 Maintain a QA approved master validation/qualification plan for the facilities, equipment/instruments, manufacturing process, cleaning procedures, analytical procedures, in process control tests, and computerized systems, as applicable for the services provided to MC3.

8.6.9 Notify QSU of all critical deviations/investigations, complaints, and out of specification (OOS) results associated with the product or service provided to MC3, upon identification of the event.

8.6.10 Investigate all critical deviations/investigations, complaints, and OOS results associated with the product or service provided to MC3 and provide written documentation of investigation conclusions and corrective and preventive actions (CAPA).

8.7 Terms of Quality Agreement and Dispute Resolution

8.7.1 The Quality Agreement commences on the last date of the last signature and remains in effect for as long as the Service Provider supplies products or services to MC3, unless the Quality Agreement is terminated earlier with written notification from either party.

8.7.2 Every effort will be made to resolve quality related disagreements between the Service Provider and MC3 in the normal course of business. If both parties agree that a resolution of the disagreement is reasonably possible, then both the Service Provider and MC3 shall agree to work jointly to develop a strategy for such resolution. Service Provider and MC3 further agree to record such resolution in writing.

8.8 System Review

8.8.1 A review should be performed on a regular interval of all supplier qualifications to ensure qualifications remain current and to proactively identify upcoming deadlines.

8.8.2 The database used to track supplier status should be reviewed minimally quarterly as a way to facilitate this requirement.
9 RELATED DOCUMENTS/FORMS
9.1 COMM-QA-002 JA1 Supplier Risk Assessment
9.2 COMM-QA-002 FRM1 Supplier Questionnaire
9.3 COMM-QA-002 FRM2 Supplier Impact Assessment
9.4 COMM-QA-002 FRM3 Qualifications Review Form
9.5 COMM-QA-002 FRM4 Service Provider Quality Agreement
9.6 COMM-QA-039 Quality Systems Unit Audit
9.7 COMM-QA-039 JA5 Supplier Qualification Audit Report
9.8 COMM-QA-042 Deviations and Investigations

10 REFERENCES
10.3 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT) and Netcord. International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release, Current edition
10.4 FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration, Current Edition
10.5 Foundation for the Accreditation of Hematopoietic Cell Therapy Common Standards for Cellular Therapies, Current Edition
10.7 21 CFR Part 820.50, Purchasing Controls
10.8 21 CFR Parts 211.22, 606, 1271.210

11 REVISION HISTORY

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<th>Author</th>
<th>Description of Change(s)</th>
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| 11           | P. Killela | • Updated titles of document references throughout  
|              |         | • Updated 3.2 to reflect manufacturer of material is preferred provider to be qualified  
|              |         | • Updated 3.6 to include Program/Medical director in audit determination assessment  
|              |         | • Removed COMM-QA-002 FRM3 reference in 8.1.2.2.2  
|              |         | • Replaced COMM-QA-077 reference with COMM-QA-042 reference in 8.1.3.3.3  
|              |         | • Updated 8.3.4 to clarify audit response and  

COMM-QA-002 Supplier Qualifications
Office of Regulatory Affairs and Quality, Duke University
Durham, NC

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<td>remediation plans</td>
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**Medical Director**

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