Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

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Supplier Qualifications

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COMM-PAS-017
Supplier Qualification

1 PURPOSE

1.1 To define the procedure for the selection, qualification, and monitoring of suppliers and vendors for the Adult and Pediatric Blood and Marrow Transplant Program (APBMT) and Stem Cell Laboratory (STCL).

1.2 To ensure that suppliers provide materials/services that comply with applicable quality requirements.

2 INTRODUCTION

2.1 Suppliers are selected according to their ability to reliably provide high-quality supplies/services that meet requirements and expectations. Supplier qualification is based on a Quality Management System (QMS) that ensures that any goods, supplies, 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 material or component, and/or supplier, who provides testing or a service (including a computer service), that can directly affect the quality, safety, and/or efficacy of the product being produced, has a reasonable expectation that failure will fail the finished product, and/or a sole source service provider for which a replacement would be difficult or impossible to locate then that material, component, and supplier is considered **critical**.

2.3 Quality Agreements, a facet of supplier qualifications, are used to define the responsibilities of critical suppliers and prompt communication of changes, complaints, deviations/investigations, and out-of-specification that may have impacted a product or process. A quality agreement may be deemed necessary for critical supplies/services used in APBMT and STCL. The determination will be based on APBMT leadership and the APBMT Clinical Quality Program (CQP). If a quality agreement is established, it will be retained by CQP with the objective of preempting quality problems, preventing defects, and facilitating consistent quality through effective management and monitoring.

2.4 All suppliers are qualified, but suppliers providing critical materials/services that have the potential to affect quality should be qualified before use.

2.5 Once qualified, the periodic evaluation of all suppliers' performance (requalification) described in this procedure helps to ensure suppliers are continuing to meet requirements.

3 SCOPE AND RESPONSIBILITIES

3.1 This procedure applies to supplier qualifications conducted by the CQP, who is responsible for the execution and maintenance of this procedure.

3.2 The Program and Facility Medical Directors, APBMT Leadership, Managers, and CQP are responsible for ensuring the requirements of this procedure are successfully met. The Program and Facility Medical Directors and/or APBMT Leadership may designate staff to evaluate suppliers.

3.3 The CQP (with Medical Director's input, as needed) will make the final decision as to which suppliers require an audit.

3.4 Retention of supplier contracts is the responsibility of the APBMT and the STCL Operations Director or designee.

3.5 The CQP will retain documentation of supplier qualifications and quality agreements as applicable.

4 DEFINITIONS/ACRONYMS

4.1 **APBMT** Adult and Pediatric Blood and Marrow Transplant Program

4.2 **CCR:** Chain Control Request

4.3 **cGMP:** Current Good Manufacturing Practices

4.4 **CQP:** APBMT Clinical Quality Program

4.5 **FDA:** Food and Drug Administration

4.6 **SDS:** Safety Data Sheets

4.7 **STCL:** Stem Cell Laboratory

4.8 **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

8.1.1 Suppliers should be selected based on their ability to meet specified requirements, including quality requirements.

8.1.2 When completing any supplier qualification, considerations should include, but are not limited to:

- Regulatory risk
- Frequency of use
- Type of supplier/material or service provided, (e.g., critical versus non-critical supplies or services)
- Prior experience with the supplier, including:

- Audit history
- Industry/colleague report of experience
- Problems associated with the product or service
- Delivery and support history
- Review of complaints, reports, and any changes that may impact contractual expectations

8.1.3 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.

8.1.4 Following notification of a new supplier or, change in scope to an existing supplier via a change control request (CCR), per COMM-PAS-004 *Change Control*, the qualification of the supplier will be the responsibility of the CQP.

8.1.4.1 The associated CCR will not be approved by CQP for implementation until COMM-PAS-017 FRM2 *Supplier Impact Assessment* is approved.

8.1.4.2 Additional qualifications may also be required depending on the outcome of the assessment, but these additional qualifications may be completed following approval of the associated CCR.

8.1.4.3 If applicable, the CCR should be cited on COMM-PAS-017 FRM2 *Supplier Impact Assessment.*

8.1.4.4 If an approved COMM-PAS-017 FRM2 *Supplier Impact Assessment* is already on file, CQP will review the updated supply or service to determine if an update is needed before the next qualification review cycle.

- If an update is required, a new COMM-PAS-017 FRM2 *Supplier Impact Assessment* will be created and approved, superseding the existing Supplier Impact Assessment.
- If no update is required, this review and rationale will be documented in the review section on the existing COMM-PAS-017 FRM2 *Supplier Impact Assessment*.

8.1.4.5 If a CCR must be approved before the completion of required initial supplier qualifications (as defined by the risk grade), a memo to file must be completed and approved explaining why implementation without these items is deemed acceptable.

8.1.5 Documented failures by supplies/services in meeting defined supplier requirements should be promptly reported to the CQP, affected personnel/departments, and the supplier.

8.1.5.1 A plan of action will be devised in coordination with APBMT and/or STCL, and if necessary, will be documented per the procedures outlined in COMM-PAS-013 *Deviations and Investigations*.

8.1.5.2 If issues persist or ongoing concerns are present, additional options will be considered, including:

8.1.5.3 Aa “for cause” audit of the supplier

8.1.5.4 Qualification of back-up suppliers

8.1.5.5 Complete removal of the supplier from the approved supplier list.

8.1.5.6 In these cases, a new or alternate supplier will be qualified, and documentation will be retained. Actions taken and rationale will be documented in the supplier’s qualification packet and retained as required.

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

8.2 Risk Grades

8.2.1 Guidance for determining supplier risk grade, and thus the manner and frequency of supplier qualification, is provided in COMM-PAS-017 JA1 *Supplier Risk Assessment*.

8.2.2 Documentation of supplier qualifications, noting critical versus non-critical and risk grades, will be recorded and retained by the CQP.

8.2.3 If an external facility is performing critical contracted services, it will minimally be assigned a risk grade of C, and thus requalified on an annual basis to ensure that it continually meets the requirements of written agreements.

8.3 Methods of Qualification

8.3.1 Supplier Impact Assessment

8.3.1.1 COMM-PAS-017 FRM2 *Supplier Impact Assessment* is completed by the CQP for each supplier and dictates whether further qualification is required based on an assigned supplier risk grade.

8.3.1.2 All supplier impact assessments and applicable associated documentation (certifications, licensure, etc.) will be reviewed at a frequency dependent on the assigned risk grade.

8.3.1.3 Separate from the defined frequency, the COMM-PAS-017 FRM2 *Supplier Impact Assessment* and associated documentation will also be reviewed if and when the CQP becomes aware of any significant changes to the scope of the service or material following the process.

8.3.2 Supplier Questionnaire

8.3.2.1 COMM-PAS-017 FRM1 *Supplier Questionnaire* is sent by the CQP to any supplier receiving a grade of ‘A’ or higher (i.e., B,

C, D, or E) on COMM-PAS-017 FRM2 *Supplier Impact Assessment*.

8.3.2.2 Prior to sending a questionnaire to a supplier, the staff member initiating the request should:

8.3.2.2.1 Gather all available information on the supply or service provided by the supplier, and enter that information into the section of the questionnaire titled “Product/Service Name/Number”. Information can include, but is not limited to:

- MSPEC number and name of associated supply
- Name of service(s) provided

8.3.2.3 Upon receipt of the completed questionnaire, responses and any other data packages or submissions are reviewed by the CQP.

8.3.2.4 If approved, the risk grade, method, and frequency of requalification, and any additional information will be documented under the “Internal Use Only” section of the form if deemed necessary based on the assigned risk grade.

8.3.2.5 If the risk grade assigned based on review of the questionnaire differs from the risk grade assigned via the supplier impact assessment, a new supplier impact assessment should be completed, documenting this updated risk grade to ensure that all supplier documentation is consistent.

8.3.2.6 If the supplier does not agree to complete, sign, and return the Questionnaire within a target of 30 days, the CQP may document rationale for why the supplier is currently acceptable via a memo to file.

8.3.2.6.1 CQP may also choose to continue to work with the supplier to determine alternative methods for qualification.

8.3.2.6.2 CQP will assess the documentation at the next qualification review date to determine if the supplier should be contacted again, or if instead the review of documentation is sufficient for requalification.

8.3.2.7 Standardized Quality Responses developed by the supplier can be substituted for COMM-PAS-017 FRM1 *Supplier Questionnaire* at the discretion of CQP after a thorough review of the document.

8.3.2.7.1 In these cases, supplier-provided documentation should be attached to COMM-PAS-017 FRM2 *Supplier Questionnaire* with a footnote stating that supplier documentation will substitute for a

completed questionnaire, and the "Internal Use Only" section will be completed, documenting the review of all documentation, and the risk grade will be reassessed.

8.3.3 Audit

8.3.3.1 For suppliers receiving a risk grade of D or E, an audit will be performed at the frequency defined based on risk grade.

8.3.3.1.1 Suppliers receiving a risk grade of D receive an annual questionnaire and a quadrennial audit.

8.3.3.1.2 Suppliers receiving a risk grade of E receive an annual questionnaire and a biennial audit.

8.3.3.2 The form of the audit (desk or on-site) will be determined in conjunction with CQP leadership.

8.3.3.3 If the service provider does not agree to an audit, the CQP may work with the service provider to determine alternative methods for qualification, or will document rationale for why the service provider is currently acceptable via a memo to file that will be reviewed on the frequency required by the risk grade assigned.

8.3.4 Quality Agreement

8.3.4.1 CQP evaluates each supplier performing testing or providing a material, component, or service to determine if that service or material is deemed critical and the service or material directly affects the quality, safety, and efficacy of the product.

8.3.4.2 Critical suppliers and/or service providers may require a Quality Agreement, which outlines responsibilities, terms of agreement, and details on dispute resolution. Final determination of whether these critical suppliers and/or service providers require a quality agreement is at the full discretion of the CQP. If CQP determines that a quality agreement is necessary:

8.3.4.2.1 CQP will provide COMM-PAS-017 FRM4 *Service Provider Quality Agreement* to critical service providers or the COMM-PAS-017 FRM3 *Supplier Quality Agreement* for critical material providers.

8.3.4.2.2 A supplier or service provider's internal quality agreement template, if available, may also be used.

8.3.4.2.3 If a supplier is both a material supplier and a service provider, only one quality agreement is required.

8.3.4.3 CQP completes the service provider or supplier section, including contact information and description of product/service prior to providing to the service provider.

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

8.3.4.5 CQP reviews and approves the signed service provider or supplier Quality Agreement, and retains all documentation.

8.3.4.6 If the service provider or supplier does not agree to sign and return the Quality Agreement (target 30 days), the CQP may work with the service provider or supplier to determine alternative methods for qualification, or will document rationale for why the service provider or supplier is currently acceptable via a memo to file. CQP will assess the documentation at the next qualification review as defined below in Section 8.4 to determine if the service provider or supplier will need to be contacted again.

8.3.4.7 Terms of Quality Agreement and Dispute Resolution

8.3.4.7.1 The Quality Agreement commences on the last date of the last signature and remains in effect for as long as the Service Provider/Supplier supplies products or services to Duke, unless the Quality Agreement is earlier terminated with prior written notice from either party.

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

8.4 Frequency of Qualification

8.4.1 The frequency of supplier requalification is dictated by the risk grade assigned via COMM-PAS-017 JA1 *Supplier Risk Assessment.* These due dates are monitored and updated by CQP.

8.4.2 For suppliers graded Z and A, barring any change to the supplier's scope, biennial review of qualifications documented in the review section of COMM-PAS-017 FRM2 *Supplier Impact Assessment* negates the need to complete a new Supplier Impact Assessment biennially.

8.4.2.1 In these cases, documentation of Supplier Impact Assessment review on COMM-PAS-017 FRM2 is sufficient for requalification and will be recorded in the supplier database as such, with the review date being the date of requalification.

8.4.3 For suppliers graded B, C, D, or E, an updated supplier questionnaire is requested on the defined frequency.

8.4.3.1 In these cases, a new COMM-PAS-017 FRM1 *Supplier Questionnaire,* or equivalent, is requested from the supplier on the required frequency and reviewed/approved by CQP.

8.4.3.2 After the required documentation is approved as defined by the risk grade, the Supplier Impact Assessment should be reviewed in the context of the updated questionnaire. An entry should be made in the review section of the Supplier Impact Assessment detailing the requalification steps performed, along with the next due date. Requalification will be recorded in the supplier database as such, with the review date being the date of requalification.

8.4.3.3 For example, if an annual questionnaire has been received and approved for a supplier, a note similar to the one below should be added to the Supplier Impact Assessment:

"Annual requalification completed via review of completed questionnaire and review of existing Supplier Impact Assessment."

8.4.4 For suppliers graded D or E, in addition to review of the Supplier Impact Assessment, and receipt of updated questionnaires, completion of audits should be documented on COMM-PAS-017 FRM2 *Supplier Impact Assessment*.

8.4.4.1 In these cases, in addition to the steps described above for questionnaires, an audit report should be completed as detailed in Section 8.6.

8.4.4.2 Following approval of this report, an entry should be made on COMM-PAS-017 FRM2 *Supplier Impact Assessment* similar to the note below to document that requalification activities were completed:

"Audit of supplier completed, see approved audit report on file."

8.4.4.3 In addition to the note, the updated due date should be recorded in the associated field based on the frequency dictated by the supplier's risk grade.

8.4.5 At the time of re-qualification of all suppliers, at the frequency dictated by the risk grade assigned, CQP will review all current qualifications on file to ensure that all documentation is up-to-date and accurate. If applicable to the risk grade, this review will include:

- Supplier Impact Assessment
  - A review of vendor performance, including a review of the event management system to identify Deviations and/or CAPAs associated with vendor performance.

- This review may be captured as a component of the regular SIA review on the defined schedule.
- Supplier Questionnaire
- Quality Agreement
- Memo to File
- Previous audit reports
- Any other qualifications on file, including certificates, processing methods, etc.

8.4.6 In conjunction with the review and updating of the documentation listed above, monitoring of critical suppliers will include ongoing review of the considerations detailed in Section 8.1.1. If any of these considerations warrant revision of the supplier's risk grade and assigned frequency, qualifications will be updated to reflect this change.

8.4.7 A new risk grade may be assigned at the time of review based on the documentation on file or any significant changes since the last assessment. If a new risk grade is assigned, all documentation must be updated accordingly.

8.4.8 Should any updates to the qualifications on file be required, a note should be added to the review section of the existing COMM-PAS-017 FRM2 *Supplier Impact Assessment* stating that updated documentation is required, along with the reason, date, reviewer name/title, and signature. The "next review due date box" can be marked N/A. At that point, the new documentation will supersede the existing documentation, and the lineage of documentation will be traceable.

8.4.9 If, during re-qualification activities, it becomes clear that a supplier is no longer in use, this is documented on COMM-PAS-017 FRM2 *Supplier Impact Assessment*, and the supplier is removed from the approved supplier list. All documentation should be retained according to procedure.

8.5 Conducting the Supplier Audit

8.5.1 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 at the frequency required according to the risk grade unless rationale can be provided in writing by the CQP.

8.5.1.1 To meet EU GMP regulations, a physical, on-site audit must be performed, if applicable.

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

8.5.3 Identify key personnel who will need to be available if an on-site audit is performed.

8.5.4 Prior to the audit, request the following documentation, as needed:

- Standard operating procedure (SOP) table of contents

- Copies of accreditations/certifications
- Contract
- Scope of work
- Timelines and schedules
- List of contracted or proposed contracted activities
- Organizational chart

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

8.5.6 The auditor conducts the audit, which may include:

8.5.6.1 Interviews with key personnel

8.5.6.2 Tour of the facility

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

8.5.6.4 Review Regulatory Authority Inspectional history

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

8.5.6.6 Training and development database/curriculum for key positions

8.5.6.7 Validation Activities Associated with the Contracted Services

8.5.6.8 Review of Quality Management System

8.5.6.9 Storage and archival of records

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

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

8.6 Audit Observations, Classifications, and Scoring

8.6.1 Audit reports will be written in accordance with COMM-PAS-018 *APBMT Clinical Quality Program (CQP)Audit Procedure*.

8.6.2 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.

8.6.3 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.

8.6.4 All observations must be discussed with the supplier 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 supplier may still be utilized, with continued follow-up by CQP deemed as necessary.

8.6.5 The supplier risk grade will be reassessed following the audit to determine if a change in grade or audit frequency is required based on observations. This reassessment will be documented on *COMM-PAS-018 JA5 Supplier Qualification Audit Report*.

8.6.6 Documentation pertaining to the audit report will be filed and retained, and a note detailing the completion of the audit and the next audit due date will be documented on COMM-PAS-017 FRM2 *Supplier Impact Assessment* as detailed in Section 8.4.4.

8.7 System Review

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

9 RELATED DOCUMENTS/FORMS

9.1 COMM-PAS-017 JA1 Supplier Risk Assessment

9.2 COMM-PAS-017 FRM1 Supplier Questionnaire

9.3 COMM-PAS-017 FRM2 Supplier Impact Assessment

9.4 COMM-PAS-017 FRM4 Service Provider Quality Agreement

9.5 COMM-PAS-017 FRM3 Supplier Quality Agreement

9.6 COMM-PAS-004 Change Control

9.7 COMM-PAS-018 APBMT Clinical Quality Program (CQP) Audit Procedure

9.8 COMM-PAS-018 FRM5 Supplier Qualification Audit Report

9.9 COMM-PAS-013 Deviations and Investigations

10 REFERENCES

10.1 American Association of Blood Banks. Standards for Hematopoietic Progenitor Cell and Cellular Product. Current edition

10.2 FDA Guidance for Industry “Contract Manufacturing Arrangements for Drugs: Quality Agreements.

10.3 FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration, Current Edition

10.4 Foundation for the Accreditation of Hematopoietic Cell Therapy Common Standards for Cellular Therapies, Current Edition

10.5 U.S. Food and Drug Administration. Vaccines, Blood & Biologics. 7342.001 – Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors. Completion Date: January 31, 2019.

10.6 21 CFR Part 820.50, Purchasing Controls

10.7 21 CFR Parts 211.22, 606, 1271.210

11 REVISION HISTORY

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