DUKE

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Supplier Qualifications

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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 for the Marcus Center for Cellular Cures (MC3), and associated laboratories.

1.2 To assure 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 materials/products that meet MC3-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 Quality Agreements, a facet of supplier qualifications, are used to define the responsibilities of critical suppliers and prompts communication of changes, complaints, deviations/investigations, and out of specifications that may have impact products or processes at MC3. A quality agreement will be established and retained by QSU for all critical suppliers with the objective of preempting quality problems, preventing defects, and facilitating consistent quality through effective management and monitoring.

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

2.4 Once qualified, the periodic evaluation of all suppliers' performance 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 Quality Systems Unit (QSU). Within the QSU, the Supplier Qualifications Subteam is responsible for execution and maintenance of this procedure.

3.2 Throughout this document, supplier may refer to vendor, manufacturer, laboratory, facility, supplier, or service provider. For material providers, the manufacturer and vendor and/or distributor will both be qualified.

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

3.5 Retention of supplier contracts is the responsibility of the Program Operations Director or designee.

3.6 QSU will retain documentation of supplier qualifications and quality agreements as applicable.

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 Supplier:** A qualified supplier (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 **cGMP:** Current Good Manufacturing Practices

4.4 **FDA:** Food and Drug Administration

4.5 **SDS:** Safety Data Sheets

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

4.7 **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).

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

4.9 **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 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 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 *COMM-QA-019 Change Control* and/or the program-specific material specification form) qualification of the supplier will be the responsibility of QSU.

8.1.4.1 The associated change control and/or material specification form will not be approved by QSU for implementation until *COMM-QA-002 FRM2 Supplier Impact Assessment* is approved.

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

8.1.4.3 If applicable, the change control should be cited on COMM-QA-002 FRM2 *Supplier Impact Assessment.*

8.1.4.4 If an approved COMM-QA-002 FRM2 *Supplier Impact Assessment* is already on file, QSU will review the updated supply or service to determine if an update is needed prior to the next qualification review cycle.

- If an update is required, a new 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-QA-002 FRM2 *Supplier Impact Assessment*.

8.1.4.5 If a change control and/or material specification must be approved prior to 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 suppliers/service providers in meeting defined requirements should be promptly reported to the QSU, affected personnel/departments, and the supplier.

8.1.5.1 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*.

8.1.5.2 In the event that issues persist or ongoing concerns are present, additional options will be considered, including a "for cause" audit of the supplier, qualification of back-up suppliers and/or complete removal of the supplier from the approved supplier list. 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 provided in COMM-QA-002 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 QSU.

8.2.3 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.

8.3 Methods of Qualification

8.3.1 Supplier Impact Assessment

8.3.1.1 COMM-QA-002 FRM2 *Supplier Impact Assessment,* is completed by QSU 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, Supplier Impact Assessments and associated documentation will also be reviewed if and when QSU becomes aware of any significant changes to the scope of the service or material following the process detailed in Section 8.1.4.

8.3.2 Supplier Questionnaire

8.3.2.1 COMM-QA-002 FRM1 *Supplier Questionnaire,* is sent by QSU to any supplier receiving a grade of 'A' or higher (i.e., B, C, D, or E) on COMM-QA-002 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 services or materials 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

8.3.2.2.2 Enter a brief description of which program the supplier supports in the section of the questionnaire titled "Description."

- If the supplier supports more than one program, ensure that all programs are listed.

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

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 QSU may document rationale for why the service provider is currently acceptable via a memo to file.

8.3.2.6.1 QSU may also choose to continue to work with the service provider to determine alternative methods for qualification.

8.3.2.6.2 QSU 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-QA-002 FRM1 *Supplier Questionnaire* at the discretion of QSU after a thorough review of the document.

8.3.2.7.1 In these cases, supplier-provided documentation should be attached to COMM-QA-002 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 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 QSU leadership.

8.3.3.3 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 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 QSU evaluates each laboratory, facility, and supplier/vendor 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 being produced.

8.3.4.2 Critical service providers and suppliers for the Carolinas Cord Blood Bank and the Robertson GMP Laboratory require a

Quality Agreement, which outlines responsibilities, terms of agreement and details on dispute resolution.

8.3.4.2.1 QSU provides COMM-QA-002 FRM4 *Service Provider Quality Agreement* to critical service providers

8.3.4.2.2 QSU provides *COMM-QA-002 FRM5 Supplier Quality Agreement* for critical material providers.

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

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

8.3.4.3 QSU 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 QSU 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 QSU 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. QSU 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.

8.3.4.7.3 Notices and correspondences shall be made directly to the Duke University MC3 Quality Systems Unit and supplier/service provider email addresses included within the Quality Agreement.

8.4 Frequency of Qualification

8.4.1 The frequency of supplier requalification is dictated by the risk grade assigned via COMM-QA-002 JA1 *Supplier Risk Assessment.* These due dates are monitored and Updated by QSU.

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-QA-002 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-QA-002 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-QA-002 FRM1 *Supplier Questionnaire,* or equivalent, is requested from the supplier on the required frequency and reviewed/approved by QSU.

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 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-QA-002 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-QA-002 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, QSU 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 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-QA-002 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-QA-002 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 on the frequency required according to the risk grade unless rationale can be provided in writing by Quality.

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

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-QA-039 Quality Systems Unit Audit*.

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/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.

8.6.5 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*.

8.6.6 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-QA-002 FRM2 *Supplier Impact Assessment* as detailed in Section 8.4.4.

8.7 Responsibilities as a Supplier for MC3, include, but are not limited to:

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

8.7.2 Maintain an independent quality unit that fulfills quality assurance (QA) and quality control (QC) functions.

8.7.3 Follow applicable current Good Manufacturing Practices (cGMPs) and current, locally imposed requirements, as applicable for the applicable material/service.

8.7.4 Maintain an internal audit program for compliance of existing quality systems with applicable cGMPs.

8.7.5 Allow Duke Personnel to audit applicable facilities, systems, and documents as they pertain to the service/product being provided to MC3.

8.7.6 Allow Duke to perform additional "for-cause" audits as needed.

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

8.7.8 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 service/product provided to Duke.

8.7.9 Notify Duke of any change in procedure, method, or release specification that affects the service/product being provided to Duke.

8.7.10 For service providers, notify Duke of all critical deviations/investigations, complaints, out of specification (OOS) results, associated with the service provided to MC3, upon identification of the event. Investigate all critical deviations/investigations, complaints, and OOS results associated with the service provided to MC3 and provide a copy of documentation of investigation conclusions and corrective and preventive actions (CAPA).

8.7.11 For service providers, notify Duke of any regulatory inspections that impact services provided to Duke.

8.7.12 For material providers, a notification system to alert clients/customers, of changes to methods or release specifications that affects the product being provided to Duke, is maintained, and, ORAQ-MC3_Quality@duke.edu must be configured to receive these notifications.

8.7.13 For material providers, Notify Duke of all recalls associated with the product provided to MC3, upon identification of the event and if product affected by this event has been distributed to Duke. Investigate all critical deviations/investigations, complaints, and OOS results associated with the recalled product provided to Duke and provide a copy of documentation of investigation conclusions and corrective and preventive actions (CAPA).

8.8 System Review

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

8.8.2 The database used to track supplier status shall 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 FRM4 Service Provider Quality Agreement

9.5 COMM-QA-002 FRM5 Supplier Quality Agreement

9.6 COMM-QA-019 Change Control

9.7 COMM-QA-039 Quality Systems Unit Audit

9.8 COMM-QA-039 JA5 Supplier Qualification Audit Report

9.9 COMM-QA-042 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 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

10.6 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.

10.7 21 CFR Part 820.50, Purchasing Controls

10.8 21 CFR Parts 211.22, 606, 1271.210

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
14	Austin Rudisill	a. The responsibilities section has been revised to clarify that responsibility for supplier qualifications is owned by the Supplier Qualifications Subteam, which is a part of the Quality Systems Unit (QSU). b. Significant reorganization of the structure of the SOP. Information on related topics have been grouped together, where previously this information had been spread throughout the document.

Revision No.	Author	Description of Change(s)
		c. Language simplification and clarification throughout. d. Definition of supplier streamlined to include both material and service providers in lieu of maintaining two separate definitions. e. Clarified what qualification actions must be completed before a supplier change control request (CCR) can be approved, and what actions can continue after approval. f. Clarification added on what information is added to supplier questionnaires by QSU staff prior to sending to supplier. g. Added guidance on how long to wait for response from supplier prior to proceeding down alternate routes of qualification. h. Clarified that supplier-provided qualification (already deemed acceptable per SOP) is attached to COMM-QA-002 FRM2 and a footnote added to provide clarity on intention. i. Added a new risk grade of E, the highest rating. j. Clarified frequency of audits for grades D (quadrennial) and E (biennial). k. Clarification added regarding frequency of supplier requalification for each risk grade to ensure clarity. l. Added detail on how qualifications are reviewed on COMM-QA-002 FRM2 when required. m. Added detail on and examples of the required documentation, and the timing of that documentation on the review section of COMM-QA-002 FRM2 during requalification activities. n. Detail added on removing vendors from the approved vendor list o. Additional, minor details added around conducting supplier audits. p. Updated references

Signature Manifest

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