

**DUKE****DOCUMENT NUMBER:** COMM-QA-002 FRM5**DOCUMENT TITLE:**

Supplier Quality Agreement

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Quality Systems Unit
 2400 Pratt Street
 9th floor
 DUMC Box 102501
 Durham, NC 27705
ORAQ-MC3_Quality@duke.edu

QUALITY AGREEMENT

Purpose/Scope

This quality agreement (“Quality Agreement”) is by and between the supplier, as set forth below, (“Supplier”) and Duke University, a tax-exempt research and educational institution, acting for and on behalf of its School of Medicine’s Marcus Center for Cellular Cures (hereinafter “Duke”). As a Supplier providing critical materials to Duke under a separate agreement, prompt communication of changes to manufacturing or release specifications, or any recalls that may impact critical materials we receive, is critical for Duke’s compliance with applicable FDA regulations. Your Quality Department is requested to review, sign, and return this document via email to: ORAQ-MC3_Quality@duke.edu within 10 business days.

Supplier:
Contact Name/Title:
Email:
Phone:
Address:
Product/Material Provided:

Responsibilities as a Supplier to Duke University

Supplier shall:

- Maintain current documentation of training for employees involved in procedures performed relating to the production and quality of the materials provided.



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- Maintain an independent quality unit that fulfills quality assurance (QA) and quality control (QC) functions.
- Follow applicable current Good Manufacturing Practices (cGMPs) and current, applicable locally imposed requirements.
- Maintain an internal audit program for compliance of existing quality systems with applicable cGMPs.
- Allow Duke personnel to audit at least 1 time per year applicable facilities, systems, and documents as they pertain to the product(s) provided to Duke.
- Allow Duke to perform additional “for-cause” audits as needed of applicable facilities, systems, and documents as they pertain to the product(s) provided to Duke.
- Maintain a change control and revision system to initiate, review, revise, approve, obsolete and archive standard operating procedures.
- Notify Duke at ORAQ-MC3_Quality@duke.edu of any change in procedure, method, or release specification that affects the product(s) provided to Duke prior to implementation, as applicable.
- A notification system to alert clients and customers, of changes to methods or release specifications that affects the product(s) provided to Duke, is maintained, and, ORAQ-MC3_Quality@duke.edu must be configured to receive these notifications.
- Maintain a QA approved master validation and qualification plan for the facilities, equipment/instruments, manufacturing process, cleaning procedures, analytical procedures, in process control tests, and computerized systems, as applicable to the product(s) provided to Duke.
- Notify Duke of all recalls associated with the product(s) provided to Duke, within 2 business days upon identification of the recall. If product(s) affected by this event was distributed to Duke. Investigate all critical deviations/investigations, complaints, and Out of Specification (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).

Terms of Quality Agreement and Dispute Resolution

- This Quality Agreement shall commence on the date of last signature and shall remain in effect for as long as the Supplier supplies product(s) to Duke, unless earlier terminated upon thirty (30) days prior written notice from either party.
- The parties will attempt in good faith to resolve quality related disagreements between the 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 Supplier and Duke shall jointly develop a strategy for such resolution, and both parties will record such resolution in writing.
- Notices and correspondences shall be made directly to the Duke University MC3 Quality Systems Unit at the e-mail address above. Notices and correspondence to Supplier shall be sent to the e-mail address listed above.



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AGREED:

Supplier

Signature: _____

Date: _____

Printed Name: _____

Title: _____

Duke University on behalf of its Quality Systems Unit

Signature: _____

Date: _____

Printed Name: _____

Title: _____

Signature Manifest**Document Number:** COMM-QA-002 FRM5**Revision:** 02**Title:** Supplier Quality Agreement**Effective Date:** 13 Jan 2023

All dates and times are in Eastern Time.

COMM-QA-002 FRM5 Supplier Quality Agreement**Author**

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Quality

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Document Release

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