

**DUKE****DOCUMENT NUMBER:** COMM-QA-002 FRM4**DOCUMENT TITLE:**

Service Provider Quality Agreement FRM4

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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 service provider, as set forth below, (“Service Provider”) 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 Service Provider providing services to Duke under a separate agreement, prompt communication of changes, complaints, deviations, and out of specification results that may impact services provided, 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.

Service Provider:
Contact Name/Title:
Email:
Phone:
Address:
Description of Service(s) Provided:

Responsibilities as a Service Provider to Duke University

Service Provider shall:

- Maintain current documentation of training for employees involved in procedures performed relating to the services 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 service(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 service(s) provided to Duke.
- Maintain a change control and revision system to initiate, review, revise, approve, obsolete and archive standard operating procedures.
- Maintain a QA approved master validation and qualification plan for the facilities, equipment/instruments, processes, cleaning procedures, analytical procedures, in process control tests, and computerized systems, as applicable to the service(s) provided to Duke.
- Notify Duke at ORAQ-MC3_Quality@duke.edu of any change in procedure, method, or release specification that affects the service(s) provided to Duke prior to performing the service, as applicable.
- Notify Duke of all critical deviations, complaints, and out of specification (OOS) results associated with the service(s) provided to Duke within 2 business days of identification of the event, as applicable. 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).
- Notify Duke of any regulatory inspections that impact service(s) provided to Duke within 2 business days of the event.

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 Service Provider provides service(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 Service Provider 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 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 Service Provider shall be sent to the e-mail address listed above.



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AGREED:

Service Provider

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 FRM4**Revision:** 03**Title:** Service Provider Quality Agreement FRM4**Effective Date:** 13 Jan 2023

All dates and times are in Eastern Time.

COMM-QA-002 FRM4 Service Provider Quality Agreement FRM4**Author**

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Document Release

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