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

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DOCUMENT TITLE:
Supplier Quality Agreement

DOCUMENT NOTES:

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Supplier Quality Agreement

Purpose/Scope

This quality agreement ("Quality Agreement") is made by and between the supplier, as set forth below, ("Supplier") and Duke University Health System (DUHS), a tax-exempt research and educational institution, acting for and on behalf of the Duke Cancer Institute (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 regulations. Your Quality Department is requested to review, sign, and return this document via email to: APBMT_CQP@dm.duke.edu within 10 business days.

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

Responsibilities as a Supplier to Duke, if applicable

Supplier shall:

- Maintain current documentation of training for employees involved in procedures performed relating to the production and quality of the materials provided.
- Maintain an independent quality unit that fulfills quality assurance (QA) and quality control (QC) functions, such as internal audit programs.
- Follow applicable current Good Manufacturing Practices (cGMPs), Good Tissue Practices (GTP), and current locally imposed requirements, if applicable.
- Allow CQP to audit at least 1 time per year, if needed, applicable facilities, systems, and documents as they pertain to the product(s) provided to Duke.
- Allow CQP 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 APBMT_CQP@dm.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 affect the product(s) provided to Duke is maintained, and APBMT_CQP@dm.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 the product(s) affected by this event were 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 the 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 CQP at APBMT_CQP@dm.duke.edu. Notices and correspondence to the Supplier shall be sent to the e-mail address listed at the top of the agreement.

AGREED:

Supplier

Signature: _____ Date: _____

Printed Name: _____ Title: _____

APBMT Clinical Quality Program (CQP), on behalf of Duke Cancer Institute

Signature: _____ Date: _____

Printed Name: _____ Title: _____

Signature Manifest

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All dates and times are in Eastern Time.

COMM-PAS-016 FRM1--COMM-PAS-018

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Document Release

Name/Signature	Title	Date	Meaning/Reason
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