

**Duke**Medicine

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

DOCUMENT NUMBER: COMM-PAS-018 FRM5**DOCUMENT TITLE:**

Supplier Qualification Audit Report

DOCUMENT NOTES:**Document Information****Revision:** 01**Vault:** COMM-PAS-rel**Status:** Release**Document Type:** COMM-PAS**Date Information****Creation Date:** 20 Jun 2025**Release Date:** 01 Jul 2025**Effective Date:** 01 Jul 2025**Expiration Date:****Control Information****Author:** MC363**Owner:** MC363**Previous Number:** None**Change Number:** PAS-CCR-043

COMM-PAS-018 FRM5

SUPPLIER QUALIFICATION AUDIT REPORT

| | | |
|--|----------------------------|----------------------|
| CONFIDENTIAL | | |
| GENERAL INFORMATION: | | |
| Date of Audit: | | |
| Product/Service Supplied (and part number if applicable): | | |
| Supplier/Vendor Name: | | |
| Supplier/Vendor Address: | | |
| Supplier/Vendor Phone Number: | | |
| Supplier/Vendor Contact Name: | E-mail: | Phone Number: |
| AUDITOR INFORMATION: | | |
| Name/Title | Contact Information | |
| | | |
| | | |

| | |
|------------------------------------|--------------|
| PERSONNEL PRESENT AT AUDIT: | |
| Name | Title |
| | |
| | |
| | |
| | |

| Scope |
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| |

| Background |
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| |

Description of Audit and Objective Evidence

| Observations and Remediation Actions <input type="checkbox"/> N/A | | |
|---|--------------------------------------|--|
| Observation | Supplier Proposed Remediation Action | Remediation Action Plan Accepted by CQP? |
| | | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| | | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| | | <input type="checkbox"/> YES <input type="checkbox"/> NO |

| Evaluation | |
|--|---|
| 1. Have the identified observations been acceptably remediated? If no observations enter "N/A" | <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A |
| 2. Are the in place quality systems sufficient to provide a quality product/service? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 3. Is the supplier approved for use or continued use? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 4. Do any observations or the associated remediation plan require further follow up before the next audit and/or documentation update? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| Recommended risk grade: <input type="checkbox"/> Z <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E | |
| Does recommended risk grade differ from the most recent qualification? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, explain: | |
| Re-qualification and/or audit based on performance, history, organizational change(s), & documentation suggesting supplier/product quality issues. Recommended Method(s): <input type="checkbox"/> Updated Supplier Questionnaire: <input type="checkbox"/> Annual <input type="checkbox"/> Biennial <input type="checkbox"/> Audit: <input type="checkbox"/> Desk <input type="checkbox"/> On-site <input type="checkbox"/> Biennial <input type="checkbox"/> Quadrennial <input type="checkbox"/> Review of Supplier Qualifications | |

| Signature | |
|---------------|-------|
| Lead Auditor: | Date: |
| CQP Director: | Date: |

Signature Manifest**Document Number:** COMM-PAS-018 FRM5**Revision:** 01**Title:** Supplier Qualification Audit Report**Effective Date:** 01 Jul 2025

All dates and times are in Eastern Time.

COMM-PAS-018 FRM1 -- COMM-PAS-019 FRM4**Author**

| Name/Signature | Title | Date | Meaning/Reason |
|----------------------------|-------|--------------------------|----------------|
| Mary Beth Christen (MC363) | | 26 Jun 2025, 05:13:00 PM | Approved |

Management

| Name/Signature | Title | Date | Meaning/Reason |
|--------------------------------|-----------------------|--------------------------|----------------|
| Stefanie Sarantopoulos (SS595) | Professor of Medicine | 26 Jun 2025, 06:34:43 PM | Approved |

Medical Director

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|-----------------------------|-------|--------------------------|----------------|
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Quality

| Name/Signature | Title | Date | Meaning/Reason |
|----------------------------|-------|--------------------------|----------------|
| Mary Beth Christen (MC363) | | 27 Jun 2025, 12:35:34 AM | Approved |

Document Release

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| Amy McKoy (ACM93) | Document Control Specialist | 30 Jun 2025, 05:43:50 PM | Approved |