DukeMedicine

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

DOCUMENT NUMBER: COMM-PAS-018 FRM6

DOCUMENT TITLE:
Internal CQP Facility Qualification/Requalification 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 FRM6
Internal CQP Facility Qualification/Requalification Audit Report
(CONFIDENTIAL)

Date of Qualification Review:

Facility	
Facility: **Address:**	**Facility Contact:** **E-mail:** **Phone:** **Other Contact Info:**

PERSONNEL			
1. Training completed for applicable personnel. Personnel released to task.	☐ YES	☐NO	☐N/A
• Initial Training	☐ YES	☐NO	☐N/A
• On-site Training	☐ YES	☐NO	☐N/A
• MasterControl	☐ YES	☐NO	☐N/A
• SOPs	☐ YES	☐NO	☐N/A
• cGMP	☐ YES	☐NO	☐N/A
• Other, specify:	☐ YES	☐NO	☐N/A
2. Qualifications documented	☐ YES	☐NO	☐N/A
COMMENTS:			

FACILITIES			
3. Secure, limited access storage, collections, and record retention areas.	☐ YES	☐NO	☐N/A
4. Areas are clean, orderly & monitored for temperature/humidity	☐ YES	☐NO	☐N/A
5. Adequate supplies. Supply management reflects acceptable receipt, inspection & organization to support the use of first-expired supplies & when no expiration date, organized to support the use of first received.	☐ YES	☐NO	☐N/A
6. Shipping containers validated, clean (with test shipment completed.	☐ YES	☐NO	☐N/A
7. Equipment validated & functioning	☐ YES	☐NO	☐N/A
8. QC Records posted and maintained	☐ YES	☐NO	☐N/A
9. Restricted access to computer(s) with log-on capabilities to MasterControl or applicable computer systems.	☐ YES	☐NO	☐N/A
10. Access to the internet, MasterControl, or applicable computer systems.	☐ YES	☐NO	☐N/A
COMMENTS:			

EQUIPMENT LIST		
Equipment	**Serial Number**	**Calibrated/Validated**
		☐ YES ☐ NO ☐ N/A
		☐ YES ☐ NO ☐ N/A
		☐ YES ☐ NO ☐ N/A
		☐ YES ☐ NO ☐ N/A
COMMENTS:		

COMPLIANCE			
11. Business agreement(s) finalized	☐ YES	☐ NO	☐ N/A
12. Contact information available	☐ YES	☐ NO	☐ N/A
13. Site personnel instructed to notify of all deviations & unexpected events	☐ YES	☐ NO	☐ N/A
14. Site personnel are instructed to notify of any audits/inspections by external agencies	☐ YES	☐ NO	☐ N/A
15. Signature Log initiated	☐ YES	☐ NO	☐ N/A
COMMENTS:			

ITEMS for FOLLOW-UP ☐ N/A	TASK COMPLETED
	☐ YES ☐ NO

Representative Conducting Audit	
NAME	**ROLE**

By signing below, all follow-up items, if any, have been addressed, and the facility is approved for operation or continued operation.

Auditor's Signature: _____ Date: _____

CQP Director's Signature: _____ Date: _____

Signature Manifest

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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

Name/Signature	Title	Date	Meaning/Reason
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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

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	30 Jun 2025, 05:43:50 PM	Approved