


DukeMedicine


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

DOCUMENT NUMBER: COMM-PAS-018 FRM1

DOCUMENT TITLE:

Internal CQP Quality and Process Audit Report

DOCUMENT NOTES:
Document Information
Revision: 01

Vault: COMM-PAS-rel

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Control Information
Author: MC363

Owner: MC363

Previous Number: None

Change Number: PAS-CCR-043

COMM-PAS-018 FRM1
Internal CQP Quality and Process Audit Report
 (CONFIDENTIAL)

SECTION I.

The CQP will complete the fields located in Section I.

Program/Facility:	
Number of Observations:	
Composite Audit Score:	
Date of Audit:	

Audit Scope:	
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Background:	
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SECTION II.

Lead Auditor and CQP Director will sign indicating that the observations below in Section III are accurate. Once signed, the report will be distributed to the audited department's representative for completion of Section III.

Lead Auditor's Signature and Date:	
CQP Director's Signature and Date:	

SECTION III.

CQP will complete the Score, Label the Quality Management System (QMS) Process, and Description sections of each observation. The audited department's representative will complete the Person Responsible, Estimated Completion Date, and Response fields and return the form to CQP. The Lead Auditor will then complete the Response Approved Section as appropriate.

Observation #:			
Score:			
QMS:			
Description:			
Person Responsible:		Estimated Completion Date:	
Response:			
<i>Completed by Lead Auditor</i> Response Approved? <input type="checkbox"/> Yes <input type="checkbox"/> No Initials/Date:			

Observation #			
Score:			
QMS:			
Description:			
Person Responsible:		Estimated Completion Date:	
Response:			
<i>Completed by Lead Auditor</i> Response Approved? <input type="checkbox"/> Yes <input type="checkbox"/> No Initials/Date:			

SECTION IV. ☐ N/A

For observations labelled Critical or Major, the Lead Auditor will verify that the remediation action(s) described in the response(s) have been implemented and are effective. Otherwise, this section is N/A.

Observation Number	Implemented and effective?	Lead Auditor Initials/Date
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	

SECTION V.

Once the Lead Auditor has approved all the responses and, if necessary, verified the implementation and effectiveness of remediation actions, the Lead Auditor and CQP Director will sign below to close the audit.

Lead Auditor's Signature and Date:	
CQP Director's Signature and Date:	

Signature Manifest**Document Number:** COMM-PAS-018 FRM1**Revision:** 01**Title:** Internal CQP Quality and Process 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

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		26 Jun 2025, 07:29:32 PM	Approved

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