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

DOCUMENT NUMBER: COMM-PAS-015 FRM1

DOCUMENT TITLE:
CAPA 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

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Note: Reference COMM-PAS-015 Appendix A for instructions

TAB: CAPA Summary

CAPA Report Number:	**Program**	
CAPA Report Initiated By:	**Date Initiated:**	
Event Report(s) (DEV-INV; AE; Complaint) associated with this CAPA:		
Issue Statement: (Summarize the Issue and Root Cause of the issue addressed by this CAPA.)		

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Note: Reference COMM-PAS-015 Appendix A for instructions

TAB: CAPA and EC - 1

I. Corrective and Preventive Actions		
Projected Completion Date	**Date Completed**	**Responsible Person (*Initials*)**

◉ **Corrective Action** ○ **Preventive Action** (Select the action taken to effectively address each issue.)

Proposed CAPA (Explain proposed CAPA; *To be Completed on First Route*):

1.

CAPA Outcome (*To Be Completed on Second Route*)**:**

1.

Change Control Request(s) associated with this CAPA:

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Note: Reference COMM-PAS-015 Appendix A for instructions

I. Effectiveness Checks		
Projected Completion Date	**Date Completed**	**Responsible Person (*Initials*)**

Proposed Effectiveness Check

(Explain follow-up action proposed to assess CAPA effectiveness; *To be Completed on First Route*)

1.

Effectiveness Check Outcome

(Explain outcome of effectiveness check and if considered effective; *To be Completed on Second Route*)

1.

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Note: Reference COMM-PAS-015 Appendix A for instructions

TAB: CAPA and EC - 2

II. Corrective and Preventive Actions		
Projected Completion Date	**Date Completed**	**Responsible Person (*Initials*)**

◉ **Corrective Action** ○ **Preventive Action** (Select the action taken to effectively address each issue.)

Proposed CAPA (Explain proposed CAPA; *To be Completed on First Route*):

2.

CAPA Outcome (*To Be Completed on Second Route*)**:**

2.

Change Control Request(s) associated with this CAPA:

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II. Effectiveness Checks		
Projected Completion Date	**Date Completed**	**Responsible Person (*Initials*)**

Proposed Effectiveness Check

(Explain follow-up action proposed to assess CAPA effectiveness; *To be Completed on First Route*)

2.

Effectiveness Check Outcome

(Explain outcome of effectiveness check and if considered effective; *To be Completed on Second Route*)

2.

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TAB: CAPA and EC - 3

III. Corrective and Preventive Actions		
Projected Completion Date	**Date Completed**	**Responsible Person (*Initials*)**

◉ **Corrective Action** ○ **Preventive Action** (Select the action taken to effectively address each issue.)

Proposed CAPA (Explain proposed CAPA; *To be Completed on First Route*):

3.

CAPA Outcome (*To Be Completed on Second Route***):**

3.

Change Control Request(s) associated with this CAPA:

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Note: Reference COMM-PAS-015 Appendix A for instructions

III. Effectiveness Checks		
Projected Completion Date	**Date Completed**	**Responsible Person** (Initials)

Proposed Effectiveness Check

(Explain follow-up action proposed to assess CAPA effectiveness; *To be Completed on First Route*)

3.

Effectiveness Check Outcome

(Explain outcome of effectiveness check and if considered effective; *To be Completed on Second Route*)

3.

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TAB: Risk Assessment

Pre-CAPA Risk Assessment Summary (*Include details of original risk assessment, when applicable*)
Severity Assessment Score (S): **Probability Assessment Score (P):** **Detectability Assessment Score (D):** **COMBINED RISK ASSESSMENT SCORE:**
Effectiveness Check Risk Assessment Evaluation (Summarize overall risk assessment outcome after implementation of associated CAPAs**)**
When assessing risk within one parameter, if two scores are determined (such as severity on product vs. patient), the more stringent (higher score) assessment will be used when calculating the final risk score. Rationale for the lower score should also be provided. **Severity Assessment Score (S):** **Probability Assessment Score (P):** **Detectability Assessment Score (D):** **COMBINED RISK ASSESSMENT SCORE:**
SUMMARY OF RISK OUTCOME: ☐ **N/A**

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Risk Assessment Tables (From COMM-PAS-014)

Severity Risk Matrix

S	Severity	Definition	Anticipated Harm to the Patient	GMP Non-compliance	Impact on Product
1	Negligible	Insignificant	None	None	No perceived impact on product
2	Marginal	At the outer or lower limits, minimal for requirements	Minimal	Minor	Unlikely impact on product, SQIPP not likely to be affected
3	Moderate	Within reasonable limits, transient or persistent	Transient or persistent, not life-threatening	Significant	May indirectly impact product quality/SQIPP
4	Serious	Very important	Permanent, life-threatening	Major	High likelihood of impacting product quality/SQIPP
5	Critical	Abnormal, unstable, unfavorable	May cause or contribute to death	Serious	Evidence of Product Impact, SQIPP affected

Probability Risk Matrix

P	Probability	Definition (Occurrence)	Definition (Recurrence)
1	Rare	Not likely to happen, nearly impossible	Extremely unlikely to recur
2	Low	Occurrence is hardly likely, but possible	Unlikely to recur
3	Occasional	May occur sometimes	Likely to recur sometimes
4	Probable	Repeated occurrence, high likelihood of occurrence	Recur at a moderate rate
5	Frequent	Will happen for certain, a regularly observed event	Likely to recur regularly

Detectability Risk Matrix

D	Detectability	Definition	Examples
1	High	Control system in place; automated detectability certain	An automatic detection system that is a direct measure of the failure
2	Good	Control system is in place with a high probability to detect the issue or its effects	SOP-driven process that facilitates a direct measure of the failure
3	Moderate	Control system in place could detect the issue or its effects	SOP-driven process that is NOT directly measuring or assessing the failure
4	Fair	Control system in place with a low probability to detect the issue or its effects	Non-SOP driven process for the detection of direct measures of the failure
5	Low	No control system in place to detect the issue.	No ability to detect the failure, or no SOP-driven process to indirectly detect the failure

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TAB: External Reporting / Attachments

External Reporting:

Does this event require external reporting? (•) Yes ( ) No

Explain determination for external reporting:
[This section to be populated by author/initiator if known at time of report and/or CQP at time of review]

Attachments

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TAB: Appendix

Appendix A (From COMM-PAS-015)

Signature Manifest

Document Number: COMM-PAS-015 FRM1 **Revision:** 01
Title: CAPA Report
Effective Date: 01 Jul 2025

All dates and times are in Eastern Time.

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Document Release

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