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

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DOCUMENT TITLE:
Deviation and Investigation Report

DOCUMENT NOTES:

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Note: Reference COMM-PAS-013 Appendix A for instructions.

Form Number:

Initiated By:

Date Initiated:

TAB 1: GENERAL INFORMATION

Program (select one):

Project Affected/Impacted (select all that apply):
☐ CCBB Bone Marrow
☐ CCBB CBUs
☐ CCBB PBSCs
☐ GMP Baebies
☐ GMP BM-MSC
☐ GMP CT-MSC
☐ GMP DUOC
☐ GMP Parathyroid
☐ APBMT
☐ STCL All
☐ Other
☐ NA

Specify Other

Date Discovered:

Date Affected (start):
Date Affected (end):

Title:

Supply/Reagent:

Equipment:

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Note: Reference COMM-PAS-013 Appendix A for instructions.

TAB 2: PROBLEM STATEMENT and CONTAINMENT

Problem Statement:

Containment Actions:

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Note: Reference COMM-PAS-013 Appendix A for instructions.

TAB 3: INVESTIGATION and ROOT CAUSE

Investigation (Identifying Root Cause):

Root Cause (Statement of Detailed Root Cause):

Root Cause Analysis Tool Attached?

○ Yes ○ No ○ N/A

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Note: Reference COMM-PAS-013 Appendix A for instructions.

TAB 4: DEVIATION INFORMATION and REPORTING

Deviation Identification:

Was any deviation from SOP identified?

○ Yes ○ No

If Yes, select: ○ Unplanned Deviation ○ Planned Deviation

If Yes, List SOP reference (SOP Number only): _____

Reports Associated with this Deviation/Investigation

List applicable reports (ex. DEV, CAPA, AE, OOS, COMP, Validation, Risk Assessment):

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]

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Note: Reference COMM-PAS-013 Appendix A for instructions.

TAB 5: RISK ASSESSMENT and RATIONALE

Risk Assessment (Refer to procedure COMM-PAS-014 *Risk Assessment Procedure*):

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):

Severity Assessment Rationale (S):

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 Assessment Score (P):

Probability Assessment (Occurrence and Recurrence) Rationale (P):

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 moderate rate
5	Frequent	Will happen for certain, a regularly observed event	Likely to recur regularly

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Note: Reference COMM-PAS-013 Appendix A for instructions.

Detectability Assessment Score (D):

Detectability Assessment Rationale (D):

D	Detectability	Definition	Examples
1	High	Control system in place; automated detectability certain	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 detection of direct measure 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

COMBINED RISK ASSESSMENT SCORE:

☐ **N/A**

Risk Assessment Summary/Conclusion (*If one risk parameter is scored a 5 and no CAPA is launched, justification is required as detailed in Appendix A on "Attachments and Appendix Tab"***):**

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Note: Reference COMM-PAS-013 Appendix A for instructions.

TAB 6: CAPA

CAPA Number (if applicable): CAPA Report-_____

Summary of CAPA (Provide an Overview of CAPA(s) to be implemented, if applicable):

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Note: Reference COMM-PAS-013 Appendix A for instructions.

TAB 7: UPIs/QUARANTINE/LICENSURE

Unique Product Identifier(s):

List UPI(s)

Was quarantined applied to product associated with this report? Yes No N/A
Describe Rationale For Selection:

If all specifications for licensure are met, is there any reason that product(s) cannot be released under the license due to this event? Yes No N/A
Describe Rationale For Selection:

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Note: Reference COMM-PAS-013 Appendix A for instructions.

TAB 8: EVENT CODING and BPDR

QA Assessment (Completed by CQP), if applicable:

If a BPDR is required, enter the BPDR Number:_____ (text field)

Event Code (select) **Specify Other (Describe)**

Deviation Category (Select)

TAB 9: ATTACHMENTS and APPENDIX

Attachment(s)

Appendix from COMM-PAS-013

Signature Manifest

Document Number: COMM-PAS-013 FRM1 **Revision:** 01
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