DukeMedicine

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

DOCUMENT NUMBER: COMM-PAS-006 FRM1

DOCUMENT TITLE:
Product Complaint Form FRM1

DOCUMENT NOTES:

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Control Information

Author: BS76	**Owner:** RB232
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Product Complaint Form

Note: Reference COMM-PAS-006 Appendix A for instructions.

Complaint Number:
Initiated By:
Date Initiated:

TAB 1: GENERAL INFORMATION

Program:

Date Complaint Received:
Complaint Received By:
Complaint Received From:
Name
Facility
Phone Number
Email

Date Problem Discovered
Unique Product Identifier(s)

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Product Complaint Form

Note: Reference COMM-PAS-006 Appendix A for instructions.

TAB 2: PROBLEM STATEMENT and CONTAINMENT

Problem Statement:

Containment Actions:

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Note: Reference COMM-PAS-006 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-006 Appendix A for instructions.

Tab 4: Associated Reports and Reporting

Reports Associated with this Complaint:
List applicable reports (ex. Other Complaint, DEV, AE, BPDR):

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 QSU at time of review]

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Note: Reference COMM-PAS-006 Appendix A for instructions.

TAB 5: RISK ASSESSMENT and RATIONALE

Risk Assessment (Refer to procedure COMM-QA-077 *Risk Assessment Procedure*):

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-006 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:
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"***):**

N/A

COMM-QA-077 Table 4 Image

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Note: Reference COMM-PAS-006 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):

Tab 7: ATTACHMENTS and APPENDIX

Attachment(s)

Appendix A from COMM-PAS-006

Signature Manifest

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