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

DOCUMENT NUMBER: COMM-PAS-006

DOCUMENT TITLE:
Product Complaint Management

DOCUMENT NOTES:

Document Information

Revision: 04	**Vault:** COMM-PAS-rel
Status: Release	**Document Type:** COMM-PAS

Date Information

Creation Date: 07 Jan 2020	**Release Date:** 10 Nov 2020
Effective Date: 10 Nov 2020	**Expiration Date:**

Control Information

Author: BS76	**Owner:** RB232
Previous Number: COMM-PAS-006 Rev 03	**Change Number:** COMM-CCR-136

COMM-PAS-006
PRODUCT COMPLAINT MANAGEMENT

1 PURPOSE

1.1 To describe the procedure for handling product complaints from external customers for the Stem Cell Laboratory (STCL) and/or the Adult and Pediatric Blood and Marrow Transplant Programs.

2 INTRODUCTION

2.1 A documented product complaint management system is necessary to promptly alert the Quality Systems Unit (QSU), Medical Director, and applicable program personnel and associated parties of the complaint, and facilitates timely documentation, investigation, and corrective and preventive actions, as applicable.

2.2 Complaints are documented via MasterControl

3 SCOPE AND RESPONSIBILITIES

3.1 This procedure is applicable to the management of product complaints received by the Stem Cell Laboratory (STCL) and/or the Adult and Pediatric Blood and Marrow Transplant Programs. Complaints may include but are not limited to: post thaw product sterility results, product labeling discrepancies, and damage to the product container.

3.1.1 This procedure does not address the receipt, evaluation, or reporting of adverse experiences (AE). Refer to *STCL-DIST-006 FRM2 Adverse Event Reporting Form* when addressing AEs.

3.2 All program personnel receiving a product complaint are responsible for following this procedure.

3.3 Medical Director and QSU review all complaints documented via the MasterControl System.

4 DEFINITIONS/ACRONYMS

4.1 **Adverse Experience (AE):** Any undesirable event associated with the use of a biological product in humans, whether or not considered product related, including: An undesirable event occurring in the course of the use of a biological product in professional practice; an undesirable event occurring from overdose of the product whether accidental or intentional; an undesirable event occurring from abuse of the product; an undesirable event occurring from withdrawal of the product; and any failure of expected outcome.

4.2 **Biological Product Deviation Reporting (BPDR):** Required for any event associated with the manufacturing, to include testing, processing, packing, labeling, or storage, or with the holding or distribution of a licensed biological product (if applicable) or Human Cells, Tissues and Cellular and Tissue-Based Product (HCT/P), in which the safety, purity, or potency of a distributed product may be affected.

4.3 **Complaint:** Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a product after it is released for distribution. A complaint is any indication of the failure of a product to meet customer or user expectations for quality or to meet performance specifications. A complaint may be lodged against any product that has been released for distribution.

4.4 **DCO:** Document Control Operations

4.5 **MasterControl:** A validated, 21CFR11 compliant document management system.

4.6 **Serious Adverse Experience (SAE):** Any adverse event (AE), as described above, occurring at any dose that results in any of the following outcomes: Death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a SAE when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

4.7 **Unexpected Adverse Experience:** Any AE, as described above, that is not listed in the current labeling for the cellular product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event because of greater severity or specificity.

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 Access to MasterControl

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 Program personnel receiving an oral or written complaint must document the complaint concurrently via the *COMM-PAS-006 FRM1, Complaint Form.*

8.2 Program personnel will also refer to *COMM-QA-077 Risk Assessment* when completing the complaint form.

8.3 QSU reviews the details of the complaint and facilitates the necessary documentation as well as any associated, investigation, and corrective and preventive actions (CAPA).

8.4 Complaint investigations should be as thorough as possible, using all available data at the time of the investigation to determine the root cause and to assess quality impact to other products.

8.5 If the complaint investigation reveals a deviation from a policy, process, or procedure, initiate a report per *COMM-QA-042 Deviations and Investigations*.

8.6 If the complaint investigation reveals that CAPA is necessary to mitigate system nonconformities and performance problems with respect to the quality system, manufacturing, customer complaints, and discrepancies; initiate a CAPA per *COMM-QA-076 Corrective and Preventive Actions*.

8.7 QSU will provide a written response to the complainant and other affected parties, as appropriate, based on investigation results.

8.8 Documentation of complaint investigations are maintained in MasterControl and are accessible for printing and review. Reports may be generated by Document Control Operations (DCO) and Quality Systems Unit (QSU) upon request.

9 RELATED DOCUMENTS/FORMS

9.1 COMM-PAS-006 FRM1 Complaint Form

9.2 COMM-QA-077 Risk Assessment

9.3 COMM-QA-042 Deviations and Investigations

9.4 COMM-QA-076 Corrective and Preventive Actions

9.5 COMM-QA-076 FRM1 CAPA Report Form

10 REFERENCES

10.1 21CFR 211.198 – Complaint File

10.2 21CFR 211.192 – Production Record Review

10.3 1271.320 – Complaint File

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
04	B. Shen	Updated to align with changes to COMM-QA-077 Risk Assessment Procedure. Added Appendix A Form Instructions.

Appendix A

Instructions for completing COMM-PAS-006 FRM1 Product Complaint Form

- Complete the Complaint Report, filling in all required information.
- Record N/A in any section that does not apply.

Data Field	Instructions
Complaint Number	Event number is auto-populated by MasterControl.
Initiated By	This field is auto-populated by MasterControl to indicate which user initiated the Complaint Report.
Date Initiated	This field is auto-populated by MasterControl to indicate what date the Complaint Report was initiated.
Tab 1: General Information	
Program	Select applicable program for the complaint
Date Complaint Received	Enter date complaint received
Complaint Received By	Enter who received the complaint
Complaint Received From	Enter where/who the complaint was received from: name, facility information, phone number, and email
Date Problem Discovered	Enter the date the problem was discovered
Unique Product Identifiers	Enter unique product identifier(s) associated with the complaint
Tab 2: Problem Statement and Containment	
Problem Statement	Clearly describe the situation. Identify the problem being addressed at the start of the narrative. State the date the event occurred. Include a description of how and when the complaint was identified.
Containment Actions	Detail all containment (immediate) actions taken, in chronological order to resolve the problem. Include dates completed. This could include an immediate action on the part of a transplant center or receiving facility, if shared with STCL and/or APBMT as part of the complaint or investigation. Examples: Stop of shipment/supply, Destruction of Product or Product Recall.
Tab 3: Investigation and Root Cause	
Investigation (Identifying Root Cause)	Define the scope of the complaint in greater detail and include applicable dates on which events/actions occurred. If investigation is conducted over time, update/refine the investigation as new information is discovered. Include: ○ Information that was gathered, reviewed and/or evaluated ○ Applicable dates/date ranges and an explanation of each ○ Results of the reviews/evaluations of the information ○ Summary of information gathered to help identify root cause(s) and/or contributing factors ○ Consideration if the event may have impact to product, other processes, documents, samples, results, etc. If other programs/departments will be impacted, notify the department/management, as appropriate. ○ Detail applicable outcomes/resolutions.
Root Cause (Statement of Detailed Root Cause)	Statement of Root Cause identified during investigation.

Data Field	Instructions
	Please ensure that this is a statement of the root cause of the issue and not solely a re-statement of what happened. If needed, utilize root cause analysis tool (some details below), such as "5 Whys".
Root Cause Analysis Tool Attached?	In scenarios where root cause is not readily identifiable or is undetermined, documentation of the formal Root Cause Analysis tool/exercise utilized to determine this root cause should be in the report or attached. Other tools could include brainstorming, fishbone analysis, or FMEA, among others.
Tab 4: Associated Reports and Reporting	
Report(s) associated with this Complaint	Enter any report number(s) associated with this Complaint (Ex. other Complaints, Deviation(s), Adverse Events, BPDR).
External Reporting	This section is completed to document the determination if additional regulatory or other external reporting such as to a vendor or sponsor may be required per the applicable quality agreement. If notification is required prior to event closure, then documentation, such as email, FAX etc., should, ideally, be attached to the document in the Attachments section. This section is to be populated by author/initiator if known at time of report and/or QSU at time of review.
Tab 5: Risk Assessment and Rationale	
Risk Assessment	Reference SOP *COMM-QA-077 Risk Assessment Procedure* to assess risk on all three parameters (severity, probability, and detectability). An individual score should be assigned and detailed rationale provided for that assigned score. Risk assessments should be expanded to include potential, related outcomes that could occur in the future despite not having occurred in this specific complaint so that any potential preventive actions can be evaluated and captured appropriately as a CAPA. To accomplish this, a systemic view should be taken when looking at the event/issue to help determine if any changes can be made to facilitate reduced risk of a similar complaint occurring in the future. The final score will help assess if a CAPA is required due to risk. A CAPA may still be appropriate even if not required due to risk.
Combined Risk Assessment Score	Use the Risk Assessment Matrix to assign a numerical value for each risk parameter in the risk assessment. Multiply the scores to obtain the final, combined risk assessment score.
Risk Assessment Summary/Conclusion	Use this field to populate a summary of the overall risk assessment if not sufficiently detailed in the individual parameter fields above; any additional information about the expanded risk assessment can also be described here. If one risk parameter is scored a 5 during the risk evaluation and no CAPA is launched, justification will be required and captured within this field, addressing specifically how the risk was evaluated to be at an acceptable level. Finally, this field may be utilized to describe any impact to risk assessment reports per *COMM-QA-080 Quality Risk Management* if not otherwise addressed in the event or risk documentation already provided. The field can be N/A if no additional details are needed.

Data Field	Instructions
Tab 6: CAPA	
CAPA Number	Enter number of CAPA Report generated. Enter N/A if no CAPA.
Summary of CAPA	Give an overview of CAPA(s) to be implemented in associated CAPA report (if applicable). As a best practice, please route any associated CAPA (first routing) concurrently with the corresponding Complaint.
Tab 7: Attachments and Appendix	
Attachment(s)	Use this function to attach all applicable documents.
Appendix from COMM-PAS-006	The Appendix from COMM-PAS-006 is attached for easy reference.

Signature Manifest

Document Number: COMM-PAS-006 **Revision:** 04
Title: Product Complaint Management
Effective Date: 10 Nov 2020

All dates and times are in Eastern Time.

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