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 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 receives automatic notification of the complaint entered in the MasterControl System.

8.4 QSU reviews the details of the complaint and facilitates the necessary documentation as well as any associated, investigation, and corrective and preventive actions (CAPA).
8.5 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.

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

8.7 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.

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

8.9 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

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<th>Author</th>
<th>Description of Change(s)</th>
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<tr>
<td>03</td>
<td>R. Bryant</td>
<td>Updated related documents/forms section 9. Updates throughout to harmonize flow with other event management procedures.</td>
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# Signature Manifest

**Document Number:** COMM-PAS-006

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All dates and times are in Eastern Time.

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## COMM-PAS-006 Product Complaint Management

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