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

DOCUMENT NUMBER: COMM-PAS-016 FRM3

DOCUMENT TITLE:
Process Validation Protocol

DOCUMENT NOTES:

Document Information

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Control Information

Author: MC363	**Owner:** MC363
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Validation Protocol Number:

Process Validation Title:

Prepared By:	Date:
Approved By: Department Supervisor/Manager	Date:
Approved By: Medical Director	Date:
Approved By: APBMT Clinical Quality Program (CQP)	Date:

This form is to be used as a guide in the development of a process validation. Applicable contents can be imported into an MS Word document to create the validation protocol and final report.

1. Table of Contents

2. Objective and Scope

Clearly state the objective of the validation to validate a particular process. List names/numbers of relevant SOPs to be followed during this process. Insert information about scope, such as how many samples will be run through the process or how many process runs will be included, etc.

2.1. Validation Execution Prerequisites

Detail any pre-execution requirements for the validation protocol. This may include verification of the qualification status of any equipment/systems required in the execution of the protocol, and any change controls necessary.

3. Background and Introduction

Insert background information about the process to be validated. The intent regarding use of batches/products manufactured as part of this process validation should also be specified (i.e., specify if the batches will be for human use and/or released under the license vs. IND).

Example:
This protocol will validate the X process using the currently approved SOPs. Steps will be performed per the following SOPs:

Table 3.1

SOP Number	SOP Title

This protocol has been drafted with input from the FDA guidance document, Process Validation: General Principles and Practices, November 2008 and January 2011, and SOP COMM-PAS-016*, Approaches to Validation.*

Following the execution of this protocol, a final report will be generated, including data and final conclusions.

4. List of Equipment and Reagents

Provide details of equipment and reagents used in the process validation. Equipment should be appropriately qualified before use.

Example:
All reagents, equipment, personnel, and raw materials will be the same as those used in the regular production of HPC. This information will be captured in Tables 4.1 and 4.2, if not already captured on SOP XXX FRMX, used.

Table 4.1

Equipment	***Serial Number/Label***	***Location***

Table 4.2

Reagents	***Lot Number***	***Expiration Date***

5. Protocol Design and Acceptance Criteria

Insert details about the process conditions, if needed, and/or protocol design. There is no need to repeat all process steps already outlined in an approved SOP, but the SOP should be referenced in the relevant location in the instructions below. If there is anything that is part of this validation protocol that is not similar to how the process will really be done for manufacturing, please note and explain rationale/justification (i.e., facility difference, method not validated, personnel training, etc.).

What types of samples will be used, and where do the samples come from? For Table 5.1 below, analytical methods/testing used to examine the process should be listed with a description of the type of sample needed for that assay and acceptance criteria. Analytical testing should be done per approved SOPs as well, as appropriate. Specify data to be collected and when/how it will be evaluated. Acceptance criteria for all testing performed and/or each significant processing step should be outlined.

The sampling plan includes sampling points, the number of samples, and the frequency of sampling for each unit operation and attribute.

Example:

Table 5.1: Analytical Method Testing and Acceptance Criteria

Test	***Test Sample***	***Acceptance Criteria***
XXX	*XXX*	*define*

6. Analysis Methodology

List and describe statistical analyses here or how the data analysis will be performed, if applicable.

7. Amendment Revision History (as applicable)

Provide a brief description of the change(s) from the previous review and approval. Include justification for the change(s).

8. Final Report

A final report will be generated after execution of this protocol and provided to the Medical Director and CQP for review and approval. The final report will include completed tables with data and other information as described in this protocol. In addition, summaries, conclusions, and recommendations will be included. Furthermore, any process changes that may be warranted following this validation should be noted.

8.1. Non-Conformances

Describe any protocol generation errors, non-conformances, or deviations that occurred during the execution of the protocol. Minimally, this will also include an assessment/justification of any perceived impact on the validation. If no instances of non-conformance are noted, thus deviations are not required, this rationale should be stated within the summary report.

If, during the execution of a validation protocol, there is a deviation from an existing, effective version of an SOP in MasterControl, a formal deviation and investigation report, per COMM-PAS-015 *Deviations and Investigations, will be launched and referenced. All events associated with the execution of a validation protocol must be closed before signoff of the associated validation summary report.*

NOTE: If a deviation is launched within MasterControl, this number must be referenced in the validation summary report. See COMM-PAS-016 *Approaches to Validation for clarification on requirements for situations when a MasterControl event is required.*

8.2. Post-Execution Requirements

Following execution of the validation protocol, describe in the report if any change control requests are necessary as a result of this validation in order to ensure the validated parameters/processes are incorporated into applicable SOPs/batch records. If change controls are not determined to be necessary, this rationale should be stated within the summary report.
NOTE: If a change control request is launched within MasterControl, this number must be referenced in the validation summary report.

Signature Manifest

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All dates and times are in Eastern Time.

COMM-PAS-016 FRM1--COMM-PAS-018

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