**DOCUMENT NUMBER:** COMM-QA-075

**DOCUMENT TITLE:**
Management Review and Responsibility

**DOCUMENT NOTES:**

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**Document Information**

- **Revision:** 03
- **Vault:** COMM-QA-rel
- **Status:** Release
- **Document Type:** COMM-QA

**Date Information**

- **Creation Date:** 27 Dec 2018
- **Release Date:** 26 Apr 2019
- **Effective Date:** 26 Apr 2019
- **Expiration Date:**

**Control Information**

- **Author:** RB232
- **Owner:** RB232
- **Previous Number:** COMM-QA-075 Rev 02
- **Change Number:** COMM-CCR-086
COMM-QA-075
MANAGEMENT REVIEW AND RESPONSIBILITY

1 PURPOSE
1.1 This Standard Operating Procedure (SOP) provides an overview of how management reviews the quality management systems (QMS).

2 INTRODUCTION
2.1 This procedure ensures Management reviews the quality systems to ensure continuing adequacy, suitability, effectiveness and to evaluate the need for changes to the systems at planned intervals. Management reviews are also used to identify and assess opportunities to change quality policy and quality objectives to address resource needs and to look for opportunities to improve products.

3 SCOPE AND RESPONSIBILITIES
3.1 This SOP applies to all members of management with responsibilities related to the quality management system and processes.
3.2 Management Representative: Communicates with employees, as needed, regarding scheduled management reviews. Reviews and signs off on reports or minutes, if applicable.
3.3 QA: Provides and compiles data related to the quality systems, as needed, for the Management Reviews.

4 DEFINITIONS/ACRONYMS
4.1 Adequacy: Sufficient to satisfy a requirement or meet a need. A quality management system should be capable of satisfying applicable requirements including those specified by the organization, the customer, and any applicable standards and/or regulations.
4.2 APBMT: Adult and Pediatric Blood and Marrow Transplant Program
4.3 BLA: Biologics License Application
4.4 CAP: College of American Pathologists
4.5 CCBB: Carolinas Cord Blood Bank
4.6 Complaint: An event in which customer expectations are not met. Complaints are also documented when a vendor or supplier fails to meet the expectations of the program/manufacturer. Complaints may or may not also be classified as deviations.
4.7 DCO: Document Control Operations
4.8 Effectiveness: Adequate to accomplish a purpose; producing the intended or expected result. A quality management system should enable the organization to meet its own needs, those of the customer and those of other interested parties
4.9 FACT: Foundation for the Accreditation of Cellular Therapy
4.10 FDA: Food and Drug Administration
4.11 GvHD: Graft versus Host Disease
4.13 Out of Specification Result: Any measurement or assay result that falls outside of established specifications or other established acceptance criteria as defined by the Program.
4.14 Quality Management System (QMS): Set of interrelated or interacting elements used to direct and control how quality policies are implemented and quality objectives are achieved
4.15 Quality Manual: Documents an organization's quality management system. It should define the scope of the QMS, describe how the QMS processes interact, and documents the quality procedures or refers to them.
4.16 QSU: Quality Systems Unit
4.17 SOP: Standard Operating Procedure
4.18 STCL: Stem Cell Laboratory
4.19 Suitability: The quality of having properties that are right for the specific purpose. A quality management system should be able to sustain the current performance levels of the organization utilizing an acceptable amount of organizational resources.

5 MATERIALS
5.1 Supporting reports/documents; e.g., product recall notification, email correspondences.

6 EQUIPMENT
6.1 Computer access to MasterControl

7 SAFETY
7.1 N/A

8 PROCEDURE
8.1 General
8.1.1 Management and Program Directors review information at multiple time-points throughout the year. These reviews are done via quarterly reports, regular meetings, and/or through annual process and product reviews.
8.1.2 At a minimum, QSU and the Program Director(s) will document these reviews through signed reports and/or meeting minutes.
8.1.3 Should corrective or preventive actions result from these reviews/reports/meetings, these action items will be documented in the Event Management System.
8.1.4 It is the ultimate responsibility of Management to ensure that action items are addressed and that the in-place processes and systems are functioning appropriately with respect to the program.

8.2 Adult and Pediatric Blood and Marrow Transplant Program (APBMT)

8.2.1 The APBMT clinical program is accredited by the Foundation for the Accreditation of Cellular Therapy (FACT). The program reviews its clinical quality indicators in quarterly meetings, quarterly reports, and annual reports. These reviews occur with the Program Director(s) and Management Representatives in attendance.

8.2.2 These meetings are documented with minutes. Quarterly and annual reports provide summaries of the program and its processes, which are reviewed and signed by the Program Director(s) and QSU.

8.2.3 The following clinical and nonclinical inputs are reviewed:

Clinical:

8.2.3.1 Time to engraftment
8.2.3.2 Catheter infections
8.2.3.3 Acute and chronic Graft versus Host Disease (GvHD)
8.2.3.4 30 day mortality
8.2.3.5 100 day mortality
8.2.3.6 1 year mortality
8.2.3.7 1 year overall survival
8.2.3.8 30 day treatment related, non-relapse, mortality
8.2.3.9 100 day treatment related, non-relapse, mortality
8.2.3.10 1 year treatment related, non-relapse, mortality

Non-Clinical:

8.2.3.11 Facilities
8.2.3.12 Equipment Management
8.2.3.13 Inventory Control/Supply Management
8.2.3.14 Document Control/Records Management
8.2.3.15 Process Management and Control
8.2.3.16 Quality System Audits and Supported Inspections

8.2.4 It is expected that the Program Director(s) and Management Representatives in this meeting will disseminate information from the quarterly meetings, quarterly reports, and annual reports to applicable staff.

8.2.5 Conversely, it is expected that the Management Representative’s staff will alert them of concerns in the program/process, and the Management Representative will bring those concerns to the meetings for discussion.
8.2.6 Flowchart 1 describes how reporting information moves through the APBMT program.

8.3 Stem Cell Laboratory (STCL)

8.3.1 The STCL program is accredited by the Foundation for the Accreditation of Cellular Therapy (FACT), College of American Pathologists (CAP), and is a processing laboratory for the clinical program. The STCL is also CLIA certified. The program reviews some inputs in quarterly meetings with the Program Director(s) and Management Representatives or designees.

8.3.2 The following inputs are reviewed in quarterly and annual reports:

8.3.2.1 Facilities
8.3.2.2 Equipment Management
8.3.2.3 Inventory Control/Supply Management
8.3.2.4 Document Control/Records Management
8.3.2.5 Process Management and Control
8.3.2.6 Quality System Audits and Supported Inspections

8.3.3 It is expected that the Program Director(s) and Management Representatives will disseminate information from the quarterly meetings, quarterly reports, and annual reports to applicable staff.

8.3.4 Conversely, it is expected that the Management Representative’s staff will alert them of concerns in the program/process, and the Management Representative will bring those concerns to the meetings for discussion.

8.4 Robertson GMP Laboratory

8.4.1 The Robertson GMP Laboratory is a cGMP manufacturing facility accredited by the Foundation for the Accreditation of Cellular Therapy (FACT). This program reviews its inputs quarterly. These reviews occur in quarterly reports, which are reviewed by the Program Director(s) and Management Representatives.

8.4.2 The following inputs are reviewed in the quarterly reports:

8.4.2.1 Personnel/Training
8.4.2.2 Facilities
8.4.2.3 Environmental Monitoring
8.4.2.4 Equipment Management
8.4.2.5 Inventory Control/Supply Management
8.4.2.6 Document Control/Records Management
8.4.2.7 Process Management and Control
8.4.2.8 Product Release
8.4.2.9 Event Management
8.4.2.10 Quality System Audits and Supported Inspections

8.4.3 It is expected that the Program Director(s) and Management Representatives will disseminate information from the quarterly reports to applicable staff.

8.4.4 Conversely, it is expected that the Management Representative’s staff will alert them of concerns in the program/process, and the Management Representative will elevate those concerns for discussion, as applicable.

8.5 Carolinas Cord Blood Bank (CCBB)

8.5.1 The Carolinas Cord Blood Bank (CCBB) is a cGMP manufacturing facility accredited by the Foundation for the Accreditation of Cellular Therapy (FACT), College of American Pathologists (CAP), and approved by the United States Food and Drug Administration (FDA) to manufacture DUCORD under a Biologics License Application (BLA). The program reviews its inputs in regular meetings between QSU and executive management, quarterly reports, and an annual product review (per CCBB-QA-021).

8.5.2 The following inputs are reviewed in the quarterly reports:

8.5.2.1 Personnel/Training
8.5.2.2 Facilities
8.5.2.3 Environmental Monitoring
8.5.2.4 Equipment Management
8.5.2.5 Inventory Control/Supply Management
8.5.2.6 Document Control/Records Management
8.5.2.7 Process Management and Control
8.5.2.8 Product Release
8.5.2.9 Event Management
8.5.2.10 Quality System Audits and Supported Inspections

8.6 It is expected that the Program Director(s) and Management Representatives will disseminate information from the quarterly reports to applicable staff.

8.7 Conversely, it is expected that the Management Representative’s staff will alert them of concerns in the program/process, and the Management Representative will elevate those concerns for discussion, as applicable.
8.8 The flowchart below describes how reporting information moves through each program:

[Diagram of flowchart showing the movement of information through various programs such as CDS input, Personnel/Training, Environmental Monitoring, etc.]
9 RELATED DOCUMENTS/FORMS
9.1 CCBB-QA-021 Annual Product Review
9.2 GMP-QA-001 Robertson GMP Laboratory Quality Management Plan
9.3 STCL QA-006 STCL Quality Management Plan
9.4 APBMT-COMM-027 APBMT Quality Management Plan
9.5 CCBB-QA-014 CCBB Quality Management Plan

10 REFERENCES
10.1 FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration, Current Edition
10.2 NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration, Current Edition
10.3 FACT Common Standards, Current Edition

11 REVISION HISTORY

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<th>Author</th>
<th>Description of Change(s)</th>
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<td>03</td>
<td>R. Bryant</td>
<td>Removed reference to CT2 and replaced with Robertson GMP Laboratory.</td>
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<td>Updated names of FACT and APBMT throughout the SOP.</td>
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<td>Updated the APBMT quality indicators.</td>
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<td>Minor edits for clarity.</td>
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## Signature Manifest

**Document Number:** COMM-QA-075  
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**Revision:** 03  

All dates and times are in Eastern Time.

### COMM-QA-075 Management Review and Responsibility

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#### Medical Director

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