

**DUKE****DOCUMENT NUMBER:** COMM-QA-042 FRM4**DOCUMENT TITLE:**

Deviation and Investigation Report FRM4

**DOCUMENT NOTES:****Document Information****Revision:** 05**Vault:** COMM-QA-rel**Status:** Release**Document Type:** COMM-QA**Date Information****Creation Date:** 29 Oct 2019**Release Date:** 30 Oct 2020**Effective Date:** 30 Oct 2020**Expiration Date:****Control Information****Author:** BS76**Owner:** RB232**Previous Number:** COMM-QA-042 FRM4 Rev 04 **Change Number:** COMM-CCR-131

## COMM-QA-042 FRM4 DEVIATION AND INVESTIGATION REPORT

**Note: Reference COMM-QA-042 Appendix A for instructions.**

Form Number:

Initiator:

Date Initiated:

### **TAB 1: GENERAL INFORMATION**

Program (select one):

Project Affected/Impacted (select all that apply):

- ☐ CCBB Bone Marrow
- ☐ CCBB CBUs
- ☐ CCBB PBSCs
- ☐ GMP Baebies
- ☐ GMP BM-MSC
- ☐ GMP CT-MSC
- ☐ GMP DUOC
- ☐ GMP Parathyroid
- ☐ GMP RVT-802
- ☐ STCL All
- ☐ Other
- ☐ NA

Specify Other

Date Discovered:

Date Affected (start):

Date Affected (end):

Title:

Supply/Reagent:

Equipment:

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### **TAB 2: PROBLEM STATEMENT and CONTAINMENT**

Problem Statement:

Containment Actions:

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**Note: Reference COMM-QA-042 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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### **TAB 4: DEVIATION INFORMATION and REPORTING**

#### **Deviation Identification:**

**Was any deviation from SOP identified?**

☐ Yes ☐ No

If Yes, select: ☐ Unplanned Deviation ☐ Planned Deviation

If Yes, List SOP reference (SOP Number only): \_\_\_\_\_

#### **Reports Associated with this Deviation/Investigation**

List applicable reports (ex. DEV, CAPA, AE, OOS, COMP, Validation, Risk Assessment):

#### **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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### DEVIATION AND INVESTIGATION REPORT

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#### **TAB 5: RISK ASSESSMENT and RATIONALE**

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

*When assessing risk within one parameter, if two scores are determined (such as severity on product vs patient), the more stringent (higher score) assessment will be used when calculating the final risk score. Rationale for the lower score should also be provided.*

##### **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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**Detectability Assessment Score (D):**

**Detectability Assessment Rationale (D):**

<b>D</b>	<b>Detectability</b>	<b>Definition</b>	<b>Examples</b>
<b>1</b>	High	Control system in place; automated detectability certain	Automatic detection system that is a direct measure of the failure
<b>2</b>	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
<b>3</b>	Moderate	Control system in place could detect the issue or its effects	SOP driven process that is NOT directly measuring or assessing the failure
<b>4</b>	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
<b>5</b>	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:**

☐ N/A

**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”):*

**Image of Table 4 From COMM-QA-077**

## **COMM-QA-042 FRM4 DEVIATION AND INVESTIGATION REPORT**

**Note: Reference COMM-QA-042 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):**



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### **TAB 7: UPIs/QUARANTINE/LICENSURE**

#### **Unique Product Identifier(s):**

#### **List UPI(s)**

Was quarantined applied to product associated with this report? ☐ Yes ☐ No ☐ N/A  
Describe Rationale For Selection:

If all specifications for licensure are met, is there any reason that product(s) cannot be released under the license due to this event? ☐ Yes ☐ No ☐ N/A  
Describe Rationale For Selection:

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### **TAB 8: EVENT CODING and BPDR**

#### **QA Assessment (Completed by QSU):**

If a BPDR is required, enter the BPDR Number: \_\_\_\_\_ (text field)

**Event Code (select)**

**Specify Other (Describe)**

**Deviation Category (Select)**

### **TAB 9: ATTACHMENTS and APPENDIX**

**Attachment(s)**

**Appendix from COMM-QA-042**

**Signature Manifest****Document Number:** COMM-QA-042 FRM4**Revision:** 05**Title:** Deviation and Investigation Report FRM4**Effective Date:** 30 Oct 2020

All dates and times are in Eastern Time.

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**Document Release**

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