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

**DOCUMENT TITLE:**
Deviation and Investigation Report FRM4

**DOCUMENT NOTES:**

### Document Information

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### Date Information

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### Control Information

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<th>Author:</th>
<th>BS76</th>
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<td>Owner:</td>
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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:
COMM-QA-042 FRM4
DEVIAITON AND INVESTIGATION REPORT

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

TAB 2: PROBLEM STATEMENT and CONTAINMENT

Problem Statement:

Containment Actions:
COMM-QA-042 FRM4
DEVIATION AND INVESTIGATION REPORT

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
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]
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):

<table>
<thead>
<tr>
<th>S</th>
<th>Severity</th>
<th>Definition</th>
<th>Anticipated Harm to the Patient</th>
<th>GMP Non-compliance</th>
<th>Impact on Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Negligible</td>
<td>Insignificant</td>
<td>None</td>
<td>None</td>
<td>No perceived impact on product</td>
</tr>
<tr>
<td>2</td>
<td>Marginal</td>
<td>At the outer or lower limits, minimal for requirements</td>
<td>Minimal</td>
<td>Minor</td>
<td>Unlikely impact on product, SQIPP not likely to be affected</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td>Within reasonable limits, transient or persistent</td>
<td>Transient or persistent, not life threatening</td>
<td>Significant</td>
<td>May indirectly impact product quality/SQIPP</td>
</tr>
<tr>
<td>4</td>
<td>Serious</td>
<td>Very important</td>
<td>Permanent, life threatening</td>
<td>Major</td>
<td>High likelihood of impacting product quality/SQIPP</td>
</tr>
<tr>
<td>5</td>
<td>Critical</td>
<td>Abnormal, unstable, unfavorable</td>
<td>May cause or contribute to death</td>
<td>Serious</td>
<td>Evidence of Product Impact, SQIPP affected</td>
</tr>
</tbody>
</table>

Probability Assessment Score (P):

Probability Assessment (Occurrence and Recurrence) Rationale (P):

<table>
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<tr>
<th>P</th>
<th>Probability</th>
<th>Definition (Occurrence)</th>
<th>Definition (Recurrence)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rare</td>
<td>Not likely to happen, nearly impossible</td>
<td>Extremely unlikely to recur</td>
</tr>
<tr>
<td>2</td>
<td>Low</td>
<td>Occurrence is hardly likely, but possible</td>
<td>Unlikely to recur</td>
</tr>
<tr>
<td>3</td>
<td>Occasional</td>
<td>May occur sometimes</td>
<td>Likely to recur sometimes</td>
</tr>
<tr>
<td>4</td>
<td>Probable</td>
<td>Repeated occurrence, high likelihood of occurrence</td>
<td>Recur at moderate rate</td>
</tr>
<tr>
<td>5</td>
<td>Frequent</td>
<td>Will happen for certain, a regularly observed event</td>
<td>Likely to recur regularly</td>
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COMM-QA-042 FRM4
DEVIATION AND INVESTIGATION REPORT

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

Detectability Assessment Score (D):

Detectability Assessment Rationale (D):

<table>
<thead>
<tr>
<th>D</th>
<th>Detectability</th>
<th>Definition</th>
<th>Examples</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>High</td>
<td>Control system in place; automated detectability certain</td>
<td>Automatic detection system that is a direct measure of the failure</td>
</tr>
<tr>
<td>2</td>
<td>Good</td>
<td>Control system is in place with a high probability to detect the issue or its effects</td>
<td>SOP driven process that facilitates a direct measure of the failure</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td>Control system in place could detect the issue or its effects</td>
<td>SOP driven process that is NOT directly measuring or assessing the failure</td>
</tr>
<tr>
<td>4</td>
<td>Fair</td>
<td>Control system in place with a low probability to detect the issue or its effects</td>
<td>Non-SOP driven process for detection of direct measure of the failure</td>
</tr>
<tr>
<td>5</td>
<td>Low</td>
<td>No control system in place to detect the issue.</td>
<td>No ability to detect the failure or no SOP-driven process to indirectly detect the failure</td>
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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
DEVIAITION 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):
COMM-QA-042 FRM4
DEVIAATION AND INVESTIGATION REPORT

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

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:
COMM-QA-042 FRM4
DEVIATION AND INVESTIGATION REPORT

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

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  
**Title:** Deviation and Investigation Report FRM4  
**Effective Date:** 30 Oct 2020  

All dates and times are in Eastern Time.

## COMM-QA-042 FRM4 Deviation and Investigation Report FRM4

### Author

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<tr>
<td>Bing Shen (BS76)</td>
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<td>23 Oct 2020, 03:42:46 PM</td>
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### Medical Director

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<td>Joanne Kurtzberg (KURTZ001)</td>
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<td>Richard Bryant (RB232)</td>
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### Document Release

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