DUKE

**DOCUMENT NUMBER:** COMM-QA-076 FRM1

**DOCUMENT TITLE:**
CAPA Report FRM1

**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-076 FRM1 Rev 04 | **Change Number:** COMM-CCR-132 |

# COMM-QA-076 FRM1
# CAPA REPORT

**Note: Reference COMM-QA-076 Appendix A for instructions**

**TAB: CAPA Summary**

| **CAPA Report Number:** | **Program** | |
|---|---|---|
| **CAPA Report Initiated By:** | **Date Initiated:** | |
| **Event Report(s) (DEV-INV; AE; Complaint) associated with this CAPA:** | | |
| **Issue Statement:** (Summarize Issue and Root Cause of the issue addressed by this CAPA.) | | |

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# CAPA REPORT

**Note: Reference COMM-QA-076 Appendix A for instructions**

**TAB: CAPA and EC - 1**

| **I. Corrective and Preventive Actions** | | |
|---|---|---|
| **Projected Completion Date** | **Date Completed** | **Responsible Person (*Initials*)** |
| | | |

◉ **Corrective Action** ○ **Preventive Action** (Select the action taken to effectively address each issue.)

**Proposed CAPA** (Explain proposed CAPA; *To be Completed on First Route*):

1.

**CAPA Outcome** (*To Be Completed on Second Route*)**:**

1.

**Change Control Request(s) associated with this CAPA:**

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**Note: Reference COMM-QA-076 Appendix A for instructions**

| **I. Effectiveness Checks** | | |
|---|---|---|
| **Projected Completion Date** | **Date Completed** | **Responsible Person (*Initials*)** |
| | | |

**Proposed Effectiveness Check**

(Explain follow-up action proposed to assess CAPA effectiveness; *To be Completed on First Route*)

1.

**Effectiveness Check Outcome**

(Explain outcome of effectiveness check and if considered effective; *To be Completed on Second Route*)

1.

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**Note: Reference COMM-QA-076 Appendix A for instructions**

**TAB: CAPA and EC - 2**

| **II. Corrective and Preventive Actions** | | |
|---|---|---|
| **Projected Completion Date** | **Date Completed** | **Responsible Person (*Initials*)** |
| | | |

◉ **Corrective Action** ○ **Preventive Action** (Select the action taken to effectively address each issue.)

**Proposed CAPA** (Explain proposed CAPA; *To be Completed on First Route*):

2.

**CAPA Outcome** (*To Be Completed on Second Route*)**:**

2.

**Change Control Request(s) associated with this CAPA:**

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**Note: Reference COMM-QA-076 Appendix A for instructions**

| **II. Effectiveness Checks** | | |
|---|---|---|
| **Projected Completion Date** | **Date Completed** | **Responsible Person (*Initials*)** |
| | | |

**Proposed Effectiveness Check**

(Explain follow-up action proposed to assess CAPA effectiveness; *To be Completed on First Route*)

2.

**Effectiveness Check Outcome**

(Explain outcome of effectiveness check and if considered effective; *To be Completed on Second Route*)

2.

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**Note: Reference COMM-QA-076 Appendix A for instructions**

**TAB: CAPA and EC - 3**

| **III. Corrective and Preventive Actions** | | |
|---|---|---|
| **Projected Completion Date** | **Date Completed** | **Responsible Person (*Initials*)** |
| | | |

◉ **Corrective Action** ○ **Preventive Action** (Select the action taken to effectively address each issue.)

**Proposed CAPA** (Explain proposed CAPA; *To be Completed on First Route*):

3.

**CAPA Outcome** (*To Be Completed on Second Route*)**:**

3.

**Change Control Request(s) associated with this CAPA:**

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# CAPA REPORT

**Note: Reference COMM-QA-076 Appendix A for instructions**

| **III. Effectiveness Checks** | | |
|---|---|---|
| **Projected Completion Date** | **Date Completed** | **Responsible Person** (Initials) |
| | | |

**Proposed Effectiveness Check**

(Explain follow-up action proposed to assess CAPA effectiveness; *To be Completed on First Route*)

3.

**Effectiveness Check Outcome**

(Explain outcome of effectiveness check and if considered effective; *To be Completed on Second Route*)

3.

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# CAPA REPORT

**Note: Reference COMM-QA-076 Appendix A for instructions**

**TAB: Risk Assessment**

| **Pre-CAPA Risk Assessment Summary**<br>(*Include details of original risk assessment, when applicable*) |
|---|
| **Severity Assessment Score (S):**<br><br>**Probability Assessment Score (P):**<br><br>**Detectability Assessment Score (D):**<br><br>**COMBINED RISK ASSESSMENT SCORE:** |
| **Effectiveness Check Risk Assessment Evaluation**<br>(Summarize overall risk assessment outcome after implementation of associated CAPAs**)** |
| *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.*<br><br>**Severity Assessment Score (S):**<br><br>**Probability Assessment Score (P):**<br><br>**Detectability Assessment Score (D):**<br><br>**COMBINED RISK ASSESSMENT SCORE:** |
| **SUMMARY OF RISK OUTCOME:**<br><br>☐ **N/A** |

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# CAPA REPORT

**Note: Reference COMM-QA-076 Appendix A for instructions**

## Risk Assessment Tables (From COMM-QA-077)

**Severity Risk Matrix**

| 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 Risk Matrix**

| 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 |

**Detectability Risk Matrix**

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

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**Note: Reference COMM-QA-076 Appendix A for instructions**

## TAB: External Reporting / Attachments

**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]

## Attachments

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**Note: Reference COMM-QA-076 Appendix A for instructions**

## TAB: Appendix

## Appendix A (From COMM-QA-076)

## Signature Manifest

**Document Number:** COMM-QA-076 FRM1 **Revision:** 05
**Title:** CAPA Report FRM1
**Effective Date:** 30 Oct 2020

All dates and times are in Eastern Time.

### COMM-QA-076 FRM1 CAPA Report FRM1

### Author

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Bing Shen (BS76) | | 23 Oct 2020, 03:52:40 PM | Approved |

### Medical Director

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Joanne Kurtzberg (KURTZ001) | | 23 Oct 2020, 05:18:07 PM | Approved |

### Quality

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Richard Bryant (RB232) | | 26 Oct 2020, 10:30:27 AM | Approved |

### Document Release

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Sandy Mulligan (MULLI026) | | 27 Oct 2020, 11:36:23 AM | Approved |