**CAPA Form**

Refer to *Procedure QP809: Corrective and Preventative Actions*

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| --- | --- | --- |
| CAPA ID: | Date initiated: | |
| CAPA criticality: | Proposed completion date: | |
| Associated records – ID #s: | | |
| Extension - New date: | | Cancelled - Date: |

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| Section 1: CAPA details (Completed by the Initiator/Department Manager as the ‘Owner’) | | | | | | | | |
| Initiator’s name: | | | | | | | Department: | |
| Description of the CAPA: | | | | | | | | |
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| Is this CAPA linked to a deviation? | | | | No | Yes. Dev ID: | | | |
| Is this CAPA linked to an audit citation? | | | | No | Yes. Audit ID: | | | |
| Is this CAPA linked to another quality system record? | | | | No | Yes. Reference: | | | |
| Have batches been impacted? | | | | No | Yes. #: | | | |
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| Does this CAPA affect registration? | | | | No | Yes. Products: | | | |
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| Department Manager: | | Signature: | | | | | | Date: |
| QA initial reviewer: | | Signature: | | | | | | Date: |
| Section 2: Investigation | | | | | | | | |
| Describe the investigation (tools used to identify root cause): | | | | | | | | |
| [If root cause established in parent quality system (eg, deviation, customer complaint), provide reference number.  If root cause established within CAPA, provide details as attachment.] | | | | | | | | |
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| Define the root cause(s) of the issue: | | | | | | | | |
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| Section 3: CAPA implementation plan (completed by the Initiator) | | | | | | | | |
| Corrective actions to address the issue (short term) | | | | | | | | |
| List corrective actions: | | | | | | | | |
| [Add or remove lines as required] | | | | | | | | |
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| Preventative actions to address deficiencies (longer term) | | | | | | | | |
| List preventative actions: | | | | | | | | |
| [Add or remove lines as required] | | | | | | | | |
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| **Risk Assessment required?**  **No**  **Yes** (attach) | | | | | | | | |
| Change Control required? | Yes  No | | CC Number: | | |  | | |

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| CAPA Tasks: | | | | | |
| Task no. | Task description | Resp. | Due date | Completed (Initial/Date) | Evidence  (ref. attachment if applicable) |
|  | [Add or remove tasks as required] |  |  |  |  |
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| Section 4: CAPA effectiveness check | | | | | | | | | | | | | | | |
| Define time from implementation to effectiveness review: | | |  | | | | | | |  | | | | |  |
| Define what should be reviewed/checked: | | | | | | | | | |  | | | | |  |
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| CAPA effectiveness summary | | | | | | | | | |  | | | | |  |
| Was the CAPA effective? | | | | | | | | | |  | | | | |  |
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| Are there any further actions required? | | | | | | | | | |  | | | | |  |
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| Section 5: Pre-implementation approval | | | | | | | | | | | | | | | |
| CAPA Owner: | Signature: | | | | | | | Date: | | | | | | | |
| Stakeholder: | Signature: | | | | | | | Date: | | | | | | | |
| Quality Manager: | Signature: | | | | | | | Date: | | | | | | | |
| CAPA is approved to commence: | | | | | | | | Yes | | | | | No | | |
| **QA CAPA Register** updated – date: | | | | | | | | | | | | | | | |
| Section 6: Implementing actions (completed by the Initiator) | | | | | | | | | | | | | | | |
| All documentation is complete and appropriate: | | | | | | | | Yes | | | | | No | | |
| All CAPA tasks in Section 3 have been completed: | | | | | | | | Yes | | | | | No | | |
| CAPA evidence is present and correct: | | | | | | | | Yes | | | | | No | | |
| CAPA actions are effective to prevent recurrence/occurrence: | | | | | | | | Yes | | | | | No | | |
| *Section 6: Implementing actions continued…* | | | | | | | | | | | | | | | |
| Summarise the outcome of the CAPA: | | | | | | | | | | | | | | | |
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| The CAPA implementation is complete and ready for QA approval and closeout | | | | | | | | | | | | | | | |
| CAPA Owner: | Signature: | | | | | | Date: | | | | | | | | |
| Section 7: QA closeout – post-implementation approval | | | | | | | | | | | | | | | |
| CAPA outcome acceptable? | | | | | | | | | Yes | | | | | No | |
| Implementation plan was followed? | | | | | | | | | Yes | | | | | No | |
| All evidence is attached (reports, data or records etc.)? | | | | | | | | | Yes | | | | | No | |
| Were the corrective actions effective? | | | | Ongoing monitoring | | | | | Yes | | | | | No | |
| All implementation risks were appropriately managed? | | | | | | | | | Yes | | | | | No | |
| Comments: | | | | | | | | | | | | | | | |
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| QA Manager: | | Signature: | | | | | | | | | Date: | | | | |
| CAPA is closed: | | | | | | Yes | | | | | | No | | | |
| **QA CAPA Register** updated – date: | | | | | | | | | | | | | | | |
| Section 8: Cancellation or Extension | | | | | | | | | | | | | | | |
| Type of action:  Cancellation  Extension | | | | | | | | | | | | | | | |
| Reason: | | | | | Date notified: | | | | | | | | | | |
| Requested by: | | | | | | | | | | | Date: | | | | |
| Approved  Rejected. Reason for rejection: | | | | | | | | | | | | | | | |
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| QA Manager: | | Signature: | | | | | | | | | Date: | | | | |

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP809 | Corrective and Preventative Action |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.