Deviation Report

Refer to Procedure QP805: Managing Deviations

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| --- | --- | --- | --- |
| Dev ID number: | | Date initiated: | |
| Deviation level: | | Proposed date completed: | |
| Deviation type: | Non-conforming material/product/result/data | | |
| Deviation from procedure | Deviation from regulations | | Planned deviation |
| Deviation within facility/services/environment | | | Adverse trend detected |

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| Section 1: Deviation details (Completed by the Department Manager (or delegate) as the ‘Owner’) | | | | | | | | | | | |
| Name: | | | | | | | | | Department: | | |
| Description of the deviation: | | | | | | | | | | | |
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| Has product been quarantined? | | | No | | | Yes - Location: | | | | | |
| Batch numbers/codes quarantined: | | | | | | | | | | | |
| List other immediate/containment actions taken: | | | | | | | | | | | |
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| Section 1: Deviation details *continued…* | | | | | | | | | | | |
| Does this deviation affect registration? | | | | | No | | | Yes. Products/countries: | | | |
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| Department Manager: | | | | | Signature: | | | | | | Date: |
| Quality Manager: | | | | | Signature: | | | | | | Date: |
| Section 2: Assigning deviation level | | | | | | | | | | | |
| Has a risk assessment been completed for the deviation? | | | | | | | Yes. See attached record | | | | |
| No. Justification for no risk assessment: | | | | | | | | | | | |
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| Deviation level assigned: | | Minor | | | | | Major | | | Critical | |
| Quality Manager: | | | | Signature: | | | | | | | Date: |
| Section 3: Complete the investigation (Complete each subsection as required by QO805 – Managing Deviations) | | | | | | | | | | | |
| Sources of information to review: | | | | | | | | | | | |
| Trend analysis & historical assessment | List any previous events related to this deviation (include frequency & impact): | | | | | | | | | | |
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| List any trends related to this deviation: | | | | | | | | | | |
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| Other comments: | | | | | | | | | | |
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| Section 3: Complete the investigation *continued…* | | | | | | | | | | | | | | | |
| Determine root cause  Not required | Type of root cause analysis tool used: | | | | | | | | | | | | | | |
| Root cause category: | | | | | Method | | | | | Materials | | | | |
|  | | | | | Measurement | | | | | Machines | | | | |
|  | | | | | People | | | | | Environment | | | | |
| Summary of root cause analysis: | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | |
| Detailed root cause analysis attached? | | | | | | | | | Yes | | | Not required | | |
| Impact assessment | List any impacts of the deviation on related batches or products (including those in the marketplace), results, locations or systems not already included: | | | | | | | | | | | | | | |
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| List supplier(s) of raw materials or components associated with the deviation: | | | | | | | | | | | | | | |
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| Detailed impact assessment report attached? | | | | | | | | | Yes | | | Not required | | |
| Section 3: Complete the investigation *continued…* | | | | | | | | | | | | | | | |
| Corrections & Corrective actions  Not required | List the proposed corrections required to address the outcome of the deviation: | | | | | | | | | | | | | | |
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| List the proposed corrective actions to prevent the deviation from reoccurring: | | | | | | | | | | | | | | |
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| Non-conforming product  Not applicable | Identify how non-conforming product shall be managed:  Reprocessed  Reworked  Accepted  Rejected  Re-assigned  Returned | | | | | | | | | | | | | | |
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| Section 4: QA review of the investigation (completed by the Quality Manager) | | | | | | | | | | | | | | | |
| Approved to implement | | Approved to implement with the following additional actions: | | | | | | | | | | | | | |
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| Rejected. Justification: | | | | | | | | | | | | | | | |
| Any QA-related comments: | | | | | | | | | | | | | | | |
| **QA Deviation Register** status updated? Date: | | | | | | | | | | | | | | | |
| Quality Manager: | | | | Signature: | | | | | | | | | Date: | | |
| Section 5: Evidence of implemented corrections/corrective actions (Completed by the Department Manager (or delegate) as the ‘Owner’) | | | | | | | | | | | | | | | |
| Description or Quality System reference (e.g. CAPA or CC) | | | | | | | | | Date initiated | | | Closed (Yes/No) | | | |
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| Copies of reports, data or records attached? | | | | | | | | Yes | | | | | | | Not required |
| Any samples or rejects have been disposed of or placed in appropriate storage? | | | | | | | | Yes – Date: | | | | | | | Not required |
| Retention samples have been returned to the retention store? | | | | | | | | Yes – Date: | | | | | | | Not required |
| Date effectiveness check(s) completed (if required): | | | | | | | | | | | | | | | |
| Were the corrective actions effective? | | | | | | | | Yes | | | | | | | No |
| If no, describe the outcome and proposed further actions to eliminate the deviation: | | | | | | | | | | | | | | | |
| Section 6: Cancellation or Extension (if not applicable, strike out section and initial/date) | | | | | | | | | | | | | | | |
| Type of action:  Cancellation  Extension | | | | | | | | | | | | | | | |
| Reason: | | | | | | | | | | | Date notified: | | | | |
| Requested by: | | | | | | | | | | | | | | Date: | |
| Approved  Rejected. Reason for rejection: | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| Quality Manager: | | | Signature: | | | | | | | | | | | Date: | |
| Section 7. Closeout | | | | | | | | | | | | | | | |
| Final batch disposition status: | | | | | | | | | | | | | | | |
| Is the risk class still appropriate? | | | | | | | Yes | No – attach supporting risk assessment | | | | | | | |
| Summary justification for change in risk class: | | | | | | | | | | | | | | | |
| Comments: | | | | | | | | | | | | | | | |
| Quality Manager: | | | | | Signature: | | | | | | | | | Date: | |

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
|  |  |  |  |

Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP805 | Managing Deviations |

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.

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