Change Control Form

Refer to *Procedure QP703: Change Control*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Change request information: | | | | | | | | |
| Change requested by: | | | | Ext: | | | Date: | |
| Description of change: | | ❒ Document ❒ Equipment ❒ Product ❒ Other | | | | | | |
| [list what changes are required, systems/product affected etc] | | | | | | | | |
|  | | | | | | | | |
| Reason for change: [Justify why the change is necessary] | | | | | | | | |
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|  | | | | | | | | |
| Effect of change: | | | | | | | | |
| Product affected: | ❒ Yes ❒ No ❒ NA | | Revalidation required: | | | ❒ Yes ❒ No ❒ NA | | |
| Equipment/facility change: | ❒ Yes ❒ No ❒ NA | | Process flowchart affected: | | | ❒ Yes ❒ No ❒ NA | | |
| Procedures/Training update required: | ❒ Yes ❒ No ❒ NA | | Customer approval required: | | | ❒ Yes ❒ No ❒ NA | | |
| Registration impacted: | ❒ Yes ❒ No ❒ NA | | Document update(s) required | | | ❒ Yes ❒ No ❒ NA | | |
| Risk Assessment required: | ❒ Yes ❒ No ❒ NA If ‘No’ provide justification: [eg. Minor change] | | | | | | | |
|  |  | | | | | | | |
| Other impacts of the change: | | | | | | | | |
| Edit the above check boxes for standard effects of change to be relevant to your type of products and processes | | | | | | | | |
| For example, customer approval would only be required if you are a subcontractor. | | | | | | | | |
|  | | | | | | | | |
|  | | | | | | | | |
| Department Manager: | | | Title: | | | | | Date: |
| Approval of change | | | Implementation date: | | | | | Date: |
| Approved ❒ Rejected ❒ Reason for Approval/Rejection: | | | | | | | | |
|  | | | | | | | | |
| Review, verification and validation instructions and acceptance criteria: | | | | | Additional pages attached? ❒ Yes ❒ No | | | |
| [List or reference inspections, tests and other activities required to implement / validate the change; and applicable acceptance criteria] | | | | | | | | |
| [Add rows as required.] | | | | | | | | |
|  | | | | | | | | |
| Approved by Quality Manager: | | | Title: | | | | | Date: |
| Implementation verification and close out | | | | | | | | Date: |
| Documentation update completed/reviewed | | | ❒ Yes ❒ No ❒ Not Applicable | | | | | |
| Change Verification/Validation Records: | | | | | | | | |
| [List or reference of records of change implementation, verification and/or validation. Include attachments as required] | | | | | | | | |
| [Add rows as required.] | | | | | | | | |
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|  | | | | | | | | |
| Corrective Action: Yes ❒ No ❒ CAPA No.: | | | | | | | | |
| Implementation Authorised by Quality Manager (or delegate): | | | Title: | | | | | Date: |

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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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 |
| QP703 | Change Control |

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.