Audit Non-Conformity Report

Refer to *Procedure QP802: Internal Quality Audits*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Department | Audit ref: Date or number/letter code | | | |
| Area/Operation: | | Responsible Supervisor: | | |
| Procedure/Work Instruction/Standard:  Reference the document/requirement against which this non-conformity is noted | | | | |
| Auditor: | | ISO13485:2016Clause: | | |
| Non-conformity | Date: | | | Finding No.: |
| Auditor uses this block to describe the non-conforming condition | | | | |
| Auditor: (date, sign) | | Responsible Supervisor: (date, sign) | | |
| Corrective action | Date: | | | Finding No.: |
| Responsible manager/supervisor uses this block to propose a corrective action | | | | |
| Auditor: (date, sign) | | Responsible Supervisor: (date, sign) | | |
| Follow-up and closeout | Date: | | Finding No.: | |
| Initial follow-up assessment:  Approved ❒ Yes ❒ No ❒ Extension | | Subsequent follow-up assessment: Date:  Approved ❒ Yes ❒ No ❒ Extension | | |
| Documenter references what objective evidence was reviewed for closeout | | Use this block only when the non-conformity could not be closed out on the first follow-up visit | | |
| Auditor: (date, sign) | | Auditor: (date, sign) | | |

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
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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 |
| QP802 | Internal Quality Audits |

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.

DOCUMENT END