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| --- | --- | --- | --- |
| **­­­­­Report Number**  (ie IQA- or MON-) |  | | |
| **Non-conformance number:**  (ie IQA-NC- or MON-NC) |  | | |
| **Response to Non-conformance**  **(Including correction)** |  | | |
| **Root Cause** |  | | |
| **Corrective Action Plan:**  (Action taken to eliminate the cause of the identified non-conformance) |  | | |
| **Preventive Action Plan:**  (Action taken to prevent the occurrence of a potential non-conformance in the future) |  | | |
| **Responsible Personnel:** |  | **Signature and Date:** |  |

This template may be used for audit, monitoring or anomaly.

Example

|  |  |  |  |
| --- | --- | --- | --- |
| **­­­­­Report Number**  (ie IQA- or MON) | IQA-1 Audit of TRIAL | | |
| **Non-conformance number:**  (ie IQA-NC- or MON-NC) | IQA-NC-1 | | |
| **Response to Non-conformance**  **(Including correction)** | Correction fluid was used to obscure incorrect study data entry. | | |
| **Root Cause** | Insufficient training on good documentation practice. | | |
| **Corrective Action Plan:**  (Action taken to eliminate the cause of the identified non-conformance) | The study team will no longer allow the use of correction fluid on study documents. Corrections to data entry will be lined through once, initialed and dated, with an explanation as to why the changes were made. | | |
| **Preventive Action Plan:**  (Action taken to prevent the occurrence of a potential non-conformance in the future) | All study team members will be re-trained in SOP-QA-27 - Good Documentation Practice. Training will be documented in a Training log. | | |
| **Responsible Personnel:** | Prof Smith | **Signature and Date:** | J Smith  12.2.19 |