**Validation Exception Report**

Refer to Procedure QP710: Validation of Processes and Equipment

| Project Name or Change Control No. | | | |  | | |
| --- | --- | --- | --- | --- | --- | --- |
| Exception Report Number: | | | | [Protocol number-ERXX]  Must align with site procedure | | |
| Title of Document Under Test | | | |  | | |
| Reference Number of Document Under Test | | | |  | | |
| Tests Affected (section numbers) | | | |  | | |
| Date Exception Observed | | | |  | | |
| Exception Observed by: | | | |  | | |
| Description of Exception | | | | | | |
| Provide details of the specific event that has given rise to the exception, in particular, how the actual event differed from the criterion or instruction. Do not make judgements or provide explanations at this point. | | | | | | |
| Cause of Exception | | | | | | |
| Explain the cause of the exception if known, or the most probable explanation where uncertainty exists (the uncertainty should also be stated). This section should summarise the results of any root-cause analysis performed. Attach data to support the assertion where appropriate. | | | | | | |
| Impact of Exception | | | | | | |
| Explain the impact to the validation exercise of the exception. The impact should be considered in terms of the ability to complete the exercise, and also the effect on the risk categorisation of the requirement. Categorise as:  None: There is no impact on the validation outcome and no further corrective action is required.  Minor: No retesting is required, but minor corrective action, such as retraining or equivalency data is required.  Major: Modification or retraining, followed by retesting or revalidation is required, or the result has highlighted an “unvalidatable” item. | | | | | | |
| Prepared By | | | | | | |
| Name: |  | Signature: |  | | Date: |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Proposed Actions | | | | | | | | |
| Action | | | | Responsibility | | | Due Date | |
| List all actions arising from the impact assessment. These may be actions to enable successful completion of the test / protocol, or actions arising from the failure to validate. | | | |  | | |  | |
| Prepared By | | | | | | | | |
| Name: |  | Signature: |  | | Date: | | |  |
| Corrective Action Approval | | | | | | | | |
| Signatures below indicate that QA concurs with root cause analysis and approves the implementation of proposed corrective actions.  Note: Where implementation of emergency corrective actions was required prior to preparation of the report, this signatory box shall be crossed out and marked “NA”. Signature below shall represent Approval to Proceed. | | | | | | | | |
| Quality Approval | | | | | | | | |
| Name: |  | Signature: |  | | Date: | | |  |
| Verification of Corrective Actions | | | | | | | | |
| Action | | | | | | Completed Date | | |
| List all completed corrective actions for verification by QA. Where appropriate, attach supporting data. | | | | | |  | | |
| Exception Report Approval  Signature below verifies that:  The stated actions have been implemented and are deemed appropriate to resolve the exception.  Where actions were completed prior to preparation of the report, justifications provided in the Proposed Corrective Actions section adequately explain why actions were required in advance.  Where actions have not been implemented, the ongoing actions are assigned to [Company] quality systems. The ongoing actions are appropriately referenced in the report and are traceable to conclusion.  The exception report number is listed in the protocol document exception report register and will be included in the final validation package. | | | | | | | | |
| Quality Approval | | | | | | | | |
| Name: |  | Signature: |  | | Date: | | |  |

**DOCUMENT END**

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 |
| QP710 | Validation of Processes and Equipment |

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.