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| **GENERAL INFORMATION ABOUT THE AUDIT** | | |
| Auditor: | Audit Report #, Name or Title: | Date of Audit (YYYY-MM-DD): |

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| **RESPONSE TO AUDIT FINDINGS** | | | | |
| **Audit finding #:** | | *<Enter the # from the audit report>* | | |
| **Description:** | | *<Describe finding>* | | |
| **Significance:** | | *<Enter significance provided by auditor (e.g. minor/major, high/medium/low, etc.) or determine significance>* | | |
| **Impact** | | *<Enter the impact or potential impact of the audit finding relative to business and operations>* | | |
| **ROOT CAUSE ANALYSIS** | | | | |
| *<Add details about the root cause analysis.>* | | | | |
| **Type** | **#** | **Description** | **Assigned to** | **Due Date**  (YYYY-MM-DD) |
| **Corrective** Action(s) | *<e.g. CA1>* | *<If applicable, describe the corrective action(s) required to correct the defect/deviation. Be as specific as possible with quantifiable actions that can be verified. Make sure to address the root cause of the finding and auditor’s recommendations. If none are required, enter NONE.>* |  |  |
| *<e.g. CA2>* | *<Add lines if needed>* |  |  |
| **Preventive** Action(s) | *<e.g. PA1>* | *<If applicable, describe the preventive action(s) required to ensure repeat violations/deviations are eliminated. Be as specific as to what actions are taken. They should be tied to root cause of the finding and include follow-up actions to ensure continued compliance. If none are required, enter NONE.>* |  |  |
| *<e.g. PA2>* | *<Add lines if needed>* |  |  |
| **Comments:** | | | | |
| *<Enter any relevant comment here>* | | | | |

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| **PLAN APPROVAL** | |
| RAQA Representative *(Print Name)*: | Signature & Date: |

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| **IMPLEMENTATION AND EFFECTIVENESS VERIFICATION** | |
| **Implemention Discussion:** *<Include references where corrective and preventive actions planned were implemented. If appropriate, use the following table.>*   |  |  |  |  | | --- | --- | --- | --- | | **Action #** | **Status** | **Implementation** | **Objective Evidence** | | *CA1* | *Completed YYYY-MM-DD* | *<Describe the actions that were implemented.>* | *<e.g. attachment ref #>* | | *CA2* | *Completed YYYY-MM-DD* | *<Describe the actions that were implemented.>* | *<e.g. attachment ref #>* | | *PA1* | *Open* | *<Describe the actions that were implemented.>* | *<e.g. attachment ref #>* | | *PA2* | *Open* | *<Describe the actions that were implemented.>* | *<e.g. attachment ref #>* | | *…* | *…* | *<Add lines if needed>* | *<Add lines if needed>* | | |
| **Effectiveness Verification:** *<Describe how items were verified for effectiveness in fully correcting the issue and actions did not cause other quality problems>* | |
| Quality Representative *(Print Name)*: | Signature & Date: |

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| **AUDIT RESPONSE CLOSURE** | |
| Quality Representative *(Print Name)*: | Signature & Date: |