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| **FSOP050.1**  **CORRECTIVE AND PREVENTATIVE ACTION REPORT (CAPA)** |

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| **CAPA Number :** |  | **Location of Adverse Event/Non-conformity :** |
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| 1. **Details of the adverse event/non-conformity** *(i.e. Problem definition statement, description of the event, non-conformity)***:** | |
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| **Detected/observed by:** | **Date:** |

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| 1. **Disposition:** (*immediate remedial action taken; include an assessment of impact***):** | | |
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| **Risk to Project - Impact Categorisation: Minor Major** | | |
| Proposed by: | | Date: | Implementation date: |

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| 1. **Investigation: Details of findings and causes with supporting evidence if applicable:**   *(There is always a prexisting condition and an action (or catalyst) that when combined result in a*  *problem. Always look for at least 2 causes of any problem)* | | |
| Investigated by: | Date started: | Date finished: |

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| 1. **Details of Corrective/Preventative Action(s),** including consequences, quality improvement   suggestions, SOP changes, verification testing (\*indicate as CA or PAe.g. PA/23/001)   |  |  |  |  | | --- | --- | --- | --- | | **Number\*** | **Action** | **Responsible Person** | **Implementation Date** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | | |
| **Submitted to Quality Manager:** | **Date:** |

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| 1. **Verification of validity of Corrective and/or Preventative Action** | | | |
| **Corrective Action:**  Addresses the root cause?  Prevents recurrence?  Valid  Invalid. Issue new CAPA  Remarks: | | **Preventative Action:**  Addresses the root cause?  Prevents occurrence?  Valid  Invalid. Issue new CAPA  Remarks: | |
| Signature (QM): | Date: | Signature (QM): | Date: |

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| 1. **Follow up of Corrective/Preventative Action taken** | | | |
| **Implementation of corrective action(s) is:**  Implemented  Not implemented. Issue new CAPA  Remarks: | | **Implementation of preventative action(s) is:**  Implemented  Not implemented. Issue new CAPA  Remarks: | |
| Signature (QM): | Date: | Signature (QM): | Date: |

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| 1. **Verification of Effectiveness of Implemented Corrective/preventive Action** | | | |
| **Corrective Action is:**  Effective  Not effective. Issue new CAPA  Remarks: | | **Preventative Action is:**  Effective  Not effective. Issue new CAPA  Remarks: | |
| Signature (QM): | Date: | Signature (QM): | Date: |

Instructions:

1. The person observing or detecting the adverse event or non-conformity shall fill in section A
2. The affected person shall fill in sections B, C, D
3. The Quality Manager (QM) or Management representative shall fill in sections E, F, G