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| **CAPA Request** | |
| **CAPA Number**  (to be assigned by Quality Organization) |  |
| **Initiator**  Position/Name/Date/Signature |  |
| **Related documents**  (Deviations/OOS/Complaints/Quality Defects investigation reports, audit reports, risk assessments, process/product/system reviews, Change records), if any |  |

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| **Summary of non-conformity or another undesirable situation** |
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| **Summary of Investigation** |
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| **Summary of Risk Assessment results** |
|  |
| **Summary of Root Cause(s)** |
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| **Proposed CAPA** | |
| **Corrective Action  Preventive Action** | |
| **Action description** | |
| Target Start Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Target End Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Expected output results after implementation** | |
| **CAPA Effectiveness Criteria** (for Corrective Actions only) | |
| **Affected Functions/Departments** **and their responsibilities** (additional evaluation and review may be required) | |
| **Expected CAPA Owner** (Position/Function/Department) | |

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| **CAPA Request approval** | | |
|  | Name/Position | Date/Signature |
| Initiated by: |  |  |
| Reviewed by:  Affected Functions/Departments representatives |  |  |
| Reviewed by CAPA Owner: |  |  |
| Reviewed by:  Quality Organization representative |  |  |
| Approved by: | Quality Management Director |  |