|  |  |
| --- | --- |
| **<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 |  |

|  |
| --- |
| **Summary of non-conformity or another undesirable situation** |
|  |
| **Summary of Investigation** |
|  |
| **Summary of Risk Assessment results** |
|  |
| **Summary of Root Cause(s)** |
|  |

|  |  |
| --- | --- |
| **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) | |

|  |  |  |
| --- | --- | --- |
| **<CAPA\_Request> approval** | | |
|  | Name/Position | Date/Signature |
| Initiated by: |  |  |
| Reviewed by:  Affected Functions/Departments representatives |  |  |
| Reviewed by CAPA Owner: |  |  |
| Reviewed by: | <QualityDesignee1> |  |
| Approved by: | <QualityOrganizationHead> |  |