**SECTION A:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **CHANGE REQUEST** | | | | | |
| **Change No.**  **Assigned by Quality Organization** |  | | | **Request Date** |  |
| **Applicable to** | Area  Utility  Product  System  Document  Equipment  Material  Instrument  Other | | | | |
| **Title of Change** |  | | | | |
| **Previous Change reference No. (if any)** | | |  | | |
| **Initiated By**  **(Name)** |  | | **Logged By:**  **(Name/Date/Signature)**  **Quality Organization** |  | |
| **Department** |  | |
| **CHANGE REQUEST (INITIATION)** | | | | | |
| **Existing system** | | | | | |
|  | | | | | |
| **Proposed change** | | | | | |
|  | | | | | |
| **Justification** | | | | | |
|  | | | | | |
| **Initiated by**  **(Name/Date/Signature)** | |  | **Approved by:**  **Initiator’s Manager**  **(Name/Date/Signature)** |  | |

**SECTION B:**

| **IMPACT ANALYSIS (EVALUATION)** | | | |
| --- | --- | --- | --- |
| **Impacted areas** | **Impact (Yes/No)** | **Impact description and justification** | **SMEs**  **(Name/Date/Signature)** |
| Process |  |  |  |
| Environment |  |  |  |
| Quality Parameter |  |  |  |
| Calibration |  |  |  |
| Stability |  |  |  |
| Process Validation |  |  |  |
| Qualification studies |  |  |  |
| Cleaning validation |  |  |  |
| Training |  |  |  |
| Hold time studies |  |  |  |
| Regulatory Approval |  |  |  |
| Product license / authorization |  |  |  |
| Product list |  |  |  |
| Cleaning/  Passivation/  Sanitation |  |  |  |
| Preventive Maintenance |  |  |  |
| Equipment / Instruments |  |  |  |
| Layout/ Drawing/ Diagrams/Design |  |  |  |
| Utility Impact |  |  |  |
| Specification for Product, Material |  |  |  |
| Stability studies |  |  |  |
| SOP / Protocol |  |  |  |
| Computerized Systems |  |  |  |
| Packing Material/ Pack type |  |  |  |
| Change parts / tools |  |  |  |
| Artwork |  |  |  |
| Risk Assessment |  |  |  |
| CAPA |  |  |  |
| Any Other |  |  |  |
| **Reviewed by:**  **Quality Management Director**  **Name/Date/Signature** | | |  |

**SECTION C:**

|  |  |  |  |
| --- | --- | --- | --- |
| **IMPLEMENTATION PLAN** | | | |
| **Action**  **item**  **number** | **Action item description** | **Responsible Department / Team** | **Expected completion date** |
|  |  |  |  |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
|  | **Name** | **Date/Signature** |
| **Prepared by:**  **Change Owner** |  |  |
| **Reviewed by:**  **Impacted Departments Heads** |  |  |
| **Approved by:**  **Quality Management Director** |  |  |

**SECTION D:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ACTION ITEM CLOSURE** | | | | |
| **Action item number** | **Action item completion date** | **Responsible Department / Team** | **Reference Document Details** | **Action item status** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

|  |  |
| --- | --- |
| **CHANGE SUMMARY** | |
| **Change implemented  Change not implemented** | |
| **Closure assessment conclusion:** | |
| **Reviewed by:**  **Quality Organization representative** | **Name/Date/Signature** |
| **Change status:**  **Closed**  **Cancelled** |

|  |  |  |
| --- | --- | --- |
|  | **Name** | **Date/Signature** |
| **Prepared by:**  **Change Owner** |  |  |
| **Reviewed by:**  **Impacted Departments Heads** |  |  |
| **Approved by:**  **Quality Management Director** |  |  |