**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** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
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| --- |
| **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** |  |  |