|  |  |
| --- | --- |
|  | **Function** |
| **Type of change / Function** | **Quality Management** | **Quality Control** | **Manufacturing** | **Supply Chain Operations** | **Regulatory Affairs** |
| **Change in Process/ Parameters / Control** | + |  | + |  | + |
| **Packaging Material** | + | + | + | + | + |
| **Labeling** | + | + | + | + | + |
| **New production Equipment** | + |  | + | + |  |
| **Product/Equipment Discontinuation** | + |  | + | + | + |
| **Batch Size** | + | + | + |  | + |
| **New Product** | + | + | + |  | + |
| **Site Transfer** | + | + | + | + | + |
| **Utilities/Equipment** | + | + | + | + |  |
| **Facility/Layout** | + | + | + | + |  |
| **Vendor** | + | + | + | + | + |
| **Raw Materials** | + | + | + |  | + |
| **Shelf Life** | + | + | + |  | + |
| **Composition** | + | + | + |  | + |
| **Art Work/ New Pack** | + | + | + | + | + |
| **GxP Computerised System** | + | + | + | + |  |
| **Analytical Test Method** | + | + |  |  | + |
| **Change in Equipment (production)**  | + |  | + | + |  |
| **Supplier Change** | + | + | + | + | + |
| **Cleaning Procedure** | + | + | + | + |  |
| **Sampling Procedure** | + | + |  |  |  |
| **Hazards** | + |  |  | + |  |
| **Environmental Monitoring** | + | + | + |  |  |
| **QC/ Instruments** | + | + |  |  |  |
| **Material Storage Area** | + |  |  | + |  |