|  |  |  |
| --- | --- | --- |
| **Examples of change** | **Type of change** | **Guideline to initiate change** |
| * Introduction of new product * Introduction of new system | Permanent change | * Raise Permanent change |
| Modification of existing area | Permanent change | * Raise direct change control |
| Introduction of new Machine | Permanent change | * Raise direct change control |
| * Change in expiry * Change in specification/test method * Change in packaging material / pack style / printed text * Change in stability program * Change in control systems (eg. Computers) * Change in SOP * Change in batch manufacturing record (for formatting change). * Change in storage condition. | Direct permanent change | * Raise direct change control for permanent change if scientific rational or R& D batches data or historical data available. |

**Note: The above are only general guidelines and may change from case to case.**