**Change Control**

In pharmaceutical industries change control has an important role. In pharmaceuticals, every change is reported by change control process.

When a change is being made in any process or procedure it is reported by change control procedure and that is approved by the company authority. Change control is used to control the changes made in the pharmaceutical industry

Following are the changes which are to be reported by change management process:

#### Production

* Change in Location.
* Change in Equipment.
* Critical Process control parameters.
* Change in Batch size.

1. **Engineering**

•Change in any equipment.

•Critical Part of any equipment.

* Facility, Design layout

1. **Research & Development**

•Change in Specifications of Raw Material/Packaging Material/Finished product.

•Addition / Deletion of any Raw material in the product.

•Change in quantity of Raw material in the product.

•Addition / Deletion of any manufacturing Steps.

•Change in Shelf Life.

•Change in Environmental Conditions.

•Change in Specifications of In-process / Intermediate materials.

•Change in Storage conditions.

•Change in method of analysis or change in sampling plans and method.

•Change in Hardware / Software of any Computerized Analytical Instruments.

Change in Stability Protocols

1. **Materials (Raw & Packaging Material)**

•Change in source of any Raw Material or primary packaging material.

1. **Quality Control**

•Change in method of analysis or change in sampling plans and method.

•Change in Hardware / Software of any Computerized Analytical Instruments.

•Change in Stability Protocols.

•Change in specifications of Raw Material / Packaging Material / Finished product.

•Change in Specifications of In Process / Intermediate Materials.

1. **Quality Assurance**

•Change in Sampling Plan/Quantity of Samples.

•Change in Documents and SOPs.

•Change in Validation Protocols.

1. **Information Technology**

•Change in Hardware / Software.

1. **Cleaning Procedure**

Change in cleaning steps.

•Change in cleaning aids.

•Change in cleaning agents.

**Types and Procedure of Change Control**

1.The initiating department shall initiate the change as per the change control format no.

2.The initiating department shall furnish the details very clearly in the form of present process/use, proposed change, Justification & impact analysis and acceptance criteria.

3.The initiating department shall also define changes as major or minor based on product quality or its impact on safety, health and environmental aspects. Some of the major and minor changes are listed below: -

**3.1Major Changes**

For a substance of chemical and microbiological quality evaluation.

* Addition or deletion of a step or addition of an alternative/new step in the formulation manufacturing process.
* Addition of a new manufacturing site with modification of the formulation manufacturing process described in the original dossier/document.
* Change in input quantities of formulation manufacturing process.
* Changes in the quality of raw material(s) or key intermediate(s) used in the formulation manufacturing process

**3.2Minor Changes**

•Change in the administrative references (name/company name, address) of the certificate holder.

•Change in the references (name/company name, address) of the manufacturing site.

•Change or updating of the methods of analysis used to test the substance.

•Change in the specifications of the substance.

•Change in the supplier of starting and packing material.

•Change in the batch size.

•Addition of a new manufacturing site in the same site as described in the original dossier.

•Change in the documents like SOPs etc.

4.The Initiating department shall forward the proposal as per the requirement to Formulation & Development Department for comments and clearance.

5.After giving comments/clearance, Formulation & Development shall forward the change control form to Quality assurance department.

6.On receipt of Change control form from F & D department, QA shall assign the Change control number as per the procedure is given below:

Assigning a change control number

-Each change control number contains seven digits.

-First two digits represent change control code.

-Third, fourth and fifth digit represent sequential change control No. (001 to 999)

-Sixth and seventh digit represents last two digits of the current year. (e.g.01, 02, 03… 99).

For example, following change control no is decoded as explained. CC-001/ 18.

CC = Change control code.

001= Sequential Change control Number (001, 002, 003… 999).

18= Current year 2018 (Last two digit of current year)

1. QA shall enter the details of Change in the Change control register.
2. QA shall evaluate the feasibility of the change and forward the change control form to Regulatory affairs, if required.

9.Regulatory affairs shall evaluate the change in terms of any need to inform the customer or any updation in dossiers etc. and forward the change to Site Quality Head.

10.Site Quality Head shall receive the comment from all the concerns and takes the decision of approving or rejecting the change.

11.On completion of the total procedure, QA shall formally enter the status in Change control Register and close the Change Control Procedure.

1. Put the stamp of ‘ OBSOLETE COPY’ on the old documents, where every this change control procedure is applicable.

|  |  |  |
| --- | --- | --- |
|  | Change Control No. |  |
| Stage/Document |  |
| Manufacturing Date |  |
| Implementation Date |  |
| 2. | Present Process/Use\* | Modification: Major/Minor |
| 3. | Proposed Process/Use\* |  |
| 4. | Justification/Impact of Change\* |  |
| 5. | Supporting Data(If Required) | Enclosed/Not Enclosed |
| 6. | Accepted Crieteria |  |
| 7. | Signature:  (Officer/Executive/Designee) (Head – Initiating Department) Date: | |

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| --- | --- | --- | --- | --- |
| 8. | Comments from F&D Department\*(if required) | | | |
|  | Modification: Major/Minor | | | |
|  | Date: | | | |
|  | Signature Manager-F&D | | | |
| 9. | Comments from Quality Assurance Department\* | | | |
|  | Modification: Major/Minor | | | |
|  | Regulatory Notification / approval Required / Not Required | | | |
|  | Type of analysis to be carried out (if any extra analysis | | | |
|  | is required, give details): | | | |
|  | Subsequent Stages Will be controlled/Not controlled | | | |
|  | Validation Status Will affected / not affected | | | |
|  | Date: | | | |
|  | Signature Manager - QA | | | |
| 10. | Comments from Regulatory Affairs Department\*(if required) | | | |
|  | Proposed Change is recommended/ Not recommended | | | |
|  | Date: | | | |
|  | Signature Manager – RA | | | |
| 11. | Comments from Engineering Department\* (If required) | | | |
|  | Date: | | | |
|  | Signature Manager - Engineering | | | |
| 12. | Comments | | | |
|  | Authorised / Not | | | |
|  | authorised | | | |
|  | Date: | | | |
|  | Signature: | Plant Head | Site Quality Head |  |
| \*Whenever applicable, append supporting documentation. | | | | |

Change Control Record:

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **S.No.** | **Date** | **Change**  **Control no.** | **Originating Dept** | **Product / Document** | **Stage** | **Details**  **of Change** | **Date of**  **Implementation** | **Status** | **Remarks** |
|  |  |  |  |  |  |  |  |  |  |
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