Centre for cGMP

PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA
(Set up by Ministry of Commerce & Industry, Govt. of India)

MANIPAL ACADEMY of HIGHER EDUCATION
(Institution of Eminence Deemed to be University)

Our Inspiration

Founder : Dr. T M A Pai, Padmashree awardee

Manipal College of Pharmaceutical Sciences | **In Association with IDMA and Pharmexcil**

Centre for cGMP presents to you "cGMP AWARENESS SERIES" (2025/01)
THINK cGMP – cGMP is LIFE

Commitment | Adherence | Creating Quality Culture

3 GOOD HEALTH AND WELL-BEING

Topic : Change control or Change Management in the Pharmaceutical lifecycle (Part 1 of 2)

4 QUALITY EDUCATION

What is a change control / change management?
A formal system by which qualified representatives of appropriate disciplines review proposed or actual change(s) that might affect a validated status.

What is the purpose of a change control / change management?
The intent of a change control is to determine the need for action(s) that would ensure the system is maintained in a validated state.

When a Change control is required?
Manufacturers should follow change-control procedures when a new system/plan or changes are planned to existing facility or site, equipment, instrument, test method, procedure, systems, starting material(s), packaging materials, intermediates, composition, batch size, vendor(s), processes which is considered to have a potential to have an adverse effect on the identity, strength, quality, purity, or potency of a drug product as these factors may relate to the safety or effectiveness of the drug product.

The change-control procedure and records should ensure that all aspects are thoroughly documented and approved, including regulatory approval where appropriate (variation).

Is the Change control a cGMP requirement?
Yes

How are the change(s) classified by the regulatory authorities?

USFDA Changes to an Approved NDA or ANDA,

- Change in Manufacturing Site
  - Major (e.g. A move to a different manufacturing site, when the new manufacturing site has never been inspected by FDA for the type of operation that is being moved); after obtaining prior approval
  - Moderate (e.g. A move to a different manufacturing site for the manufacture or processing of any drug product, in- process material, or drug substance that is not otherwise provided for in this guidance.), Changes Being Effected in 30 Days.
  - Minor change (e.g. A move to a different manufacturing site for secondary packaging or for labelling), Notification as part of Annual report.

Change in Manufacturing Process
- Major (e.g. changes to the particle size), after obtaining prior approval
- Moderate (e.g. Replacement of equipment with equipment of different design that does not affect the process methodology or process operating parameters.), Changes Being Effected in 30 Days
- Minor change (e.g. changes to equipment of the same design and operating principle-SUPAC guideline), Notification as part of Annual report.

Change in Specification

Change in Container Closure System (CCS)

Change in Labelling

Miscellaneous changes

Multiple Related Changes

EMA Classification of changes:
- Administrative changes (e.g. changes to date of GMP audit),
- Quality changes (e.g. introduction of new site, change in equipment, starting material, packaging material, test method, specification, procedure, method etc),
- Non-clinical changes (e.g. Pharmacovigilance),
- Editorial changes (e.g. alignment, table, flow chart, header etc.);

Changes considering the following variations
- Type IA/IAIN, (12 months/immediate notification)
- Type IB (Tell, Wait for 30 days and Do procedure) and
- Type II Variation, after approval

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In Part 2, the change control process, requirements and demystification of similar terminologies (like-for-like, exact equivalent, functionally equivalent,) and approaches such as bracketing, matrix and family (grouping) approach will be discussed.

An Initiative of Centre for cGMP, MAHE, Manipal | Designed at : Manipal Institute of Communication, MAHE, Manipal