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

Manipal College of Pharmaceutical Sciences | In Association with IDMA and Pharmexcil | Founder : Dr. T M A Pai, Padmashree awardee

Centre for cGMP presents to you "cGMP AWARENESS SERIES" (2025/02)
THINK cGMP – cGMP is LIFE

Commitment | Adherence | Creating Quality Culture

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

What is a change control / change management?

What is the change control process?

- A change control shall be assigned with a unique number, shall clearly explain the current scenario, proposed change(s), reason for the change(s), Classification of the proposed change(s) and the impact, list of actions, timelines, responsibility, review by the cross functional team (CFT) including regulatory department and approval by Quality unit.
- The proposed changes can be implemented only after the QA approval to ensure no unauthorised modification(s) or change(s) or alteration(s) has been made in the product lifecycle. The actions shall be tracked, and the documented evidence shall be provided against each listed action.
  Once all the listed actions are completed, the change control shall be reviewed by the cross functional team (CFT) including regulatory department and approval by Quality unit and the change control is closed.
- The process can be either manual or by validated electronic systems.

In the pharmaceutical lifecycle environment, selecting an appropriate replacement or spare parts or approach often depends on the classification of equivalency of change(s). The extent of verification/qualification/validation/additional evaluation depends upon the equivalency and complexity of change(s) and the impact on the product quality. When replacing equipment, spare part(s), material(s) the change must be assessed to ensure the new equipment or spare part or product is equivalent or suitable for the intended purpose and maintained in a qualified / validated state. This awareness series explores the nuances of some closely related terminologies and approaches frequently encountered in this context such as "like-for-like", "exact equivalent" and "functionally equivalent".

Considerations for a filter	Original or In-use or Existing	Replacement		
		Like-for-like (OEM)	Exact equivalent	Functionally equivalent
Manufacturer	COPS	COPS	*PAIS*	*PAIS*
Part No.#	1997	1997	*abcd*	*alpha*
Model	5"	5"	5"	5"
Nominal pore size	0.22 µm	0.22 µm	0.22 µm	0.22 µm
Filter media	PVDF	PVDF	PVDF	*PES*
Property	Hydrophilic	Hydrophilic	Hydrophilic	Hydrophilic
Bacteria retention	>10^7 CFU/cm²	>10^7 CFU/cm²	>10^7 CFU/cm²	>10^7 CFU/cm²
Purpose	Sterile filtration of liquid	Sterile filtration of liquid	Sterile filtration of liquid	Sterile filtration of liquid
Flow rate	High	High	High	High
Serial No.	*1234*	*6789*	xyz31	*beta75*
Lead time	3 Months	3 Months	1 Month	2 Weeks
Change control		Not required	Required	Required

Note:
Types of changes: Classified as Minor, Major or Critical & shall be defined in SOPs / as per Guidelines.

Identical
Meaning: Replacing a part with one that is an exact match in every way: same manufacturer, material, batch number, and specifications.


HSM 500


HSM 500

Similar
Meaning: Replacing a part with one that is close in characteristics but not an exact match. It may fit and work but could compromise performance.


HSM 500


HSM 200

Bracketing Approach:
Bracketing qualifies the process that represents the extreme of process variables under the premise that the extremes are fully representative of intermediate groups.

Assay of blend	Common Blend 100 mg drug / 200 mg		
Tablet weight	200 mg	400 mg	800 mg
Label claim	100 mg	200 mg	400 mg

Bulk	10 000 Liter		
Fill volume	50 ml	100 ml	250 ml

Matrix approach:
Configuration of the same process and the product have more than one variable, e.g. Representative to cover the highest process variability shall be covered i.e. lowest and highest fill volume, lowest and highest concentration etc.

Concentration	2mg/ml	4mg/ml	5mg/ml	6mg/ml
Fill volume	1ml	2 ml	5 ml	10 ml
Final product strength	2mg	8mg	25mg	60mg

Family (Grouping) approach:
When multiple related but different entities can be grouped so that a single one represents the common characteristics or worst case of each group.
e.g. Product Grouping, Equipment grouping, etc

	Granulation		
	1	2	3
Mixer	HSM-500	HSM-500	HSM-500
FBD	FBD-750	FBD-750	FBD-750
Blender	OGB-1000	OGB-1000	OGB-1000

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