www.gampservices.com
sanjeev@gampservices.com

Decommissioning & Decontamination Process in Pharmaceutical & Biotech Plants

Risk Based Approach to maintaining GMP throughout a decommissioning process

The retirement and decommissioning process is the last stage in application or product life cycle management.

Many different factors can trigger this event such as technological advancement, business needs & acquisitions/mergers while the underlying business process can become obsolete, etc.

In regulated life science companies, the retirement & decommissioning process should be planned & documented.

Associated records need to be retained as per the approved validation plan & procedures. The record retention requirements can vary depending on the type of records.

Once a facility or equipment has served its purpose and is no longer required, it has to be decommissioned & decontaminated in accordance with current legislation.

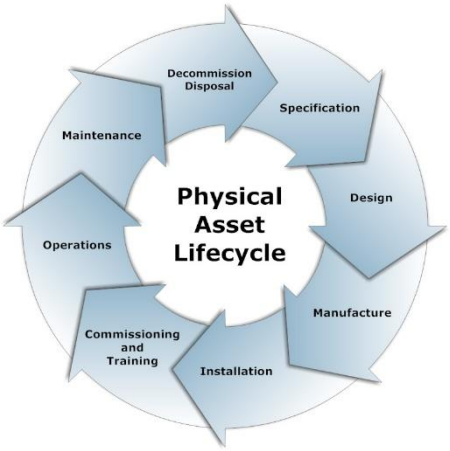
Decommissioning qualified equipment is a critical process that ensures the safe and responsible removal of assets from service. Whether it's a piece of laboratory equipment, a manufacturing machine, or an IT server, proper decommissioning procedures **protect data, the environment, and personnel.**

Properly decommissioning qualified equipment is a multi-faceted process that requires careful **planning, execution, and documentation**.

The GAMP Group can assist with the process of decommissioning in accordance with the Validation Life Cycle Model, which outlines the regulatory requirements for the decommissioning of Validated Processes, Systems, Equipment and Facilities within the Pharma and Biotech industries.

Our team also have extensive expertise in the decontamination of all types of manufacturing, clinical trials, R&D and Bulk API facilities

"Decommissioning" is a term that defines the form process of becoming non-active or "out of service' Decommissioning involves all of the activities necessary when preparing a production plant for a closing, selling or restructuring process.



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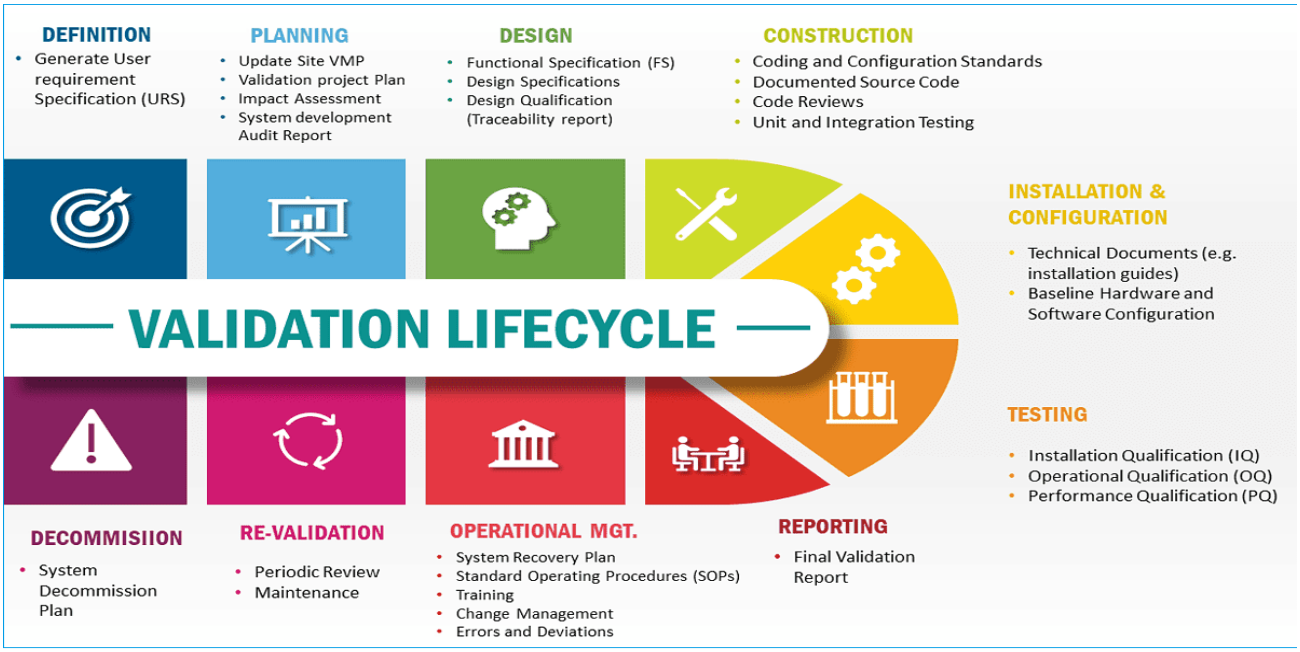
Validation Lifecycle:



Decontamination is also one of the most important activity as part of decommissioning plan. Our closure plan and report document the entire decommissioning process, evidences proper disposition of hazardous materials and provides third party certification that all legacy hazardous substances have been mitigated to an acceptable risk.

Main activities preceding a decommissioning process

In order to accomplish an efficient and quick decommissioning process, there are several activities which must be carried out before the process starts. These essential activities are:

- Identification and management of all the GMP documentation associated with equipment, systems and applications in any format or medium (electronic and paper).
- Identification and management of all GMP data generated during the life cycle of the equipment and systems.

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Main activities during a standard decommissioning process:

- Identification of instruments, equipment, systems and applications to decommission;
- Classification or categorization of the instruments, equipment, systems and applications according to their complexity and the way in which the information has been stored;
- Preparation of the decommissioning documents related to instruments, equipment, systems and applications according to their complexity and category:
- Decommissioning Checklists: these are documents written for non-computerized systems, equipment and applications or for systems which do not store any information.
- Decommissioning Plans: these are documents written for computerized equipment, applications and systems or systems which store information.
- Management of the information stored in equipment, systems and applications.

Change Control:

Initiate a change control and assess AT LEAST the following:
*Perform end-of-life tests and equipment review to establish proper functioning of the equipment up to the time of decommissioning.
*Assess in what processes the equipment is used. Are these processes retired also? If not, have they been upgraded to new equipment (validation!). Include review of registration dossiers
*Assess in what systems the equipment is logged (Equipment log, maintenance/calibration systems etc) and update systems
*Assess in what documentation the equipment is named. Update documentation
*Assess in what operator training the equipment is used. Update/retire trainings
*Make sure the equipment is physically removed from the premises when the above is done.

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