

Standard Operating Procedure

Title: Revalidation Procedure

- 3.1. In simplest sense, a change is one that may impact safety, purity, identity, effectiveness or quality of the product, for example:
 - Changes to Master processing instruction
 - Changes to raw material suppliers or components
 - Changes to formulation or batch proportion
 - Introduction of new equipment or utilities
 - After extensive preventative maintenance work
 - Replacement of spare parts (different make)

4. Basic Steps during Revalidation

- 4.1. Validation committee to determination of Revalidation qualification tests required and time frame -done as part of Performance Qualification during initial validation.
- 4.2. Validation team to Prepare and maintain Revalidation Master Plan
- 4.3. Preparation and distribution of annual revalidation schedule
- 4.4. Issue of revalidation protocols
- 4.5. Coordination of preventative maintenance / recalibration / revalidation activities
- 4.6. Consult the Change Request log for equipment/system of any changes conducted since the last validation/revalidation and include in the revalidation report.
- 4.7. Validation Manager to Analyse the Change Request Log and determine if any additional revalidation tests required
- 4.8. Update and/or Issue of Equipment Checklists and revalidation test protocols
- 4.9. Conducting of revalidation qualification tests according to protocol, e.g. Chemical analysis of samples would be the responsibility of the Laboratory Manager.
- 4.10. Validation committee to approve the revalidated equipment/systems for use by production after completion of revalidation studies when all acceptance criteria have been met. (Relevant Production Manager/Process Manager should be always notified.)
- 4.11. Review and approval of completed revalidation qualification tests file.

5. Revalidation Activities and Specific Responsibilities

- 5.1. It is the responsibility of the validation manager to provide the annual revalidation schedule. This defines dates, activities and time frames when these activities are to be carried out in consultation with production schedules. When preparing the schedule, refer to the most recent past schedule and ensure timings are within one month from previous revalidation.
- 5.2. Prior to the conducting of the revalidation tests as documented in the protocols, the Validation staff has to assess the changes that have been conducted over the previous year and determine, in consultation with the Validation Manager, if any additional revalidation studies are required.
- 5.3. The Validation staff is also responsible in coordinating with other departments to ensure that work is carried out according to schedules and actual studies follow the set protocols
- 5.4. The Validation staff is also responsible in coordinating with other departments to ensure that work is carried out according to schedules and actual studies follow the set protocols.
- 5.5. Following the preventative maintenance and calibration programme, a checklist for the equipment is to be filled out and a test run of the equipment/process/system is to be run by