Procedure

1. Revalidation Categories

1.1. Process Revalidation

With the exception of sterile/aseptic processes, process revalidation is NOT frequent as validated status is maintained via a change control process. The need for any revalidation outside of the change control process will be considered in response to repeated or unexplained batch failures or any adverse analytical trends.

1.2. Cleaning Revalidation

There is NO need to revalidate the process unless it is clear that the effectiveness of the cleaning procedures is inadequate or where significant changes in the manufacturing equipment or process have occurred.

1.3. Analytical Methods Revalidation

The routine revalidation of analytical methods is NOT necessary. Revalidation will therefore normally result from the recurrence of analytical problems or excessive out of specification results associated with the analytical method.

1.4. Revalidation of Pharmacopeial methods is NOT necessary, but need to verify when such methods are updated

1.5. Equipment and Systems Re-qualification

If the Equipment/system has NOT been to subject to any major change or repeated unexplained failures the Equipment/system is considered to remain qualified and NO need for revalidation.

2. Initiation

2.1. It is the responsibility of the Validation Committee to provide an overall plan describing and defining the subject for revalidation based on the initial Validation of the equipment/process/system. The criticality of the equipment/process/system, plus a knowledge of its inherent tendency to change, are considered when establishing the equipment/process/system revalidation programme. The revalidation requirements are documented as part of the Validation report at the time of initial validation but may be modified over time when further knowledge of the equipment/process/system is gained.

2.2. Revalidation is required by the cGMP to be carried out on annual basis on all critical processes or when significant changes have been made to the equipment/process/system. Revalidation activities are usually preceded by a major preventative maintenance/calibration programme conducted by the Maintenance Department.

3. Changes that warrant Revalidation include

the team member of the Maintenance department prior to the hand over to the Validation Department to conduct the actual revalidation qualification tests.

6. Revalidation Protocols

Revalidation Protocols are used to highlight the Test Objective, Acceptance Criteria, Test Method, and the results obtained.

7. Revalidation Timing

Revalidation schedule should be prepared taking into account the current production activities, which will determine the availability of the equipment/process/system. Therefore, studies are to be conducted in the time frame of plus or minus one month of the most recent past revalidation, (i.e. 11-13months). If an extension beyond that date occurs without revalidation being conducted, the equipment/process/system cannot be used for production activities without the specific documented approval of the Quality Assurance Manager**.**

8. Equipment Checklist

An Equipment Checklist is used to ensure that all parameters are set correctly after any maintenance/adjustments have been made. The principle is to ensure that the equipment/process/system has not altered from the original, validated parameters. Checklists are developed during the Operation & Performance Qualification by the Project Team for new equipment/processes/systems.
The checklist is stored with the Validation Department to ensure that current versions are maintained and issued by the validation staff to the Maintenance team prior to the revalidation activities. The Equipment Checklists are approved by the Maintenance Department.

9. Revalidation Discrepancy Forms

Where a problem occurs, such as acceptance criteria not being met, a Validation Discrepancy Form (**Form-370**) must be filled out detailing the discrepancy the action that has been taken to address the discrepancy and a sign off to indicate that the actions have been satisfactorily completed and are effective in addressing the problem. For production batches used under revalidation activities a Deviation Report (SOP QMS-035) is raised if the acceptance criteria was not met and a copy of DR is attached to the Discrepancy form.

10. Release of Revalidated Equipment

If all physical testing is successful at the completion of the revalidation program, conditional release may be granted to the Production Manager via Validation staff carried out the revalidation. At the same time, a DR is to be raised to ensure that no product is released to the market until the Revalidation protocol is signed off.

11. Preparation of the Revalidation File

The Revalidation file provides the documented evidence that the equipment, process or systems are performing to their predetermined use as stated in each test function. In addition, a summary of all the changes and performance checks carried out since the last revalidation campaign is included.
The file is compiled by Validation staff and checked by validation manager within 8 working days of the maintenance, calibration, checklist and test functions being completed then it is circulated to members of the Validation Committee for review and approval.
Revalidation file comprises of the following sections:

11.1. **Summary of Activities**

A summary list of all the registered forms from the Change to Control System and an outline of the Revalidation Programme are prepared by the validation staff.

11.2. **Revalidation Report - Final Review & Approval document**:

