Standard Operating Procedure
Title: Master Validation Plan

Department	Validation/Technical Services		Document no	VAL-080	
Prepared by:		Date:		Supersedes:	
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Approved by:		Date:		Review Date:	

1.0 DOCUMENT OWNER
Validation / Technical Services Manager

2.0 PURPOSE
The objective of this document is to outline the validation plan for a GMP Site and to ensure that all the necessary structures are in place to facilitate validation.

The Master Validation Plan is designed to provide a planned and systematic framework within which all validation activities will occur. This document will also ensure that the manufacturing facilities comply with the local applicable GMP regulations and Site requirements for validation.

3.0 SCOPE
This plan applies to all GMP Manufacturing facility. The site operation includes the manufacturing, packaging, testing and distribution of Therapeutic and Consumer health care pharmaceutical products.

This plan defines general validation requirements for all Direct Impact Systems and processes that support manufacture, packaging, testing and distribution of human and veterinary products.

Products manufacture and/or packed at the GMP facility may include non-sterile tablets, capsules, ointments and suppositories or others therapeutic products such as hormone, steroid, penicillin or antineoplastics.

3.1 Site Facilities
The design and operation of a GMP facility must embraces GMP considerations, as defined by the applicable regulations, for the manufacture of finished pharmaceuticals, applicable industry standards, corporate Quality Standards and Guidelines and environmental and health and safety requirements.

Details of the identification and location of the site facilities and descriptive summaries of the site's major manufacturing facilities, including equipment, utilities, laboratories and support facilities and services should be found in the Site Master Plan. The Site Master Plan will also detail all drug products manufactured and general organisation charts with names and titles for key positions.

4.0 RESPONSIBILITY \ BUSINESS RULES
The requirements for validation will be established through the following organisation structure:

4.1 Site Quality Review Team
The Site Quality Review Team consists of the members from the management team. This team may delegates the Validation functions to the Validation / Technical Services Steering Committee.

Equipment qualification provides documented evidence that the equipment consistently and without detriment achieves and maintains parameters that could directly or indirectly affect, product quality. Refer to SOP **VAL-090** *Equipment Validation Guideline.*

5.2.4 **Computer Validation**
Computer validation ensures that all computerised systems (including hardware and software) that have a direct impact on product quality, operates as per the required specifications and principles of GxP. Refer to SOP **VAL-040** *Computer System Validation.*

5.2.5 **Utility Validation**
Utility validation provides documented evidence that the utility systems that have a direct impact on product quality, operate as per requirements and consistently and without detriment achieves and maintains parameters that directly impacts product quality. Refer to SOP **VAL-095** *Facility and Utility Validation Guideline.*

5.2.6 **Analytical Method Validation**
Analytical method validation provides documented evidence that test methods are effective, reproducible and repeatable. Refer to SOP **LAB-135** *Validation of Analytical Test Procedures.*

5.3 **Validation Documentation Overview**
All validation activities are conducted according to local validation procedures as defined in **Section 5.2**.

Validation Documentation shall be organized and retained to allow for easy retrieval. Each document shall be assigned a unique document code as per site procedure and shall be retained in accordance with the site document retention procedures.

5.3.1 **Validation Master Plan**
This Validation Master Plan (VMP) documents the general approach to validation at Site, Site. The requirements for specific validation activities will be defined in guidelines and procedures.

5.3.2 **Validation Project Plans**
A Validation Project Plan or Project Commissioning and Qualification Plan shall be used for the validation of complex projects. Simple projects may be managed by the use of protocols or through the change control system together with supportive documentation.

5.3.3 **Validation Protocols**
Protocols outline the scope of work and the specific activities and tests that are required to complete the validation. They also contain the predetermined acceptance criteria for the validation.

5.3.4 **Validation Reports**
A Final Validation Report is used to summarize and document a completed validation study. The report serves as a certification of completion of validation.

Documentation (e.g. User Requirement Specifications, Vendor Operation and Maintenance Manuals) must be available that describes the system including what the system does, and how the system performs its functions. The documentation will be used to perform the Impact Assessment and will serve as the basis for defining validation acceptance criteria.

5.5.7 **Validation Deviations**

Deviations that occur during validation shall be documented and investigated in accordance with site procedures.

5.5.8 **Validation Acceptance and Approval**

Each validation event will be reviewed and approved by authorised individuals as detailed in the relevant guideline documents. Where applicable, a minimum of three consecutive events conducted on a fixed process with the same predetermined acceptance criteria will be required before the validation event is considered complete. Specific acceptance criteria for validation projects will be detailed in validation project plans and protocols.

5.5.9 **Maintaining the Validated State**

All processes and systems once validated will be maintained in a validated state through the life cycle of the process / system. Following completion of validation testing, all planned and unplanned changes with potential impact on validated systems and/or processes shall be addressed by established change management procedures (e.g. change control, deviation, investigations). These changes shall be assessed against prior validation studies and an impact assessment performed as per site procedure. Re-qualification and revalidation requirements are identified by the following mechanisms:

- Change Control System
- Product Audits (includes review of Deviations and Cross Functional Investigations)
- Periodic Review

Validated Systems and Processes are subject to Periodic Review. The results of the periodic review shall be documented, reviewed, and approved by the VC. The review may result in the need for additional studies. The periodic review frequency shall be based on the results of risk assessment and regulatory requirements. Periodic reviews shall be conducted within the time interval not to exceed five (5) years. Periodic review of process validation may be combined with the Annual Product Records Review. Where no significant changes have been made to the validated status, a review with evidence that facilities, systems, equipment and processes meet the prescribed requirements fulfils the need for revalidation.

6.0 **DEFINITIONS / ACRONYMS**

GMP	Good Manufacturing Practice
PCQP	Project Commissioning and Qualification Plan
VC	Validation Committee
VMP	Validation Master Plan
VPP	Validation Project Plan

