EXAMPLE

VALIDATION MASTER PLAN

Company: *Company Name**

Facility/Location:

Document #   **VMP- #####**   **Revision 0 (First Draft)**

* Throughout this document, items shown in *italics* are to be replaced with the appropriate name or description.

VALIDATION MASTER PLAN

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1.0   APPROVAL

The approval of this Validation Master Plan shall be the responsibility of the *\<facility\>* Validation Steering Committee (VSC) comprised of the following functional areas of the *\<Company Name\>*.

_____   _____

Author   Date

_____   _____

Engineering Manager   Date

_____   _____

Production Manager   Date

_____   _____

Quality Assurance Manager   Date

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2.0 **PURPOSE** This Validation Master Plan serves as a summary of the overall strategy for the validation of <*facility*>. The Validation Master Plan provides an overview of the each process and describes the validation approach along with supporting validation rationale.

3.0 **SCOPE**

This VMP addresses the all activities related to equipment, utilities, processes, systems, and procedures that may impact the product quality at the <*facility*> of the <*company*>. Specific systems, equipment, utilities, and procedures to be qualified and processes to be validated shall be determined based on documented risk assessment.

4.0 **RESPONSIBILITIES**

4.1 The Validation Department are responsible for preparing validation protocols, task reports, change control documents, and validation SOPs, and for maintenance and storage of all validation related documents.

4.2 The Plant Validation Steering Committee (VSC) (including principals from manufacturing, QA, and Engineering) will approve the Validation Master Plan and all validation protocols, protocol deviations, change control documents, and reports.

4.3 The <*responsible individual*> will review and approve SOPs for literary correctness, technical correctness, and approval to implement.

4.4 Quality Assurance will review and approve the Validation Master Plan, validation protocols, task reports, protocol deviations, change control documents, and SOPs for consistency with cGMPs, consistency with <*Company*> policies and procedures, and approval to implement.

4.5 Support for executing, reviewing, and approving protocols is provided by various departments:

5.0 **VALIDATION APPROACH**

The purpose of the validation plan is to demonstrate that the critical equipment, systems, and processes perform as designed and intended. All validation will be conducted prospectively following written and approved protocols. Change control and qualification of equipment and systems will be conducted in a manner consistent with <*Company*> policies and procedures. Specific equipment, systems, and processes to be validated will be determined based on a documented risk assessment.

5.1 **Validation Protocols**
Validation protocols will be identified and approved in accordance with <*SOP*>. Protocols and change control documents will be drafted and approved prior to execution. Execution of tasks associated with one qualification phase (e.g., IQ) must be completed prior to initiating the tasks in the next phase, except that reviews and approvals are not required to be completed before initiating the next qualification phase. Where one

protocol execution follows another protocol execution, (i.e., IQ followed by OQ followed by PQ) it is not necessary to execute post protocol approval prior to executing the subsequent protocol. However, the <*responsible individual*> will be responsible for monitoring and assessing any open issues and providing documented approval to proceed to the subsequent protocol. Protocol deviations will be documented within each protocol and reviewed and approved by the <*responsible individual*> and QA. Task reports will be prepared to summarize the objectives and results of each qualification phase.

5.2   Change Control

All changes with potential impact on validated systems and/or processes shall be addressed by established change management procedures <*Change Control SOP*>. These changes shall be assessed against prior validation studies. A rationale must be documented when no further validation is required.

5.3   Deviations

Deviations that occur during validation shall be documented and investigated in accordance with <*company*> procedures or as defined in validation protocols. Corrective actions taken or corrective action plans shall be reviewed and approved prior to, or concurrent with, approval of the validation report.

5.4   Standard Operating Procedures

Standard Operating Procedures will be drafted, identified, and approved in accordance with <*Standard Operating Procedures*>. However, in cases where the SOP is expected to be modified as a result of qualification findings, it is acceptable to have only the <*responsible individual*> approve the draft SOP for use during testing. Upon completion of qualification the modified SOP will be approved by according to <*Standard Operating Procedures*>. Draft SOPs used during testing will be maintained with the protocol.

5.5   Documentation

Documentation must be available that describes the system or process to be validated. The documentation will be used to perform the risk assessment to determine which systems or process steps require validation and will serve as the basis for defining validation acceptance criteria.

The documentation required for each activity will be defined within the protocol steps for that activity. All observations and results shall be documented in a manner that allows for objective determination of pass/fail status. All protocols shall define the expected results and acceptance criteria. Computer printouts, charts, or other supporting documents shall be attached to or reference in the completed protocol. Protocol deviations shall be annotated in the protocol.

Protocols will be uniquely identified according to <*SOP*>. All validation documents will be maintained according to <*SOP*>.

Reports should be written summarizing the results of execution of protocols after each validation phase (e.g., IQ, OQ, PQ). Each report should include a summary of the results obtained, analysis of the results, summary and resolution of any deviations observed, conclusions, and raw data supporting the conclusions.

Validation Documentation should be organized and retained to allow for easy retrieval. The documentation should be retained in accordance with <***company***> document retention policies and procedures.

5.6 **Calibration** – All test equipment and instruments used in the execution of validation tasks must be calibrated and within their calibration period.

5.7 **Training**
All personnel involved in the performance of qualification and validation activities must be trained in the tasks they will be performing. Personnel responsible for the maintenance or operation of equipment to be qualified must be trained and qualified prior to executing the qualification studies.

6.0 **GENERAL ACCEPTANCE CRITERIA**
General acceptance criteria must be met for a given piece of equipment, system, or process to ensure that it is operating properly and meeting its specific acceptance criteria as defined in the specific protocol for the equipment, system or process.

Qualification protocols define the specific acceptance criteria that must be met to demonstrate that the equipment or system was properly designed, installed, and operates. When commissioning activities are performed in lieu of qualification tasks, the commissioning activities should be verified during qualification rather than repeating the commissioning tasks.

7.0 **FACILITY AND PROCESS DESCRIPTION**

7.1 **Facility Description:**

Provide a general description of the facility and specifications. Include all of the major areas that are included in the validation plan (central plant, manufacturing, material storage, etc.) Reference drawings or attachments as necessary.

Identify critical areas of the facility (GMP vs. non-GMP areas). Include zoning and area classifications for GMP areas.

7.2 **Process Descriptions**:

Process Name and Description: Include a general description of the major steps and type of equipment used in the process.

8.0 **SUPPORTING DOCUMENTS AND SOPS**
Standard Operating Procedures which apply to the validation master plan include:

SOP # Calibration, Monitoring and Preventive Maintenance.

SOP # Change Control and Deviations.

SOP # Documentation Guidelines.

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SOP #	Equipment Cleaning and Verification.
SOP #	Equipment ID Numbers.
SOP #	Preparation of Specifications.
SOP #	Vendor Certification.

9.0   VALIDATION SCHEDULE

Attach a schedule of validation events. The schedule should include the following information:

Responsibility for each task.
Human resource requirements for each task.
Contractor or vendor support if needed.
Test equipment requirements for major items or test equipment that is not readily available.
Milestones and interdependent tasks.

10.0   DIAGRAMS
Diagrams of the <*facility*> depicting the facility and equipment layout should be attached to this VMP.

11.0   RELEASE FOR USE
Prior to releasing the equipment, system or process for general production use the following criteria must be met:
• Approved SOPs shall be available for the use, control, and maintenance of equipment, systems, and processes;
• Critical instruments must be calibrated and entered into the <*facility*> calibration program;
• Critical system components must be entered into the <*facility*> preventive maintenance program; and
• Training requirements must be established for personnel.

12.0   PERIODIC REVIEW
The Validation Master Plan should be reviewed at least annually to ensure that it is maintained current with the equipment, systems, and processes at the <*facility*>.

Validated systems and processes should be reviewed periodically according to risk assessment to determine the need to re-validate. The results of the periodic review shall be documented, reviewed, and approved by the <*facility*> Validation Committee.