

Purpose

This document represents the Validation Master Plan (VMP) for **xxxx**

Scope

This VMP covers all qualification & validation activities required for the products manufactured at **xxxx**. Products under development and not being released yet to production are out of scope of this VMP.

Responsibilities

xxxx is responsible for updating this VMP.

References

xxxx

Approvals

	Print Name	Signature	Approval Date
Author			
Manager xxxx			
Manager xxxx			
Manager xxxx			
Manager xxxx			

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1. General Validation Approach

The validation program (see **xxxx**) defines the minimum validation requirements.

The objectives of this Validation Master Plan are:

- To reference comprehensive lists of items requiring validation including the dates of the last validation performed.
- To provide schedules of activities (validations, re-validations, reviews).
- To document management commitment to the plans and schedules, and to allow planning for sufficient resources to meet these commitments.
- To provide a documented periodic review of progress against the schedules.

2. Product Validation Master Plans

2.1. Validation Master Plan for *Product 1*

An approved copy of the original product validation master plan xxxx, including a list of all validations required, is attached to this VMP as annex 1. Review and update, if required, of the original validation master plan will be performed as per the schedule in annex 0.

2.2. Validation Master Plan for *Product 2*

An approved copy of the original product validation master plan xxxx, including a list of all validations required, is attached to this VMP as annex 2. Review and update, if required, of the original validation master plan will be performed as per the schedule in annex 0.

2.3. Validation Master Plan for *Product 3*

An approved copy of the original product validation master plan xxxx, including a list of all validations required, is attached to this VMP as annex 3. Review and update, if required, of the original validation master plan will be performed as per the schedule in annex 0.

3. Other Activities

3.1. Validation Master Plan for test equipment and methods

The validation master plan for test equipment and methods xxxx, including a list of all qualifications and validations performed, is attached to this VMP as annex 4. Review and update, if required, of the validation master plan will be performed as per the schedule in annex 0.

3.2. Periodic Re-Validation

For the products within the scope of this VMP, the following re-validations are scheduled:

Product	Description	Last validation date	Next due date	Responsible person
Common system to all products	Cleanroom Re-qualification			
	Purified water re-validation			
	Compressed air system re-qualification			
Product 1	Sterilization process Revalidation			
Product 2	Sterilization process Revalidation			
Product 3	Sterilization process Revalidation			

3.3. Supplier Validation

Validation of injection moulded components are, if required, included to the product validation master plans.

4. Revision History

Rev	Description	Author & Date
1	Initial VMP (xxxx)	

Annex 0 – Action List

#	Action	Responsible	Due Date
1	Product Validation Master Plan for <i>Product 1</i> The existing VMP will be reviewed and updated, if required, and included/referenced into annex 1	tbd	
2	Product Validation Master Plan for <i>Product 2</i> The existing VMP will be reviewed and updated, if required, and included/referenced into annex 2	tbd	
3	Product Validation Master Plan for <i>Product 3</i> The existing VMP will be reviewed and updated, if required, and included/referenced into annex 3	tbd	
8	Validation Master Plan for <i>Test equipment and test methods</i> The existing VMP will be reviewed and updated, if required, and included/referenced into annex 4	tbd	