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| GENUS INNOVATION LIMITED |
| Validation Procedure |
| PRCD\_VALDTN.docx |
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| **Genus** |
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| Validation demonstrates that the system satisfies its operational requirements, i.e. it is the ‘right’ product to fill an operational need. |

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# Overview

Validation demonstrates that the system satisfies its operational requirements, i.e. it is the ‘right’ product to fill an operational need.

# Objective

The Validation (VAL) Process’ objective is to demonstrate that selected work products fulfill their intended use when placed in their intended environment. This also ensures the early detection of the defects and bugs prior to the delivery of the product to the end customer.

# Scope

This procedure applies to all the Development Projects.

# Inputs

* Plan of Validation Activities (TMPL\_PRJPLN)
* Requirement Documents
* Design Data
* Interface Control and Integration Design Document

# Entry Criteria/Triggers

* Verified Integrated Product.
* The practitioners have undergone QMS trainings with focus on performing their processes.

# Tasks

| Sr.No | Task | Owner/Role |
| --- | --- | --- |
|  | **Plan for Validation** |  |
|  | Identify Test Schedule and Test Environment using “System Test Case” (TMPL\_SYSCAS). | Validation Member |
|  | Prepare Test Cases. | Validation Member |
|  | Identify testing methods. |  |
|  | Identify the methods and criteria for testing. |  |
|  | Identify the intended environment and the tools required. |  |
|  | Identify the acceptance criteria for testing. |  |
|  | Review the Test Cases. Use “Test Cases Review Checklist” (CHKL\_TSTCAS). | Validation Manager |
|  | Close all the defects identified by the review of Test Cases. | Validation Member |
|  | Approve the Test Cases and update System Test Case IDs in “Requirement Traceability Table” (TMPL\_REQTRT). | Validation Manager |
|  | **System Level Testing** |  |
|  | Intimate the completion of Integration Testing to the Validation Manager. | Design Team/ Project Manager |
|  | Get integrated product. | Validation Manager |
|  | Establish Validation Environment. |  |
|  | Establish Validation Environment including required tools and enabling systems as per the Validation Plan. | Validation Manager |
|  | Instruct team members to perform validation activities. (Provide training for the same, if required) | Validation Manager |
|  | Validate the integrated product according to the testing methods defined in “System Test Case Template” (TMPL\_SYSCAS). | Validation Member |
|  | Log the system testing defects in the “Review and Testing Defects Log”   * Validation defects * Classification of defects (functional and non-functional) | Validation Member |
|  | Share the defects of System Testing with the Project Manager. | Validation Manager |
|  | **Resolve the Defects** |  |
|  | Assign the defect to the concerned person responsible for the identified module. | Project Manager |
|  | Resolve the defect. | Design Team |
|  | Update the “Review and Testing Defect Log” with the current status. | Design Team |
|  | Revalidate the defects and change the status to “closed” if resolved satisfactorily and “active” if not - in “Review and Testing Defect Log”. | Validation Member |
|  | Analyze the defects. The analysis may be performed in a meeting with the technical staff. The techniques that can be used for root cause analysis are Fishbone diagram (Ishikawa Diagram), Why-Why Analysis, FMEA, and others. Identify and document the root causes. Use template “Root Cause Analysis” (TMPL\_ROCSAN). | Project Team |
|  | **Certify Product Validation** |  |
|  | Generate a validation report using “Validation Report Template” (TMPL\_VALRPT) on the successful completion of Validation.  The Report has the following details   * 1. Validation number   2. Date   3. Project Code   4. Details of version / revision of configurable items under validation   5. Test plan used for validation | Validation Manager |
|  | **Release the Final Product** |  |
|  | Follow the “Configuration Management and Release Procedure” (PRCD\_CONFIG) to deliver the Final Product to the customer. | Project Manager |

\* Improvements/Suggestions are solicited on “Process Improvement Proposals Database”.  
\*For details on the Roles and Responsibilities of the practitioners, Refer "Roles and Responsibility" document in the QMS.

# Verification

* Review of Test Plan by Project Manager.
* Review of validation results with Design Team.
* Review of the process and its work products by PPQA members.
* Review of the process and its work products by Senior Management.

# Guidelines

Refer "Configuration Management and Release Procedure" (PRCD\_CONFIG) for Access Rights, location of work products, naming convention and types of controls.

## Definitions

1. Functional Defects- Defects that affect the functionality of the product e.g. contradiction in requirements, data width issue in DB schema, variable type issues etc.
2. Non-Functional Defects: Defects related to process adherence, aesthetics etc. are Non-Functional Defects e.g. - indentation in code, spelling, grammar, formatting etc.

# Applicable Measurements

* Number of defects observed during System Testing.

# Exit Criteria/Outputs

* Successful Validation of product & Product components with closure of all defects observed during validation.
* Validated Product