Validation Plan
(Ref.VAL-005)

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Project Name		**Project Number**	
Equipment		**Serial Number**	
Manufacturer		**Model Number**	
Process Line/Location		**Protocol number**	

PROGRAM INDEX

Validation Plan Prepared By:			
Position	**Name**	**Signature**	**Date**
Project Coordinator			

APPROVAL OF THE VALIDATION PLAN			
Position	**Name**	**Signature**	**Date**
Validation Manager			
Quality Assurance Manager			
Operations Manager			

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IQ based on Demand Specifications	Applicable to this Project*
1. Equipment Functional Demand Specification	Yes/No
2. Mechanical / Design Specification	Yes/No
3. Electrical Demand Specification	Yes/No
4. Instrumentation Demand Specification	Yes/No
5. Operatorôs Control Panel Specification	Yes/No
7. Technical Documentation Specification	Yes/No
8. Environmental, Health and Safety Requirements	Yes/No

Computer Validation

Impact Assessment on the product Quality is to be conducted for the proposed project.

Justify any computer validation activities in the plan being under taken by this project.

Any Operational Qualification testing required as part of the validation requirement is to be included.

Cleaning Validation

Cleaning Validation is to be conducted in accordance with the requirements of SOP VAL-020.

Cleaning Validation required for the process, equipment or procedures.	Yes /No
Select the Worst Case Product for Cleaning according to SOP VAL-020	
Analytical Method Validation required for Worst Case Product	Yes / No
Is analytical method validation complete? Include reference file for analytical method validation report.	Yes / No

Any Operational Qualification testing required as part of the validation requirement is to be included in the plan.

Operational Qualification Test Plan and Acceptance Criteria

Validation activities are to be conducted in accordance with the requirements of SOP VAL-005.

All documentation is to follow the requirements stipulated in SOP VAL-005. Templates for the various documents are to be sourced from the Templates.

List of Operational Qualification tests that are to be conducted.

The acceptance criteria for the operational qualification tests should be clear and unambiguous so that review and approval of the final qualification reports is expedited.

It may be more appropriate to separately record the Operational Qualification Tests and the Acceptance Criteria for each test. In which case include a separate section in the plan for the Acceptance Criteria and update the Program Index.

Required Standard Operating Procedures (SOPs)

Include the full SOP no. Ensure you reference the current version. Relevant SOPs required to conduct the validation activities are to be listed.

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9.	Writing Operational Qualification Report Documented by: Checked by:	
10.	Review of completed OQ Report Approved by:	Validation Committee Project Co-ordinator Production Manager Validation Manager Quality Assurance Manager Operations Manager
11.	Conducting Safety Audit	EHS Manager
12.	Close-off of issues raised in Safety Audit	
13.	Conducting of training activities	
14.	Conducting of a Quality Audit for New Process Lines	Required YES/NO
15.	Writing Performance Qualification Test Protocols Prepared by:	
16.	Approval of PQ Test Protocols Checked by: Authorised by:	QA or Validation Manager
17.	Conducting PQ tests	
18.	Completed PQ Test Protocols Documented by: Checked by: Approved by:	QA or Validation Manager
19.	Writing Validation Report Prepared by: Checked by:	
20.	Compiling of the Validation file and circulation for approval.	Project Coordinator
21.	Approval of the Validation Report.	Validation Committee Project Co-ordinator Production Manager Validation Manager Quality Assurance Manager Operations Manager

Note: In all cases the parties nominated for the approval process must be appropriate for the project being undertaken.