

Validation Matrix of PROCESS.ING LifeSciences GmbH



Validation Master Plan / Validation Plan per System / Unit				
Design Qualification	Installation Qualification	Operational Qualification		Performance Qualification
DQ-Plan	IQ-Plan	OQ-Plan		PQ-Plan
DQ-Test Plans 1 to 4	IQ-Test Plans 1 to 7	OQ-Test Plans 1 to 10		PQ-Stages and Test Plans
Verification Operator Requirements Specification and System Evaluation	Verification Technical Documentation	Verification Processing Parameters, Operating Ranges and Settings	Verification System-Specific Physical / Technical Measurements	Physical / Technical Examinations
Prospektive Design Reviews Concept, Basic, Detail Design	Verification Installation for P&ID / HVAD-Schemes, Parts / Components List and Technical Data Sheets	Verification Operating Modes, Unit Operations and Basic Functions	Verification System-Specific Process Instructions	Chemical Examinations
Verification Suppliers Evaluation / Verification Divergences Requirements / Obligations	Verification Welding Documents and Material Certificates	Verification Operating Messages, Warnings, Alarms	Verification due to the Risk Analysis	Microbiological Examinations
Execution GMP / Measuring Points / CSV-Risk Analyses	Verification Clean Room Interior Constructions and Installations	Verification Power Failure and System Restart		Temperature Studies / Moist or Dry Heat Sterilization Proofs
	Verification Hardware Installation for Wiring Diagram	Verification User Levels / Log-On Authorization		Cleaning Validation
	Verification Configuration of Analog and Digital Input and Output Signals (I/O-Test) / Software Registration	Verification Data Registration / Data Archiving / Data Restoration		Media hold / Media fill
Verification Calibration Status of Instruments and Measuring Devices (technical / pharmaceutical relevant)		Verification Interfaces to Superior Data Management System		
DQ Error / Deviations / Signatures List	IQ Error / Deviations / Signatures List	OQ-Error / Deviations / Signatures List		PQ Error / Deviations / Signatures Lists
DQ-Report	IQ-Report	OQ-Report		PQ-Reports
Final Validation Verification per System / Unit Validation Master Report				