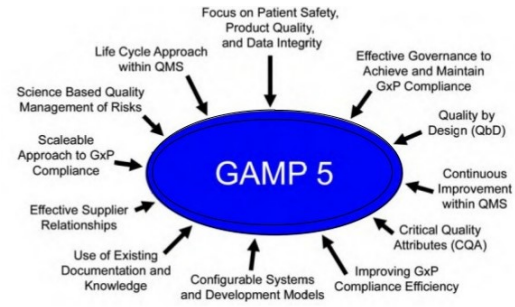
GAMP 5

Introduction

The system has been engineered to provide automated process control, flexible process sequence development, data acquisition, historical trending and batch reporting.

The process is controlled by the programmable control logic processor (PLC). Process data is acquired from the PLC via Enterprise software and stored in the SQL database on the HMI/PC. Real time and historical data trending and batch reporting functionality enable the operator with a viewing window into the acquired data.

GAMP5 provides pragmatic and practical industry guidance to achieve compliant computerized systems fit for intended use in an efficient and effective manner. This technical document describes a flexible risk-based approach to compliant GxP regulated computerized systems, based on scalable specification and verification.



Validation

Validation Plan (VP): Document determining the validation activities along with approximate timings & responsibilities.

User Requirement Specification (URS): The user requirements specification will be used as the basis for the development of the system acceptance test scripts/ performance qualification test scripts.

Functional Requirement Specification (FRS): A document that describes in detail the characteristics of the product with regard to its intended features. This document is the out come after one or more reviews by the stakeholders on the project at hand after having negotiated a cost-effective way to achieve the requirements the software needs to fulfill.

Design Specification (DS): A System Design Specification is created to define how the proposed system will fulfill the GXP Computerized System's Requirements.

Qualification: the process of determining whether a system or component is suitable for operational use.

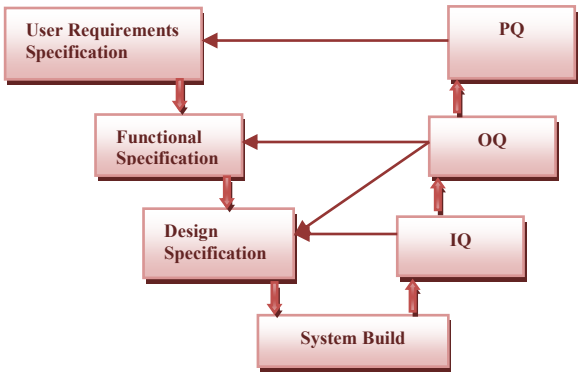
Installation Qualification (IQ): It is a document to verify that all the components of a system installed as per the documented specification.

Operational Qualification: It is a document to verify that system operates as per the documented specification.

Performance Qualification: The performance qualification ensures that the total system performs as intended in the specified operating range. The total system includes all hardware and software components, associated equipment, people and procedures that make up the system. The execution process is conducted using company specific pre-defined dataset or actual live data.

Traceability Matrix: it is very important that direct traceability is established between the specification and test performed i.e. a cross reference from the test script back to the section in the appropriate specification where the function is defined. This traceability ensures that all parts of the software are tested, and clearly establishes the acceptance criteria for a given test.

Validation Summary Report (VSR): Validation Summary Reports provide an overview of the entire validation project. Once the summary report is signed, the validation project is considered to be complete. When regulatory auditors review validation projects, they typically begin by reviewing the summary report.



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