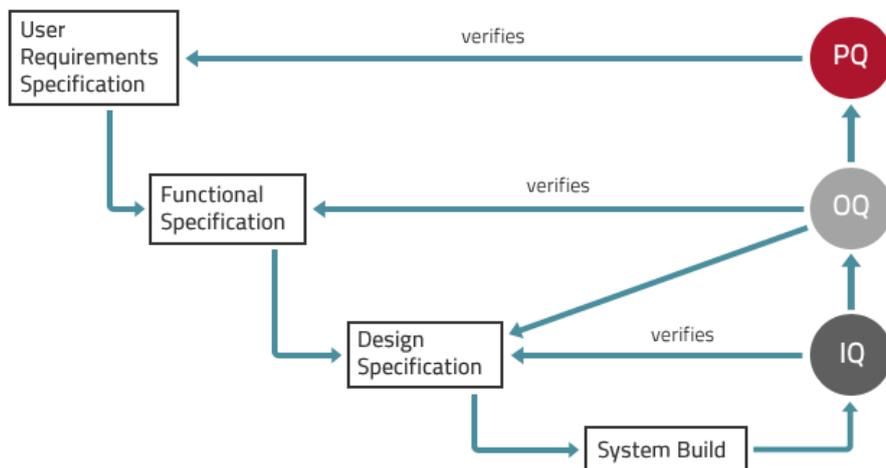


## GAMP 5 GUIDE

The system validation process proposed by the GAMP Forum basically follows the “V” software development model and requires preparing, reviewing and formally approving a series of documents for each of the stages.

GAMP 5: A basic framework for specification and qualification



The following elements, among others, must be created and inter-traced:

- Validation Plan (VPL)

It is a document where we will identify the project objectives, members of the validation team, responsibilities of each and activities that must be carried out to formally verify that the computer system is suitable for the envisaged use thereof.

- User Requirements (URS)

This document describes the system requirements in detail. Functional, non-functional (performance, usability, etc.) and regulatory (GMP: Good Manufacturing Practices, GLP: Good Laboratory Practices, GCP: Good Clinical Practices, etc.) requirements must be described. The requirements must be prioritized.

- Functional specifications (FS) / Design specifications (DS)

This document describes the functions and design of the system to be implemented. In the event of being commercial software, this document will be supplied by the manufacturer. These documents describe the hardware and software characteristics required for the system to function correctly.

- Traceability matrix for relating user requirements with system functions.

It is matrix that relates user requirements to the functions supported by the system. This matrix allows you to verify that all the functional requirements are implemented in the system and orient the work carried out during the testing phase to verify critical related functions.

- Risk analysis

An important GAMP concept is that of carrying out a formal risk analysis of the system and using the results as the main criterion for orienting the validation work towards critical functions.

There are basically two non-excluding methods for carrying out risk analysis:

- Top-down analysis, which consists of identifying and evaluating general system risks and subsequently defining activities to mitigate or lessen their impact.
  - Bottom-up analysis, which consists of individually evaluating each of the system functions (SF) and identifying the functions to be verified during the testing phase.
- IQ: Installation qualification

It consists of verifying the installation of the system in a formal and documented manner.

The "IQ protocol" is a document that describes how to verify that the system has been correctly installed. This protocol is executed during installation by qualified team, upon which an "IQ report" is finally prepared with the deviations detected, if any.

- OQ: Operation qualification

It consists of verifying the system's functions in a formal and document manner.

The "OQ protocol" is a document that describes how to verify each of the system's functions. This protocol is executed by qualified team, upon which an "OQ report" is prepared with the deviations detected, if any.

An important concept is that the effort dedicated to verifying each function is established in accordance with the result of the risk analysis.

The OQ tests are traced to system functions (SF) and user requirements (URS). This traceability matrix is important for determining that all the relevant requirements have been verified.

- PQ: Performance qualification

It consists of verifying the system under normal operating conditions in a formal and documented manner.

The "PQ protocol" is a document that describes how to verify the main processes or activities carried out by the system. This protocol is executed by qualified team, upon which a "PQ report" is prepared with the deviations detected, if any.

The PQ tests are traced to system functions (SF) and user requirements (URS). This traceability matrix is important to determine that all the relevant requirements have been verified.

- Final validation report

It is a document that is issued on completing all the activities envisaged in the validation plan. It includes a summary of the results of the different tests carried out and, where applicable, formally documents that the system fulfils the user requirements and is suitable for use by these.