

System Validation with IRQA

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Requirements Definition and Management



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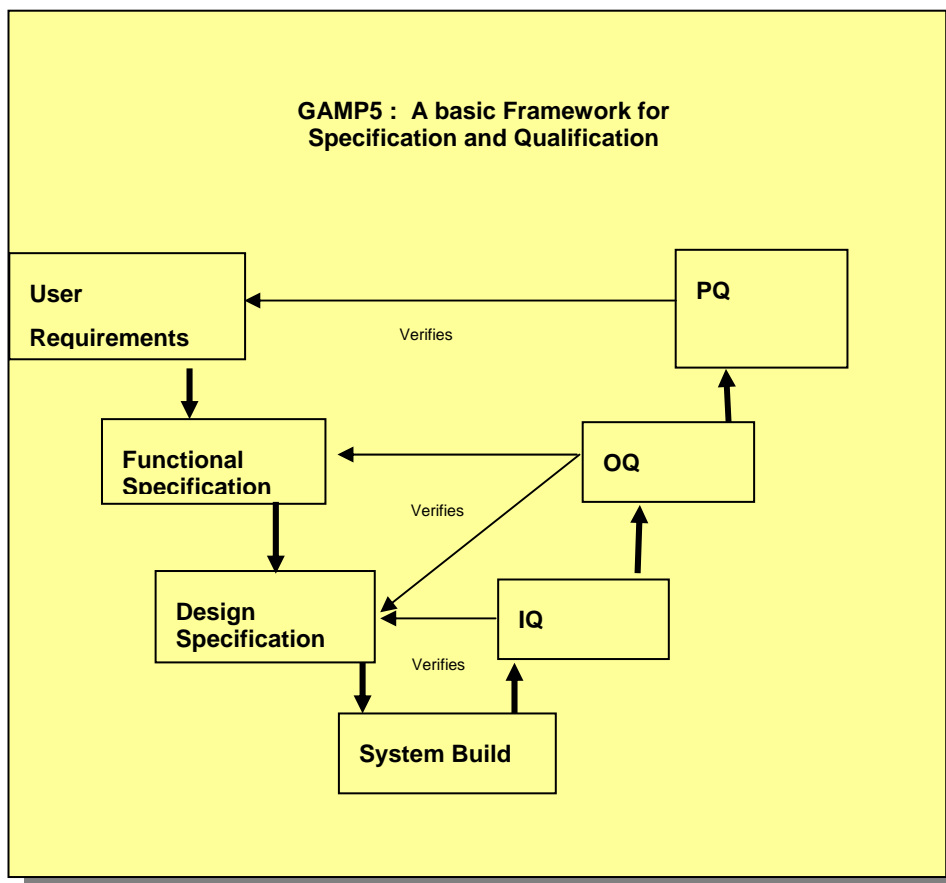
1. SYSTEM VALIDATION WITH IRQA IN MEDICAL/PHARMACEUTICAL SECTOR

1.1. Introduction

Automated systems to be used in the Medical/Pharmaceutical sector have to be validated to ensure they meet all healthcare regulatory expectations.

The GAMP Forum (today a technical subcommittee of ISPE, International Society for Pharmaceutical Engineering) is an industry group set up to promote understanding and interpretations of the regulations concerning the use of automated systems in this sector.

The GAMP Forum publishes the Good Automated Manufacturing Practice Guide, in order to provide suppliers of automated systems for the pharmaceutical industry with a set of guidelines to build systems that are compliant with European and North American regulations.



This diagram is based on the activities for validation defined in GAMP 5. PQ (Performance Qualification), OQ (Operational Qualification) and IQ (Installation Qualification) are the test plans to check that the system being validated is compliant with the Design specification, the Functional specification and the User Requirements that the customer has for that system.

This diagram resembles very closely the V-model that represents systems life cycle.

The usual set of activities that have to be performed by companies in the Pharmaceutical sector in order to validate automated systems are the following:

- Developing the User Requirements Specification: URS is the set of requirements the customer has with regard to the use of the automated system to be validated. The Functional Specification and Design Specification are the functional and design specifications of the system. They are usually provided by the system supplier.
- Risk Analysis: This is the process of evaluating the risks associated to the system functions according to the way they are intended to be used in the pharmaceutical company. Then, test effort is defined according to results of this analysis (for instance, only functions linked to risks with high business impact are thoroughly tested).
- Developing a Validation Plan.
- Developing the PQ, OQ, IQ: Qualification protocols have to be defined and executed. Result reports have to be written.
- Writing the Final Validation Report.

1.2. IRQA Support to Validation projects

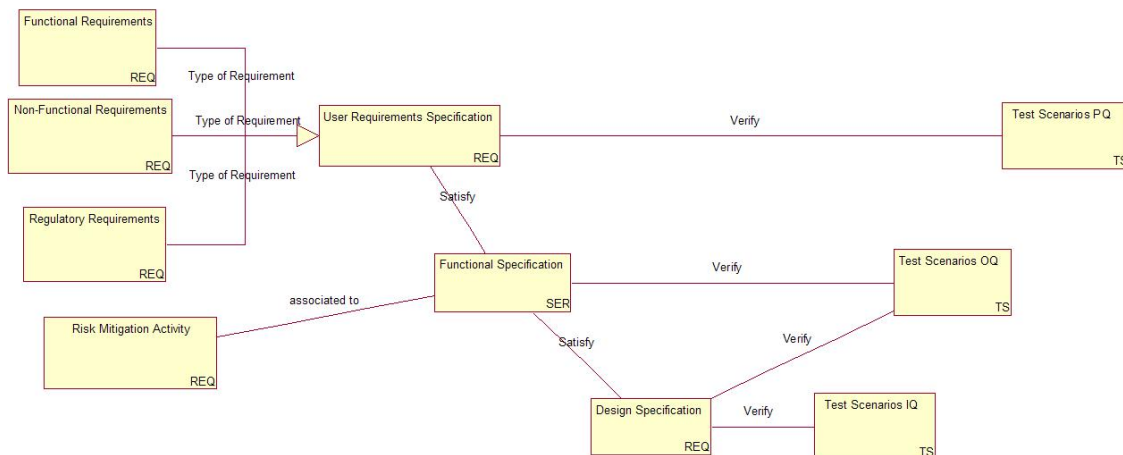
Validation projects according to GAMP 5 consist mainly of defining requirements, associated tests (IQ, OQ, PQ) and traceability between all these elements. This can be fully supported with IRQA.

Functional Specification and Design Specification can also be managed with IRQA; they normally are provided by the supplier. If they are provided in a Word or Excel document, they can be directly imported into IRQA with the goal to establish traceability with URS and with associated tests.

With regard to Design Specification, IRQA does not support design modelling but if this spec is built through textual descriptions, then IRQA can support this step through a block of requirements.

With regard to Risk Analysis, IRQA functionality can be extended in order to support risk definition and management through a specific block of requirements with the necessary attributes. Defining risks in IRQA has the advantage of supporting direct traceability of risks with the elements of the Functional Specification to which they are associated, and allows taking advantage of all filtering functions and traceability matrixes generation of IRQA.

IRQA block diagram representing the GAMP 5 validation framework:



This diagram is a general framework that can be customized according to the actual validation process followed in each company or for each validation process. For instance, if the supplier does not provide a Functional Specification, risks and all test levels could be associated directly to the User Requirements Specification developed by the customer.

The Functional Specification block is a Service block. Another option can be using a block of requirements. Actually, if no modelling techniques (such as use case diagrams) are going to be used for the functional specification, using services instead of requirements does not have any significant advantage.

USR has been categorized into Functional, Non-Functional and Regulatory Requirements; this classification can be modified, or new levels can be defined, such as a sub-categorization for non-functional requirements.

Attributes can be defined in order to manage these elements, such as:

- Priority: Indicates if the requirement is mandatory or optional.
- Support level: Indicates if the user requirement is supported in the system, could be supported through parameterization or additional development, or if it is not supported at all).
- Risk category.
- Risk complexity.
- Risk impact.

1.3. Benefits of using IRQA in validation of automated systems:

- Support to the validation process according to GAMP 5.
- Customization of the validation process according to the validation process applied in the company.
- Customization of the validation process according to the characteristics of the system being validated.
- Reuse of URS.

- Reuse of Qualification protocols (for instance, IQ may have a basic set of tests common in all validation processes, related with the operational environment in the company).
- Support to traceability between URS and functional specifications, or between functional and design specifications. Coverage analysis (are all URS traced to functional specifications?)
- Support to traceability between specifications and qualification protocols. Coverage analysis.
- Support to traceability between risks and specifications. Identification of specifications with associated high impact risks.
- Team work support.
- Report generation based on company templates.



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