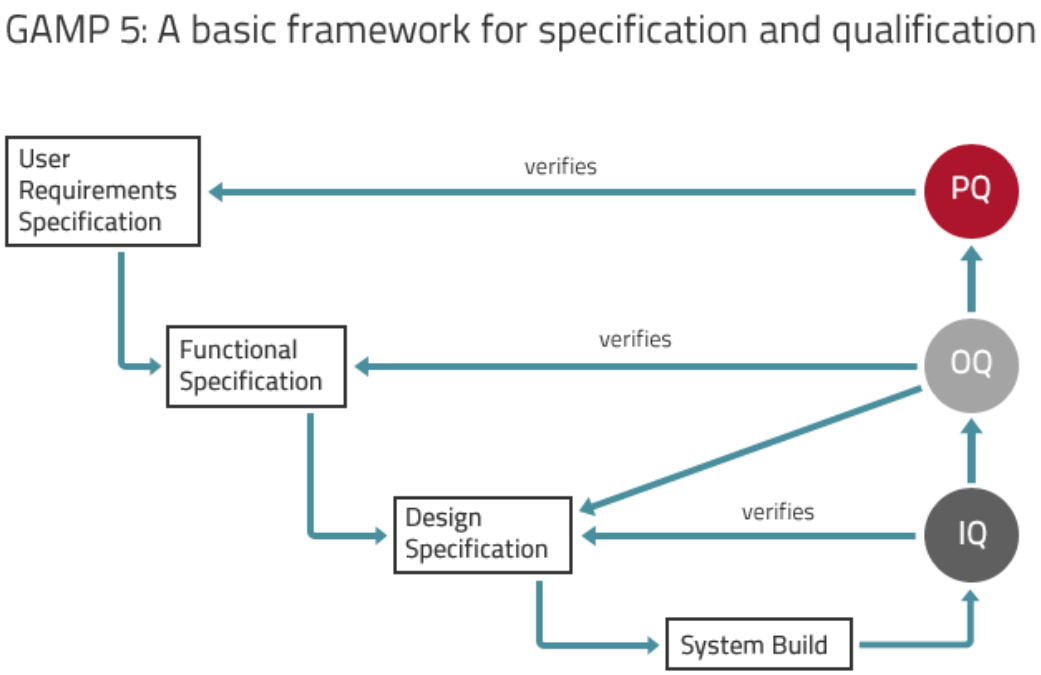
VISURE REQUIREMENTS FOR PHARMACEUTICAL AND MEDICAL SECTOR

GAMP5: A basic Framework for Specification and Qualification

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 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.

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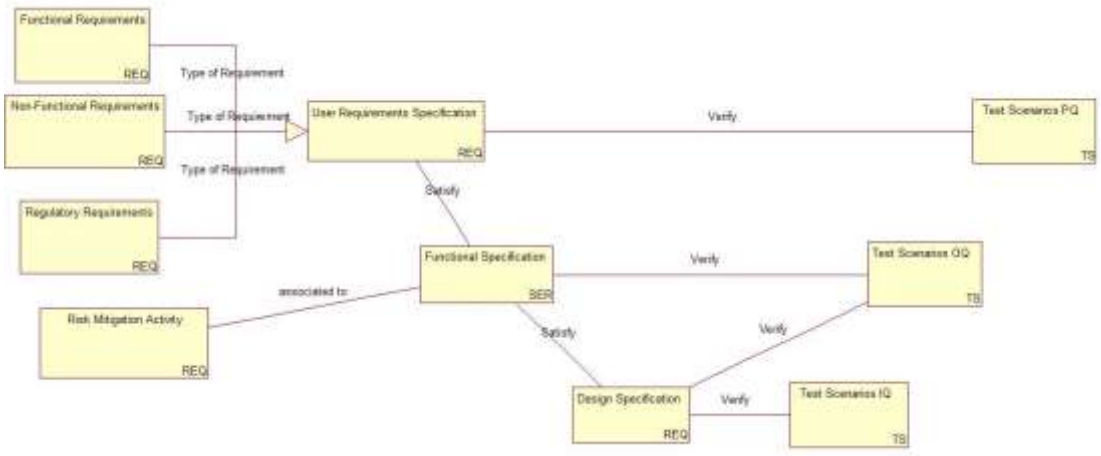
Visure Requirements support for GAMP 5

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 Visure Requirements.

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

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

With regard to Risk Analysis, Visure Requirements 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 Visure Requirements 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 Visure Requirements.



Benefits of using Visure Requirements 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.

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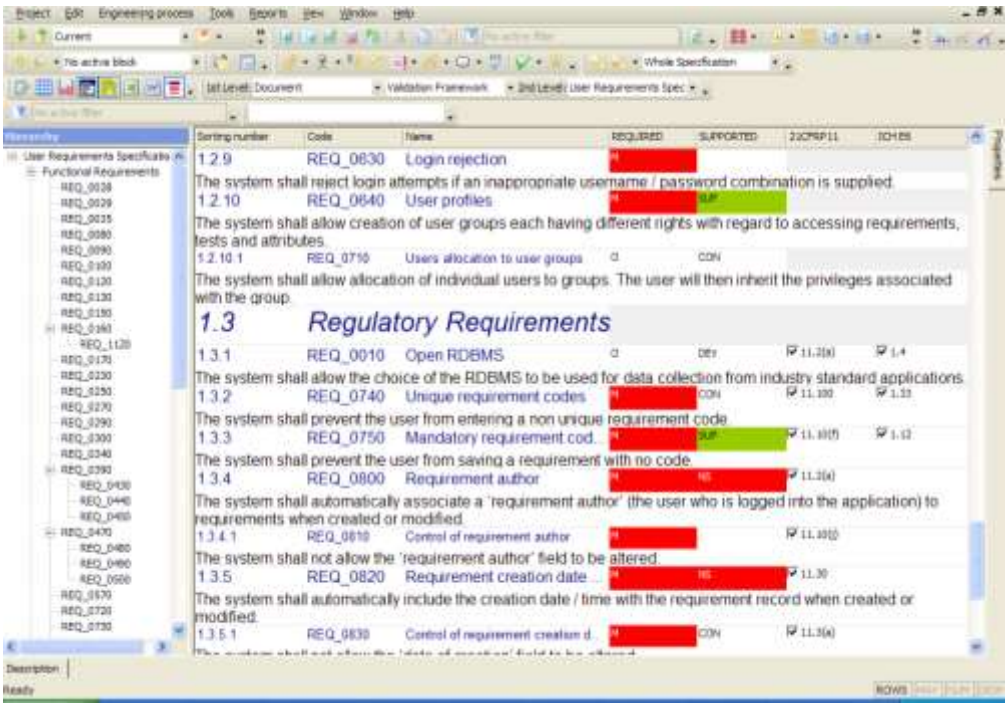
- Reuse of Qualification protocols (for instance, IQ may have a basic set of tests common in all validation processes, related with the operational environment in the company).
- Support to traceability between URS and functional specifications, or between functional and design specifications. Coverage 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.



Manage URS

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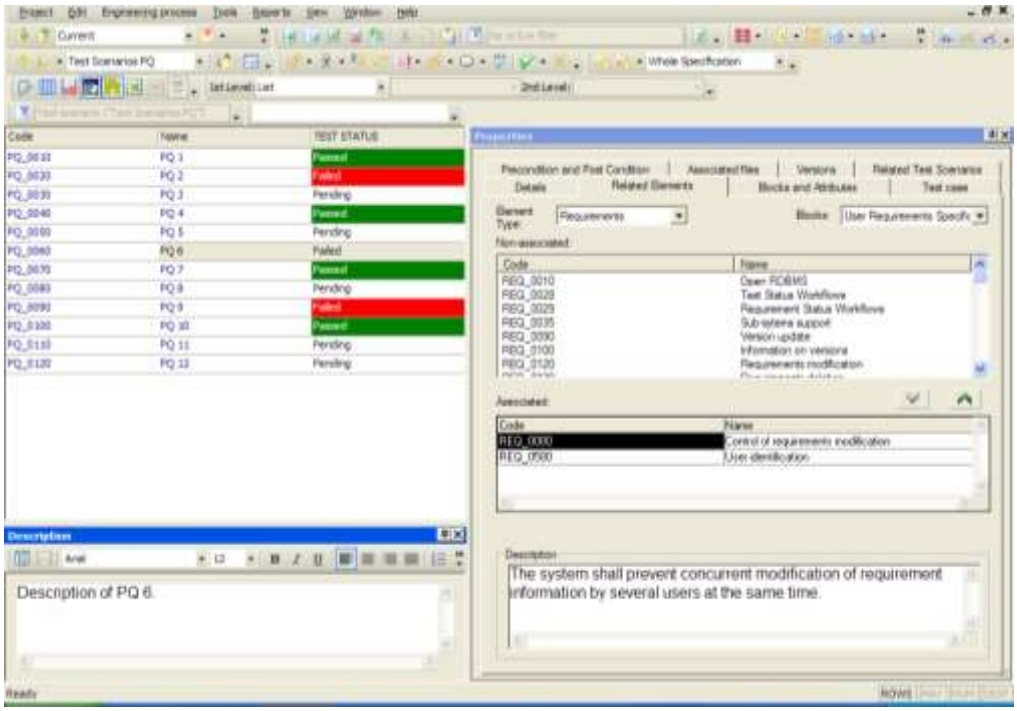

Manage IQ, OQ, PQ tests

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