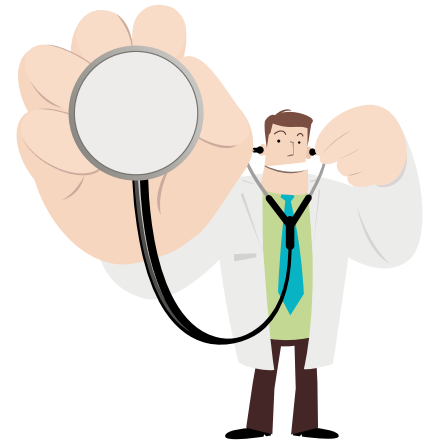


visure requirements



PharmaMar prescribes Visure Requirements as a solution for improvement in the Requirements Management processes.

THE CHALLENGE

Inside PharmaMar’s organization, the department that has pioneered the project for the purchasing of solution in Requirements Management has been the Communication Development Department.

The department’s principal activities include:

- Development of software solutions for internal clients,
- Coordination of projects for the evaluation of commercial software solutions,
- Coordination of projects for the implementation and validation of commercial software solutions.

All these activities require the **gathering and management of Life Cycle Requirements, Functional Specifications, Test Plans**, etc. with more or less detail, depending on the size of the project. In certain projects, these processes are not at all easy to manage and require a lot of time dedicated to the generation and management of the documentation.

The Company needed a Requirements Engineering tool to:

- **Speed up the collection and management of the requirements,**
- **Improve the quality of the documentation, reduce the effort, and time**
- **Give support to the projects for the validation of computer systems, as per the process described in the “Good Automated Manufacturing Practice Guide for the Validation of Automated Systems” (GAMP4) edited by ISPE (www.ispe.org).**

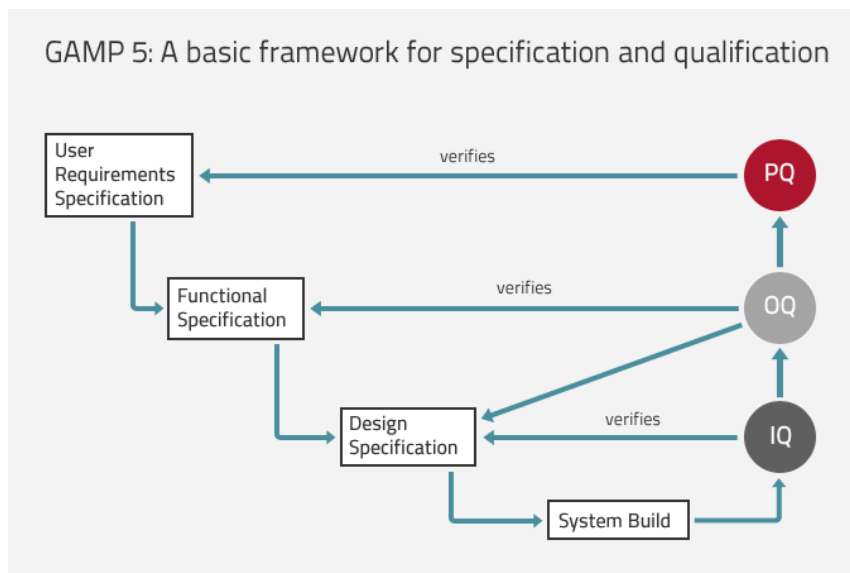
VISURE REQUIREMENTS’S MOST OUTSTANDING FUNCTIONS

It gives support to a large variety of concepts used in software engineering, such as the specification and definition of concepts, requirements, services, actors, use cases, test scenario and also relationships’ and traceability matrices among these elements.

The system allows extending the model with new concepts and attributes that are defined by the user and also define in the same tool, the adopted meta-model for each project.

The system includes a group of pre-defined reports and also allows for the definition of new user list type documents, obtaining in this way reports comprising of various sub-documents.

The powerful and intuitive user interface allows change control at each item level.



RESULTS

Visure Requirements was chosen as the Requirements Engineering tool for the department's internal use, as it covers the majority of the company's necessities due to its **rapid implementation and also for its reasonable price/ quality relationship**.

- **In internal software development projects**, Visure Requirements has had an average impact. In general they are relatively small projects, where the impact on savings in effort has been limited.

Advantages: unification of document formats, the availability of a structured and centralized replacement, improves the quality of the documentation and to have traceability in the changes of the requirements.

- **In software evaluation projects (RFP)**, Visure Requirements has had an average-high impact. In these projects, various people participate from different client areas that contribute to the definition and prioritization of the Requirements.

Advantages: the use of Visure Requirements has allowed for the speed up in the requirements collection and the generation of diverse documents used in support of RFP. (Requirements descriptive document, evaluation grid, etc.).

- **In software validation projects (GAMP4 Process)** Visure Requirements has had a high impact. Current legislation governing the pharmaceutical sector requires that the computer systems should be valid. In this type of project various people intervene from the client areas, IT and quality.

Advantages: The validation of the system requires the detailed documentation of things such as, user requirements, functional specifications, risk analysis, IQ/OQ/PQ tests, etc. and also maintains the traceability amongst all of them. The use of Visure Requirements has allowed the speed up in the requirements recollection and documentation in each of these aspects, and also the traceability amongst themselves. The use of the system represents an important saving in time and has permitted an improvement in the quality and control of the documentation produced.

To sum up, Visure Requirements has allowed us to accelerate the improvement of the Requirements Management processes, improve the quality of the documentation and give support to systems validation in the Communication Development department at PharmaMar.

ABOUT PHARMAMAR

PharmaMar, a Company from the Bio-Pharmaceutical sector, with 250-300 employees. Its corporate activity being the discovery and development of Pharmaceutical compounds for treatment in oncology, based on organisms of a marine origin.

www.pharmamar.com

ABOUT VISURE SOLUTIONS

Visure Solutions is the market leader in Requirements Definition & Management. Through its Requirement Lifecycle Management platform, Visure offers specialized and innovative solutions that enable its customers to develop the highest quality products, systems and services. Visure's quality, state-of-the-art features and benefits are endorsed by the world's leading organizations. Visure's team has unique and profound experience in the development and implementation of requirements solutions.

www.visuresolutions.com

"Visure Requirements resulted to be a very useful tool for the management of requirements in medium sized projects, especially in those for Systems Validation, following the process described in the GAMP4 guide. The use of Visure Requirements has helped in the reduction of time dedicated to the production and maintenance of project documentation, and at the same time allowing for a great improvement in its quality and control.

Visure Requirements has allowed us to pass from a requirements management based on documents, to a much more efficient Requirements Management, based on the centralized "unique replacement" concept, for all projects".

Oswaldo Nestares
Communication Development Department Manager,
PharmaMar