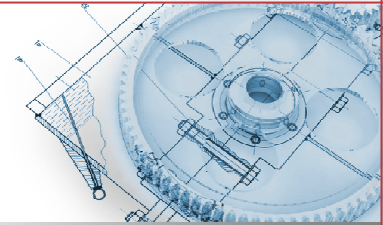


## Case Study Engineering Support



### Requirements Management for Regulatory Compliance

#### Project Background

Our client wanted to re-document the requirements for a product having to ensure regulatory compliance (ISO 62304 conformity, FDA, etc).

#### The Client

The client is a large worldwide company producing medical diagnostic systems and system components. POC (Point of Care) application, with following Product features:

- Web based technology and connectivity
- Import and export data in various formats
- Automated and manual patient and quality control result entry
- Interfaces between laboratory and hospital Information systems
- User defined system generated warnings and alerts
- Multi-site capability within a hospital network.

Centralized management of system configuration, materials, quality control, reports, operators, instruments and tests.

#### Challenges

Our client wanted to re-document the requirements in parallel with the improvement and development of the product. The requirements management and engineering processes of the project have to be conforming to the company internal processes.

The initial product requirements are rare, incomplete and most of the documentation concern only changes in the eight previous years. The product is known by few people who are product manager, developer and tester. Consequently a part of the requirements engineering is reverse engineering. In parallel with this re-documentation, there are several product releases which have to be described, developed, tested and implemented, with respect of quality, time and budget.

#### Project Scope and the Role of SynSpace

SynSpace set up a plan to deliver the service. The requirements management plan contains:

- Definition, scope, organization and project schedule
- Description of used processes
- List of deliveries
- Structure of documentation
- Documentation tool
- Change Management

#### Results

After almost two years of documentation, our client has now several thousands of product and software requirements, which

- Build the base and continue to be developed and updated for all further development of the product, release after release
- Build the reference for the tests, which are traced on both product and software levels, with
- Vertical traceability from customer requirements to the unit level
- Horizontal traceability between risk and requirements
- Horizontal traceability from requirements to test cases

In one of the phases of the project we have trained most of the software developers in requirements engineering to facilitate their understanding of requirements.

In parallel, SynSpace is developing the requirements for the product releases, the bug fixing, and the requirements to eliminate the gaps of the existing documentation. The new requirements help the customer to have good product and software documentation, also base for the worldwide distribution of the product, e.g. in the USA

#### Measurable Business Value

- Our client has seen a sensible increase of its product requirement's quality and quantity, stored in a central documentation system.
- The documentation is more and more a solid base for the development, the testing and know how transfer.
- The product ensures regulatory compliance.



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