GRIFOLS

Overview

The need
With regulatory requirements growing, Diagnostic Grifols wanted a more cost-effective way to manage product development lifecycles of up to 15 years, and across multiple product lines.

The solution
Diagnostic Grifols, working with IBM Business Partner ULMA Embedded Solutions, is using IBM® Rational® solutions to reduce the complexity of managing stringent documentation requirements for growing families of products.

The benefit
Boosts the efficiency of documenting development processes by 30 percent—facilitating compliance, ensuring consistency of design records across all product lines, and reducing operational costs.

Diagnostic Grifols

Documenting complex product development processes efficiently with IBM and ULMA Embedded Solutions

At clinical testing laboratories worldwide, the pressure is on to perform larger volumes of increasingly complex analyses. For the manufacturers that build clinical testing solutions, the challenge is to develop technologies to meet the new requirements while ensuring compliance with increasingly stringent regulations.

New regulations, new challenges

This was the situation facing Diagnostic Grifols—a world-leading medical device manufacturer headquartered in Barcelona, Spain. Jordi Manzano, Instruments R&D Director at Diagnostic Grifols, explains: "Grifols provides automatic systems that perform diagnostics on blood and plasma samples to clinical testing laboratories around the world.

"As diagnostic techniques have evolved and the regulatory landscape has changed, our product development process has grown in complexity. Every aspect of a new product—from the mechanical systems to the underlying code—must be thoroughly documented, assessed and approved by industry bodies.

"Previously, we relied on manual approaches to document our requirements and manage our development processes. As the complexity of the processes grew, it become increasingly time-consuming for our teams to manage the information using files and folders within our internal network."

"Succeeding in an industry with rapidly changing requirements requires the flexibility to adapt to new demands whenever they arise. IBM is continually building new capabilities into the IBM Rational platform, which helps us to reduce the cost and complexity of working in a heavily regulated industry," says Jordi Manzano, Instruments R&D Director, Diagnostic Grifols.

Solution components

Software
- IBM® Rational® DOORS®
- IBM Rational DOORS Web Access
- IBM Rational Lifecycle Integration Adapters
- IBM Rational Publishing Engine
- IBM Rational Quality Manager

IBM Business Partner
- ULMA Embedded Solutions

He continues: "Our finished products tend to have long lifecycles—sometimes more than 15 years. With multiple product lines and long, complex development cycles, our manual approach to documentation increased the risk of human error entering the process, and threatened our ability to achieve our rigorous compliance objectives."

Managing evolving requirements

To reduce the time required to bring new offerings to market, Diagnostic Grifols decided to implement an enterprise-class requirements management solution based on IBM Rational DOORS® software.

"One of the key factors that led us to the IBM Rational solution was the ability to build a standardized approach to requirements management based on industry best practices," says Jordi Manzano. "By adopting the IBM solution, we realized that we could accelerate the process of adding or modifying requirements information, and gain the ability to more quickly and accurately track the progress of our development, testing and regulatory approval cycles."

As a first step, Diagnostic Grifols deployed IBM Rational DOORS, enabling a collaborative platform for employees to manage changing requirements.

Based on its initial success with the IBM Rational platform, Diagnostic Grifols saw an opportunity to further reduce the time required to build and test new products.

Jordi Manzano comments: "Since first deploying the IBM platform, we have started developing families of products that share common components. Rather than testing thousands of similar components one-by-one, we saw an opportunity to streamline the regulatory approval process by reusing test cases wherever possible."

Strong partnership

To help achieve its goal, Diagnostic Grifols engaged an expert team from IBM Advanced Business Partner ULMA Embedded Solutions. By deploying IBM Rational Quality Manager software, developers at Diagnostic Grifols will be able to create reusable template tests, reducing development cycle times for similar components.

"The ULMA Embedded Solutions team has quickly helped us to develop a method for migrating large amounts of complex data to the IBM Rational Quality Manager platform—a complex process that involves a wide variety of data types," says Jordi Manzano. "Our journey with the ULMA Embedded Solutions team is just beginning, and we are confident that our collaboration will be close and productive."

"Thanks to IBM Rational software and ULMA Embedded Solutions, we were able to deploy a new set of tools that will enable us to deliver a new generation of diagnostic solutions for our healthcare clients worldwide."

— Jordi Manzano, Instruments R&D Director at Diagnostic Grifols

Getting to market faster

With IBM Rational solutions at the heart of its product development process, Diagnostic Grifols is achieving its goal of accelerating time to market for new diagnostic systems and protecting its investment in existing product lines.

"Before, our engineers were spending hours of their time on manually managing development information using files and folders," recalls Jordi Manzano. "With the IBM Rational solutions, that kind of activity is a thing of the past. Our employees now make a full account of complex development work rapidly in IBM Rational DOORS. In fact, the IBM solution helps us to improves the efficiency of documenting our product development process—a very important aspect of the overall development cycle—by 30 percent, which helps to shorten our time to market and reduce operational costs."

Intuitive platform

Today, Diagnostic Grifols can support its complex development processes more easily than ever before.

"In the past, our documentation processes were time-consuming and error-prone, which made it difficult to train new members of the team to perform all of the necessary documentation tasks correctly," says Jordi Manzano. "We anticipate that the new IBM Rational platform will help us to simplify the management of our testing data—decreasing the time needed for new employees to become proficient, and further reducing the risk of human error entering the documentation process."

He concludes: "We are very pleased with the efficiency improvements that we have driven with IBM Rational DOORS. Thanks to IBM Rational software and ULMA Embedded Solutions, we were able to deploy a new set of tools that will enable us to deliver a new generation of diagnostic solutions for our healthcare clients worldwide."

About Diagnostic Grifols

One of three divisions of Grifols—a world-leading healthcare enterprise headquartered in Barcelona, Spain—Diagnostic Grifols produces devices, instruments and reagents for clinical testing laboratories. Since its founding in 1940, Grifols has grown to employ more than 11,500 people worldwide, and reports annual revenues equivalent to approximately USD2.9 billion.

To learn more about Diagnostic Grifols, please visit: www.grifols.com

About ULMA Embedded Solutions

Founded in 2009 in Oñati, Spain, ULMA Embedded Solutions is a leading solution integrator and IBM Advanced Business Partner, focused on embedded systems for safety- and mission-critical applications. ULMA Embedded Solutions delivers solutions that meet stringent business and regulatory requirements for a comprehensive range of sectors including transportation, healthcare and aerospace.

To learn more about services and solutions from ULMA Embedded Solutions, please visit: www.ulmaembedded.com

For more information

To learn more about IBM Rational solutions, contact your IBM representative or IBM Business Partner, or visit the following website: **ibm.com**/rational

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