

## CASE STUDY

# Managing Global Growth with an Integrated Quality System in the Cloud

## In Brief

**Customer Profile:** DiaSorin S.p.A., a global in vitro diagnostics company, develops, produces, and markets reagent kits for clinical laboratory diagnostics including universities, hospitals, and private testing facilities.



**Situation:** DiaSorin needed to harmonize its facilities to better ensure satisfaction of customer requirements, and improve efficiency, productivity, and compliance with current industry regulations: cGMP (21 CFR Part 11, Part 820), ISO 9001:2008, and ISO 13485:2003.

**Solution:** Pilgrim's Cloud solution standardizes all DiaSorin sites, sharing data to resolve any quality or regulatory issues. The on-demand approach enabled a quick implementation and allowed them to focus on building expertise and efficiencies into operations rather than managing technology.

**Business Type:** In Vitro Diagnostics

**Users:** More than 1,500 employees in more than 28 locations around the world

**Pilgrim Quality's SmartSolve® Solutions:** Audit Management, CAPA Management, Change Management, Supplier Quality Management, and Training Management

## Challenge

DiaSorin S.p.A. is a global player in the in vitro diagnostics market, a rapidly growing medical field. With geographically global operations and impending growth on a global scale, it was looking to manage this growth with an integrated, harmonized system for managing quality and compliance. DiaSorin needed to simplify and standardize its processes to improve efficiency and better serve current and potential clients; to add new sites to the existing system; to improve visibility for management; and to automate trending capabilities. Without a standardized platform for these critical management needs, DiaSorin faced multiple challenges to its ongoing quality and compliance objectives.

Multiple disparate systems can force companies to contend with lengthy cycle times for activity completion; multiple, non-synchronized views of metrics; lack of communication regarding change; and delayed identification, analysis and reporting of adverse events/nonconformances, customer complaints and regulatory concerns. In the long run, these problems can result in operational inefficiencies, increasing costs, regulatory risks, and potential loss of customer confidence.

As such, DiaSorin attempted to identify an integrated enterprise-class software solution that could address each of these concerns without interrupting business operations amidst rapid growth. Therefore, this

system would need to be flexible, provide out-of-the-box best practices, require minimal configuration and maintenance, and most importantly, be easy for its users to adopt.

DiaSorin established the following criteria for selecting a quality and compliance management software solution: an out-of-the-box system that would minimize complications with installation and integration; provide a logical interface between disparate system responsibilities; involve short implementation time and a reliable maintenance plan; and require lower overall maintenance and overall total cost of ownership.

## Solution

Upon recognizing that Pilgrim's enterprise solution for compliance, risk, and quality management could deliver on the desired criteria, DiaSorin knew it had found the software to help it unify its processes across its global network. The company realized it would also improve the efficiency and effectiveness of its team and support its growth as it continues to expand its global reach.

With an on-demand Cloud, or SaaS (Software as a Service), SmartSolve solution, the automated system could be deployed rapidly, eliminating the infrastructure and ongoing costs associated with installing and managing an in-house system. Compared to traditional enterprise software implementation models, Pilgrim's Cloud eliminates the customers' traditional IT and validation burdens. The Cloud provides secure enterprise-class managed hosting services with 100 percent uptime through enterprise-grade facilities, network, and staff to build, support, and grow its customers' mission-critical infrastructure.

The rollout of Pilgrim's CAPA Management led to operational improvement and cost savings on the manufacturing side. DiaSorin can now track the source of a nonconformance, including which product and

which supplier, and shorten the time-to-resolution through improved visibility and prompt notifications. The solution also provides detailed trending and reporting capabilities for quality exception records. The enterprise-wide availability of these precise records increases management's oversight of regulatory reporting and compliance risk.

Additionally, DiaSorin has sites that share suppliers. Having one system for CAPA management reduces variability and enhances visibility and identification of supplier problems, particularly when working in tandem with Pilgrim's Supplier Quality Management. Adding to the effectiveness of integrated solutions, the CAPA system, together with Pilgrim's Audit Management, permits DiaSorin to be alerted to any vendors, anywhere worldwide, that can potentially be the source of a widespread problem.

DiaSorin has engaged SmartSolve in-the-Cloud to support a range of standard audits, including internal audits (ISO, Process, GMP, etc.), corporate audits, supplier audits, and external audits by customers and regulatory bodies. Audit Management improves the company's audit findings, reduces time-to-resolution due to improved visibility and prompt notifications, and increases management's overall oversight of compliance risk with detailed trending and reporting.

Recent growth and anticipated personnel expansion warrants a comprehensive Training Management system to maintain training and certification records for all employees. This allows for knowledge transfer among departments and sites, and knowledge verification through online assessments. DiaSorin relies on Pilgrim's Training Management solution to ease standard training processes and support the company's trainees, managers, and trainers at all sites worldwide.

Change Management further supports DiaSorin's continuous high standards for global regulatory compliance and quality performance. On the

regulatory side, the solution enables the company to meet ISO requirements for registrations as well as FDA reporting requirements surrounding change. Using this solution, DiaSorin can configure and manage any type of operational change, from infrastructure and facility changes, to product and process changes, to document, validation, or specification changes.

It was implemented to consolidate 20-plus change procedures into one, and to replace an existing Lotus Notes-based system and other legacy systems. Change Management standardizes the change recording and handling process on an enterprise-level, including the decision-making process leading up to the change, which thereby facilitates continuous improvement in these areas.

## Business Benefits

### On Demand

- Web-based system for easy access
- Reduction of process administration burden
- Optimal global system performance
- Increased management oversight without increased workload
- Decreased overhead

In the future, due to Pilgrim Cloud's integrated design and scalability, DiaSorin will be able to seamlessly harmonize the systems of any future sites or functions it may engage.

### Enterprise-Wide Solutions

- Harmonized, standardized business processes
- Reduced event time-to-resolution, recording, and reporting
- Integrated with other third-party platforms
- Satisfied industry and internal regulatory requirements with integrated compliance platform
- Incorporated Electronic Audit trails
- Increased transparency and communication between all sites
- Improved employee accountability
- Enhanced site-level productivity

- Improved visibility of supplier problems
- Enabled timely reporting submissions from all sites
- Improved resolution of complaints resulting in higher overall customer satisfaction

With Pilgrim's cost-effective, value-added Cloud solution, DiaSorin is successfully meeting its objectives for harmonizing multiple sites worldwide, thereby reducing risk, ensuring compliance with current industry regulations, strengthening overall quality and customer satisfaction, and increasing efficiency and productivity.

## About Pilgrim Quality Solutions

Established in 1993, Pilgrim Quality Solutions is the most experienced enterprise quality management provider in the life sciences industry with more than 750,000 end-users.

Pilgrim is dedicated to research and development and incorporates industry best practices into its products resulting in solutions that are specifically targeted to streamline critical quality processes and provide the bottom-line results that life sciences organizations demand. Built on leading web-based open architecture standards, Pilgrim's cost-effective solutions incorporate industry best practices and limit the need for extensive training, saving customers implementation time and labor costs.

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