

## In Brief

### Customer Profile:

DiaSorin S.p.A., a global in vitro diagnostics company, develops, produces and markets reagent kits for clinical laboratory diagnostics. It develops a vast and innovative line of products used in analysis laboratories at universities, hospitals and private testing facilities.



### Situation:

Comprised of 28 companies worldwide, DiaSorin operates a global group comprised of more than 1,500 employees at its 3 research and development facilities and 6 manufacturing sites. Thanks to its worldwide operational and distribution network, it has presence in more than 60 countries. In its ongoing commitment to leverage and expand its capabilities, support efficiently the growth of its business, while simultaneously addressing internal operations to improve its efficiency, DiaSorin was seeking a single, integrated software and solution platform for enterprise-wide risk, quality and compliance management. Harmonizing the facilities would better ensure satisfaction of customer requirements, improved efficiency and productivity, and compliance with current industry regulations, including cGMP (21 CFR Part 11, Part 820), ISO 9001:2008 and ISO 13485:2003.

### Solution:

DiaSorin selected Pilgrim Software's On Demand platform of Enterprise Risk, Compliance and Quality Management solutions to standardize its systems across the enterprise. Integrated automated solutions for capturing, managing, and reporting on **complaints, corrective and preventive actions, change management, internal/external audits, supplier management, equipment management** and **employee training** have been implemented, enabling all of the company's sites to share data rapidly, and to effectively resolve any quality or regulatory issues that arise. Additionally, the on-demand approach removed the burden of implementing an enterprise application from DiaSorin, to Pilgrim, enabling it to begin using the solution quickly and to then focus on building expertise and efficiencies into its operations rather than focusing on the technology.

### Business Type:

In Vitro Diagnostics Business

### Users:

More than 1,500 employees in more than 28 locations around the world.

### Solutions:

Audit Management, Change Management, Corrective & Preventive Action Management, Equipment Management, Supplier 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 the growth with an integrated, harmonized system for managing quality and compliance. Specific needs identified included the simplification and harmonization of processes to improve efficiency and to serve current and potential new clients with the highest level of quality; scalability to add new sites to the existing system; improved visibility for management; and, automated 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 result in potential operational inefficiencies, cost inefficiencies, regulatory risk, and potential loss of customer confidence.

As such, DiaSorin attempted to identify an integrated enterprise-class software system 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 on its part, and perhaps most importantly, be easy for its users to adopt.

DiaSorin established the following criteria for selecting a possible quality and compliance management software solution: an out-of-the-box software solution 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 cost of ownership.

### Solution:

Upon recognizing that Pilgrim Software's enterprise solution for risk management, quality and compliance could deliver on the desired criteria, DiaSorin knew it had found the software to help it to unify its processes across its global network, and in the process, to improve the efficiencies and effectiveness of its team and support its growth as it expands its global reach.

The decision to select Pilgrim Software was driven by the need for DiaSorin to partner with the top-notch company providing a solution that combines an excellent platform with level of excellence. DiaSorin has continually provided to its clients.

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

The rollout of Pilgrim's **CAPA** solution had led to operational improvement and cost savings on the manufacturing side. DiaSorin can 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, and having one system for CAPA management, particularly when working in tandem with Pilgrim's **Supplier Management** solution, reduces variability, and enhances visibility and identification of supplier problems. Adding to the effectiveness of integrated solutions, the CAPA system, together with Pilgrim's **Audit** capabilities, permits DiaSorin to be alerted to any vendors, anywhere worldwide, that potentially could be the source of a widespread problem.

Pilgrim's **Equipment Management** process has been implemented to support the Engineering department's multiple critical processes including equipment registration, calibration, preventive maintenance (scheduled or unscheduled) and quality exceptions such as failed calibration or maintenance events. The solution is accessible to various users across the enterprise, including equipment technicians, administrators and event reviewers.

DiaSorin has engaged Pilgrim's solution to support a range of standard **audits**, including internal audit (ISO, Process, GMP, etc.), corporate audits, supplier audits, external audits by customers and regulatory bodies,. Results are expected to improve recording of audit findings, quicker time-to-resolution due to improved visibility and prompt notifications, detailed trending and reporting, and overall increases in management's oversight of compliance risk.

Recent growth and anticipated expansion of personnel warrants a comprehensive **Training Management** system to maintain training and certification records for all employees, to allow for knowledge transfer among departments and sites, and knowledge verification through online assessment. 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.

Further supporting DiaSorin's continuous high standards for global regulatory compliance and quality performance is Pilgrim's solution for **Change Management** solution. 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 some existing Lotus

Notes-based system and other legacy systems, standardizing the change management recording and handling process on an enterprise-level, as well as the decision-making leading up to Change Management, thereby facilitating 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 On Demand'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
- Integrated compliance platform that satisfies industry and internal regulatory requirements
- Electronic Audit trail
- Increased transparency and communication between all sites
- Improved employee accountability
- Enhanced site-level productivity
- Improved visibility of supplier problems
- Timely reporting submissions from all sites
- Meets or exceeds overall customer satisfaction through rapid resolution of complaints

With Pilgrim's cost-effective, value-added On Demand solution, DiaSorin is successfully meeting its objectives for harmonizing its 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 Software

Established in 1993, Pilgrim Software is the most experienced enterprise risk, compliance and quality management provider in the life sciences industry with more than 750,000 end-users globally.

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.

Visit [www.pilgrimsoftware.com](http://www.pilgrimsoftware.com) for more information.

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