

Managing the Product Record for the Medical Device Industry

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“The dynamic medical device and instrumentation market depends on its ability to rapidly innovate its product offerings and, at the same time, support rigorous FDA requirements for electronic documentation. IDC believes that Agile Product Lifecycle Management can help medical device and instrumentation manufacturers develop and maintain competitive product portfolios.”

**—Gisela Wilson,
Director of Product Lifecycle
Management Solutions, IDC**

INTRODUCTION

A graying population’s increased demand for effective, efficient medical devices, combined with the advances in science and technology that have allowed device makers to meet that demand, has led to a period of unprecedented growth for the medical device industry. But the same things that are driving industry growth—scientific advances, drug and device convergence, and more—are also challenging traditional device development models. As a result, device makers find themselves struggling to remain competitive despite the market’s rosy outlook—looking for ways to reduce time to market, cut operating and material costs, and lower the cost and risk of compliance.

Oracle’s Agile Product Lifecycle Management solutions help device makers achieve these goals by providing a single view into the enterprisewide product record—all the information required to conceptualize, design, source, build, sell, service, and dispose of medical devices. By allowing companies to manage the product record throughout its lifecycle—from research and development to prototyping development, clinical trials, regulatory approval, product introduction, market acceptance, and more—Agile Product Lifecycle Management solutions enable medical device makers to

- Accelerate revenue growth
- Reduce costs
- Improve product quality
- Ensure compliance
- Drive innovation

AGILE PRODUCT LIFECYCLE MANAGEMENT

Today’s leading medical device manufacturers are responding to the demands of a constantly evolving and increasingly competitive medical device marketplace by using Agile Product Lifecycle Management to bring together the disparate organizations, information, and systems required to deliver products to market faster and at a lower cost than their competition, while still complying with regulatory requirements.

Providing a broad suite of best practice, enterprise-class product lifecycle management solutions, Agile Product Lifecycle Management helps medical device makers get the most from their products by facilitating a single enterprisewide view of the product record across the extended enterprise. Built on a secure and scalable standards-based architecture, Agile Product Lifecycle Management can be quickly and cost-effectively implemented to provide seamless interoperability with existing information technology environments, comprehensive decision support, and global support for collaborative product lifecycle processes.

As part of the Agile Product Lifecycle Management solution, Agile Product Lifecycle Management helps medical device makers

“The deployment of Agile [Product Lifecycle Management] across the company decreased our change management cycle time by up to 70 percent, creating a major positive impact on our time to market.”

**—Thor Wallace,
CIO, Analogic**

- **Drive product innovation and introduction.** By providing a central solution for collaborating internally and externally, and by managing all aspects of the product portfolio (such as resource management, intellectual property, and design history), Agile Product Lifecycle Management spurs innovation and hastens product introductions.
- **Lower product and administrative costs.** By providing workflow-enabled change management processes for core product record components (such as documents, drawings, labels and packaging, device master records, and engineering change orders), Agile Product Lifecycle Management helps reduce product and administrative costs.
- **Improve product quality.** By providing a central solution for aggregating, analyzing, and resolving product quality issues (which can range from customer complaints to manufacturing deviations, adverse event information, corrective actions from suppliers, and more), Agile Product Lifecycle Management closes the loop on such issues—resolving the quality problems and communicating their resolutions, including compiling medical device reports for submission to the U.S. Food and Drug Administration (FDA).
- **Ensure regulatory compliance.** Agile Product Lifecycle Management provides the infrastructure needed to meet the requirements outlined by the FDA’s quality system regulations (Part 820) and comply with FDA 21 CFR Part 11. (Oracle also provides solutions to help speed the validation of your Agile Product Lifecycle Management system implementation.)
- **Leverage outsourced research, design, manufacturing, and packaging services.** By providing secure, role-based access to product information and progress status, Agile Product Lifecycle Management lets medical device makers focus on their core competencies, while ensuring that their networked supply chains are making swift progress and producing high-quality work.

USING AGILE PRODUCT LIFECYCLE MANAGEMENT THROUGHOUT THE PRODUCT LIFECYCLE

With Agile Product Lifecycle Management, you can leverage industry best practices to improve profitability in every phase of your medical device's lifecycle—from concept to design, prototype, trials, production, introduction, and more.

Concept

In the concept phase, you can use Agile Product Lifecycle Management to assess market needs and manage your product specifications accordingly. Agile Product Lifecycle Management also helps you improve next-generation products by allowing you to review defect and quality improvement information from prior development efforts.

Design and Development

In the design and development phase, Agile Product Lifecycle Management enables you to leverage intellectual property, collaborate with internal and external partners, incorporate product sourcing decisions, and develop the product quality documentation that will ensure regulatory compliance.

Prototyping and Trials

In the prototyping and trial phase of your medical device's development, you can use Agile Product Lifecycle Management to manage communication across the collaborative research network, to schedule and manage milestones in the clinical trial process, and to stay on top of product defects and quality issues.

Approval, Launch, and Ramp

In the approval, launch, and ramp phase, Agile Product Lifecycle Management enables you to manage regulatory submissions and take charge of the processes and documentation surrounding approval. By taking advantage of its collaboration features, you can implement design and document changes rapidly and manage performance costs with ease. In addition, Agile Product Lifecycle Management allows you to manage changes efficiently and to communicate easily with regulatory agencies—both of which help to facilitate speedy product introductions. The results are faster times to market, reduced scrap and rework costs, and well-managed design and manufacturing relationships.

Production

In the production phase, you can use Agile Product Lifecycle Management to manage closed-loop corrective action preventative actions (CAPA) and change management processes, monitor product costs continuously, communicate quality issues and corrective action requests (CAR) internally and externally, and manage postmarket surveillance.

“Lengthy product introduction time, document control process issues, and regulatory compliance have always been challenges in the medical device industry. Agile [now part of Oracle] has created a complete solution that can really help manage a product from conception through the end of life.”

**—Dave Rudzinsky,
CIO, Hologic**

“Using Agile [Product Lifecycle Management] is an important and exciting next step in Avail’s ability to accurately speed communication and collaboration and provide the highest level of service possible to our customers. Product development time, product change management, even the continuity of supply throughout volume production can be significantly enhanced with this implementation.”

**—J. Randall Keene,
CEO, Avail**

Service, Support, Phase-Out, and Disposal

During the service, support, phase-out, and disposal stages, Agile Product Lifecycle Management enables you to retain the product record indefinitely and to provide research and development teams with information on quality and defects that they can then use in creating new products. Agile Product Lifecycle Management also makes it easy for you to comply with end-of-life regulations such as the European Union’s Waste Electrical and Electronic Equipment regulations.

AGILE PRODUCT LIFECYCLE MANAGEMENT: FOCUSED ON THE MEDICAL DEVICE INDUSTRY

The Agile Product Lifecycle Management solution for the medical device industry, includes the following:

- **Best practice templates.** These templates ensure the fastest time to value of any product lifecycle management solution.
- **Agile Validation Protocol Paks.** These tools are designed to reduce the time and costs involved in validating your instance of Agile Product Lifecycle Management.
- **MEDSIG.** This Medical Industry Special Interest Group brings together professionals and thought leaders from across the medical industry to ensure that the “voice of the customer” is driving Agile Product Lifecycle Management development.
- **Partner ecosystem.** Through partnership with Oracle, this network delivers complementary solutions, solid integrations, and consulting and validation services.
- **Quality assurance program.** This program ensures customers that their Agile solutions exceed industry standards for engineering and quality.



Agile Product Lifecycle Management maintains an accurate product record for companies in the medical device industry.

THE ENTERPRISE PRODUCT RECORD

In recent years, companies have deployed a range of enterprise systems of record to manage select business operations. These include

- Customer relationship management systems for managing the customer record
- Enterprise resource planning systems for managing the financial record
- Supply chain management systems for managing the supplier record
- Human capital management systems for managing the employee record

But although customers, suppliers, employees, and inventory all represent important assets, it's a company's products that define its competitive advantage. Agile Product Lifecycle Management ensures that you retain that competitive advantage by providing a single view into the enterprise product record. Containing the data that defines a product in each stage in its lifecycle, the enterprise product record includes all the information required by the extended enterprise, including the supply chain, to conceptualize, design, source, build, sell, service, and dispose of products.

Consisting of a broad suite of best practice, business-ready solutions, Agile Product Lifecycle Management provides secure, timely visibility into and control of product information—capabilities that help organizations accelerate revenue, reduce costs,

improve quality, ensure compliance, and drive innovation throughout the product lifecycle.

CONCLUSION

Medical device makers deploying Agile Product Lifecycle Management solutions have seen quantifiable improvements in a number of areas, including

- A 60 percent reduction in product introduction time
- A 5 percent reduction in direct material costs
- A 25 percent reduction in operational costs

In addition, companies using Oracle's Agile Product Lifecycle Management are more easily able to comply with increasingly strict regulatory requirements. As a result, such companies have been able to sustain the benefits of faster times to market, better-quality products, cost-effective compliance, and increased brand equity—all key factors in keeping competitive in today's medical device market.



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