

Unlimited Possibilities for Limited Budgets

The Issue

Like any other product-driven company, Medical Device companies are under relentless pressure to accelerate innovation, strategically manage the new product introduction process, drive product portfolio profitability, and improve quality, but have an additional unique challenge - decreasing the pain and cost of managing their products for regulatory compliance.



J-Squared Technologies Is the Right Partner for Oracle Agile PLM in Medical Device Companies.

Our proven implementation approach draws upon years of industry-specific experience in the Medical Device marketplace allowing us to consistently guide our customers to early success with Agile PLM. We utilize a templated, fixed-cost, fixed-scope services engagement to achieve initial go-live. We understand our customer's business and we understand how to deliver business results quickly with Agile, building on years of Agile PLM implementation experience.

→ AAIM for Accelerated Success with Agile PLM:

- Targeted for Medical Device companies managing to FDA regulatory compliance
- Affordable, fixed-cost, fixed-scope implementation for Oracle Agile PLM
- Industry best practice templates & solutions
- Focused on early time to benefits
- Consistent and predictable results through experience and repeatability
- Scalable to support ongoing business growth and collaboration across global product network
- Cost of implementation and ownership reduced through user adoption and customer empowerment

We employ our **Agile Accelerated Implementation Methodology (AAIM)** developed to contain startup cost, maintain predictable deliverables and project schedules, speed implementation, and promote early user adoption helping our customers achieve quick results and ROI through rapid startup and deployment of Oracle Agile PLM, with project completion in weeks not months.

Once in production, our customers are able to make better decisions on how to further extend their PLM strategy to achieve business benefits across their entire product supply chain with system growth now funded by the benefits being returned by their live Agile PLM system.

J-Squared's AAIM Accelerate Solution for Agile PLM in Medical Device Companies Provides the Following Key Benefits:

→ Industry Complete

J-Squared's AAIM approach addresses industry best practices and supporting business flows to help Medical Device companies manage their Device Master Record, Design History File, documentation and quality processes in compliance with Quality Systems Regulations. These are business-ready templates representing leading business practices. Business flows enable the customer to relate their business requirements to the Oracle Agile PLM solution functionality. Key business processes enabled include:

- Product collaboration
- Product quality management
- New Product Introduction (NPI)
- ECO, MCO, ECR, stop ship, deviation, change management workflows with electronic sign-off compliant to 21 CFR Part 11
- Complaint handling, problem reports, CARs, CAPA, and NCMRs
- DHF & DMR management, and product configuration management
- Release management
- Documentation control



Why do growing companies choose Oracle?

- Industry-focused solutions to meet your unique requirements
- Complete solutions to meet your needs today and tomorrow
- Easy-to-own solutions with predictable value

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→ **Easy to Follow** - AAIM is developed in the language of the Medical Device industry and tailored to quickly enable key business processes for managing product portfolio information through the complete lifecycle of medical device products with industry-relevant workflows to support product collaboration and quality management.

→ **Easy to Implement** - Our Medical Device Accelerate solution deploys common product lifecycle management business transactions in Oracle Agile PLM, dramatically speeding up the initial stages of an implementation, allowing solution consultants to spend more time on additional value-added activities, and ultimately increasing the return on investment for Medical Device customers.

→ **Easy to Extend** – Additionally, customers can add, modify, and expand their entire Agile PLM system footprint as their business scales, yet achieve very fast results by selecting the industry-specific business transactions they need.

**J-Squared Technologies and Oracle**

Doing more with less and quickly adapting to changing business demands are not just goals; they are organizational imperatives. Every step made toward increased business efficiency and agility in the marketplace must have a direct impact on the bottom line and provide a solid return on investment.

J-Squared Technologies and Oracle are aligned to help businesses address these challenges. Together, we have the products, services, and experience to deliver enterprise-wide information and IT adaptability, and the track record to prove it.

Long recognized as a leading technology innovator—Oracle provides an integrated suite of applications that can provide companies with immediate access to complete, high quality business information.

With a rich understanding of Oracle technology and a results-oriented approach to mission-critical business systems and consulting services, J-Squared Technologies successfully implements Oracle applications to help you:

- Gain strategic advantage and make informed business decisions with immediate access to accurate, centralized product record information while managing for regulatory compliance
- Boost productivity, cut costs, and increase revenues through operational efficiency, process automation, and enterprise integration

- Reduce risk and quickly transform your business for increased time-to-benefit

As an Oracle Accelerate partner, J-Squared Technologies can ensure that our consultants remain at the forefront of Oracle technology and that our clients receive the highest level of technical expertise and professional consulting services available.

**Service Overview: Agile PLM Solution Offering**

- Agile PLM implementation consulting with AAIM
- IQ/OQ system validation and documentation
- Data migration services
- ERP, EDA/ECAD/MCAD integration
- Training services
- Project management
- Custom development

**Getting Started from Decision to Go Live: The Process for Success**

J-Squared Technologies, founded in 1990, is a premier provider of Oracle Agile PLM solutions and consulting services. J-Squared is one of Agile’s original, full-service business partners serving the needs of Small-to-Mid-Size Enterprises (SME), to large enterprise customers across North America.

For more information on J-Squared Technologies, please visit [www.jsquared.com](http://www.jsquared.com)

**Oracle Accelerate—Unlimited Possibilities for Limited Budgets**

Oracle and its partners recognize that growing businesses with limited resources demand comprehensive business solutions that are low-cost, low-risk, and provide industry-specific functionality and faster time-to-value.

Oracle Accelerate delivers a complete set of applications, rapid implementation tools, and an extensive partner system, so mid-market businesses can maximize their budgets and achieve real business value quickly. Utilizing a fixed-scope approach, Oracle Accelerate substantially reduces the complexity of more traditional, large-scale implementations.

For customers interested in a rapid, low-risk approach, Oracle Accelerate provides the opportunity to leverage world-class functionality at unprecedented entry-level value.

For more information about Oracle or Oracle Accelerate solutions for Agile PLM, please visit [oracle.com/accelerate](http://oracle.com/accelerate)