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SOLUTIONBRIEF

ARENA QMS

Product-Centric QMS for Market Success

QMS IS A CRITICAL ADVANTAGE FOR REGULATED PRODUCT COMPANIES

Bring high-quality, life-saving products to market faster when you advance quality and drive innovation across the total product lifecycle.

Arena QMS links quality issues and change processes to the active product record, structured in a bill of materials (BOM). With Arena, your entire product team can collaborate throughout the development and quality process to deliver products to a regulated market.

ENSURE COMPLIANCE

One Secure Place

Unify quality and product—all product definitions with engineering changes and quality processes for a complete DMR—controlled access and traceability with no surprises.

CONFIDENT DESIGN CONTROL

ADVANCE QUALITY

Connected and Transparent

Manage quality processes across all products with all teams using a single product-centric QMS system—people and information connected to build continuous improvement.

FULL TEAM COLLAB-ORATION

DRIVE INNOVATION

Strategic

Leverage your product-centric QMS to enable collaboration, closed-loop CAPA management, training management, business intelligence, and integrations to meet your quality, market, and cost goals.

PRODUCT & BUSINESS SUCCESS

ARENA QMS BENEFITS

End Inspections Early

"Thank you for creating a solution that really works as promised!"
– Veteran 15-year production medical device class 2 company

Achieve Your Training Compliance Goals

Almost 100% training compliance? Yes, it is possible, according to our customers.

Scale and Grow With Success

Customers report 10x efficiencies and confidence in meeting regulatory product requirements. You can benefit at any size from startup to enterprise.

UNIFIED PRODUCT AND QUALITY PROCESSES

Executive Stakeholders

- Speed time to value and ensure strategic product goals are met with a single source of truth

Quality Control

- Cultivate a proactive quality culture of process automation, evaluation, and improvement

Engineering

- Improve innovation, quality, and design with input from extended product team, product transparency, and product quality control

Operations

- Streamline new product introduction and eliminate production mistakes with access to the product record
- Reduce cost and improve quality by reporting production problems

Training Manager

- Simplify training record administration, access, and traceability

Supply Chain

- Gain insights and take actions to improve quality and reduce risks
- Bring partners into product realization processes

Customer Service

- Accelerate complaint processes for improved customer satisfaction

Purchasing

- Factor COGS data into product team design decisions for accurate price negotiations and faster fulfillment

IT

- Eliminate upgrade, disaster recovery, and backup activities

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TRUST US WITH YOUR BUSINESS TODAY AND TOMORROW

No matter the size of your team, complexity of your products, or stage of your company, you need solutions you will never outgrow.

Arena is with you every step in the product realization journey. With included enterprise cloud functionality, Arena is available anywhere, anytime for your entire team.

TRANSPARENCY

Embrace Visibility

Visibility directly correlates to revenue. Your teams need unprecedented information transparency and access throughout the entire product lifecycle. Arena gives your teams secure, appropriate access coupled with critical audit history tracking. With Arena, each team member has the information needed to do the job.

COLLABORATION

Be Hive Minded

Everyone has a role to play in the product realization process. Arena provides multiple avenues for formal and informal collaboration, all secure, all auditable. Ensure standard workflows and controlled processes when you need them. And get lighter, fast team chat and sharing for the rapid iterations when less is more. Should everyone in your company use Arena? Read about one customer who says yes.

BUSINESS INSIGHTS

Better Business Decisions

To push for excellence, top-performing companies rely on advanced reporting and analytics to uncover gaps and opportunities in product processes. Discover how our customers use Arena's product analytics to speed up quality processes and achieve product delivery goals.

VALIDATION

Designed to Simplify Compliance

Subject to FDA, EU MDR, or ISO standards? With built-in design controls in Arena's own development cycles, our regulated customers benefit from easier, faster validation of Arena QMS and a simple path to stay current on validation with new releases. Learn more about Arena Validate.

SECURITY

A Layered Defense to Protect You

Arena is architected to address every layer of security to protect our customers' product and quality information. We have a risk-based approach and utilize industry-standard protocols and mechanisms throughout our solution, from the physical layer to policies and the application layer. We will gladly share more details with you as you need. Let us know.

INFORMATION SHARING AND INTEGRATIONS

Extend the Value

All valuable information is or will soon be digital. It is important that data can flow between Arena and other related systems to increase your process efficiency and ensure data accuracy. Explore our enterprise integrations and tools available to connect Arena to the rest of your digital environment. CAD, ERP, CRM, MES, and more—we've got you digitally connected.

SECURELY EXTEND TO YOUR SUPPLY CHAIN TEAM

Your product processes involve multiple teams, locations, partners, suppliers, and vendors. These dispersed teams must comply with the latest regulations and standards. They need to work from the same design, stay on budget, and respond to customer demands. Ensure processes are followed and everyone is collaborating.

WORLDWIDE

66%

of customers and their supply chain partners use Arena from outside the United States every day

INDUSTRY STANDARD

92%

of top EMS providers in the industry access Arena customer systems for product collaboration

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ARENA QMS

Product-Centric QMS for Market Success

Ensure Compliance and Exceed Product Quality Goals

Key Benefits	What Product-Centric Quality Management Does	Quality System Requirement	
		FDA	ISO
Compliant Device Master Record	• Controls entire product record, all components, approved manufacturer lists, user documentation, labeling and packaging specifications, manufacturing and test instructions	Design and Document Controls	Medical Device File
Reduced Design History File Administration	• Manages changes to design plans and documentation • Contains necessary records to demonstrate compliance with FDA Design Controls regulations	Design and Document Controls	Control of Design and Development Changes
Collaborative Quality Processes	• Provides complaint, CAPA, and ECO processes compliant with corporate, ISO (9001, 13485), FDA (21 CFR 820), EU MDR, and other regulations	Corrective and Preventive Action, Nonconforming Product	Quality Processes
Employee Competence and Awareness	• Notifies employees for scheduled retraining events and training triggered by a document release • Automatically creates new training assignments when a new document revision is released to streamline training processes regulations	Personnel	Human Resources
Audit Confidence	• Collects compliance evidence with time-stamped audit trails and electronic signatures on product and quality processes • Provides searches and logically connected product and process information	Audit Support, 21 CFR Part 11	Audit Support
Streamlined Supplier Quality Management	• Manages supplier standards, evaluations, and agreements and quality processes for purchased parts and suppliers	Purchasing Controls	Purchasing Process
Secure Product and Process Data	• Ensures access is granted only to those with proper security access control	N/A	Control of Records
Accelerated System Validation	• Arena performs installation and performance validation prior to each release	Production and Process Controls (Automated Processes)	Validation of Processes for Production
Traceability in Issue Handling	• Tracks issues against requirements, quality process actions, product record components, and project efforts	Nonconforming Product	Product Realization
Verify and Validate Design Requirements	• Provides connected and visible requirements management throughout product lifecycle	Design and Document Controls	Product Realization

Go Beyond Compliance to Great Products

Arena offers the most comprehensive product-centric QMS to help you innovate rapidly. We improve, accelerate, and track your product processes across multiple teams, locations, and partners using compliant processes. We help your teams collaborate through the entire product lifecycle, stay on budget, and respond effectively to customer demands. All of this helps you bring better regulated products to market, faster and easier, so you can change the world.

To find out how you can join some of the most innovative customers in the world, contact arena-sales@ptc.com.

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