



Arena QMS Package

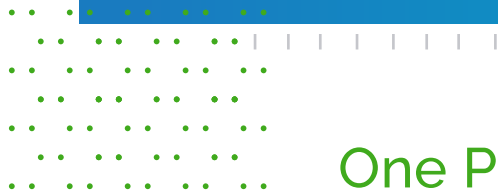
**PRODUCT-CENTRIC QMS
FOR MARKET SUCCESS**

HELPING YOU DELIVER INNOVATIVE PRODUCTS
THAT CHANGE THE WORLD



The Power of One

The work of delivering innovative products is an orchestration. Your teams must collaborate, everyone in sync, across disciplines, locations, responsibilities, time zones, and cultures. The platform for this work needs to be more than the collection of past tools—you need one platform, purpose-built, to drive product realization from start to finish.



One Platform Infinite Advantages



Connected

To bring product realization and quality management together.



Smart

Designed with your business processes in mind.



Flexible

A platform that can be what your team needs it to be—from simple to complex.



Scalable

Solutions you will never outgrow, regardless of your size or complexity.



Compliance-Ready

Built with FDA compliance in mind and supported with a release validation package to streamline compliance.



Everything Is Connected

Products are more complex and integrated than ever before. Your dispersed teams and supply chain partners require secure collaboration. Customers are only a few clicks away from you, expecting transparency and product influence. And competitors push constantly to keep focus on the market demands.

Everything in product realization is connected. Companies that execute the best win the customers. Disparate systems and unconnected processes create gaps, which means unnecessary risks.

Arena QMS provides a connected solution that brings product development and quality management together for your design control processes.

You have all the smart business objects you need to support your different processes from design plans, projects, and requirements to quality processes, changes, and training plans—all connected to your product record.

Connected Gives ...

Everything you need for today and tomorrow.



Product Record Control

- Items/Parts
- Documents
- Relational BOM
- Supplier Quality
- Regulatory & Compliance



Quality

- DHF
- CAPA
- Corrective Actions



Change



Issue Management



Design Plans and Projects



Training



Requirements



A closed-loop system with everyone collaboratively working ... to the same goals.

– Pulse Biosciences
Using Arena for quality management and product lifecycle processes since 2016



Smart Is the Only Way

Why work harder when smarter is possible?

Your teams work under market and resource pressures. You need to be wise and spend energy on the things that matter most to your team goals and company objectives.

We designed Arena QMS for product companies like you. Our interconnected platform is flexible, configurable, and spans the entire product realization process.

Match the system to your teams, data needs, and process flows. With our best practice process templates, your teams can start working smarter almost immediately.

Smart Means ...

Eliminating risky science projects.

Arena QMS can be easily configured to support your product and quality processes without costly coding. We enable easy setup and quick user adoption, with the lowest total cost of ownership (TCO) and fastest time to benefit.

1 Quickly configure what you need.



Change

- Product (ECO)
- Document (DCO)
- Deviations
- Stop Ship
- ...and more



Quality

- CAPA
- CAR/SCAR
- NCMR
- 8D
- ...and more



Requirements

- Business
- Functional
- Test
- ...and more



Issue Management

- Complaint
- Defect
- Requirements Issue
- Quality Issue
- ...and more



Training

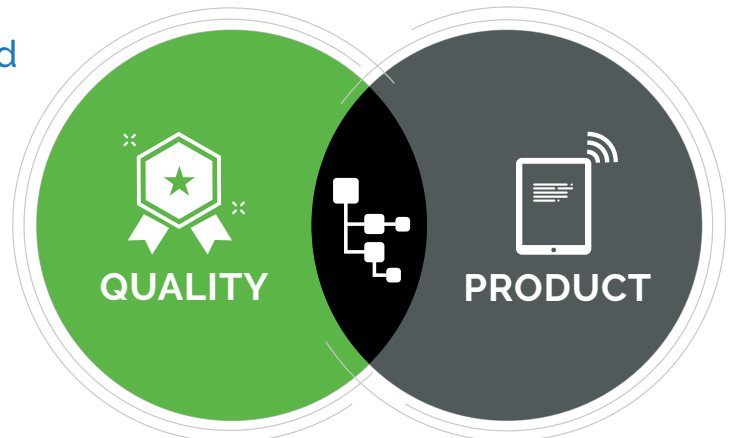
- SOP
- Product
- ...and more



Design Plans and Projects

- Product Release
- Product Portfolios
- Sustaining Product
- ...and more

2 Benefit from connected quality and product records.





You Need Flexibility

One size fits all won't provide the best fit for you. Product processes are not all the same, do not all require equal control, or follow identical collaboration and approval paths. But you don't have time for lengthy customization exercises.

With Arena QMS, you have fast configuration abilities only mouse-clicks away. We know your individual processes and data require different behaviors. With each type of product information, you have powerful configuration options and process flows based on best practices.

Flexibility Provides ...

The best of both worlds—quick deployment with minimal resources AND a system that suits your needs based on the best product practices.



Linkages

With Arena QMS, you can connect the processes that bring your product from design planning through to release and continuous improvement. You create transparent, collaborative, auditable paths through your product's life.



Approvals

Some processes move fast with one-person evaluations. Others require multistage formal reviews for compliance and proper coordination. Arena QMS provides a variety of approval behaviors matched to business processes.



Assignments

Always know who is working on what at any given time, so you can reach your product goals. Arena gives you a variety of assignment options to match each of your business processes.





We Scale With You

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 journey. With included enterprise cloud functionality, Arena is available anywhere, anytime for your entire team.

Scalability Proven ...

By 1,400+ customers from emerging startups to successful public corporations.

Enterprise Platform Attributes for Now and the Future



Transparency

Visibility directly correlates to revenue. Arena gives your teams secure, appropriate-level access coupled with critical audit history tracking.



Business Insights

To push for excellence, top-performing companies rely on Arena's advanced reporting and analytics to uncover gaps and opportunities in product processes.



Collaboration

Arena provides multiple avenues for formal and informal collaboration, all secure, all auditable. Ensure standard workflows and controlled processes when needed and get fast team sharing for rapid iterations in NPD when less is more.



Security

Arena is architected to address every layer of security to protect our customers' information. We have a risk-based approach and utilize industry-standard protocols and mechanisms throughout our solution.



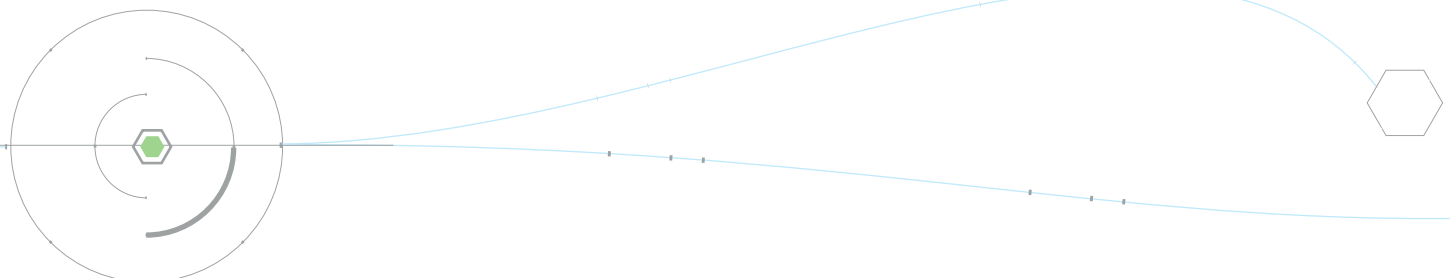
Information Sharing and Integrations

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 connected.



Deployment Options

Experience the ease of the Cloud and remove infrastructure barriers. Arena is built on a secure, multi-tenant cloud architecture, maximizing performance, reducing cost, and automating recovery.





Designed to Simplify Compliance

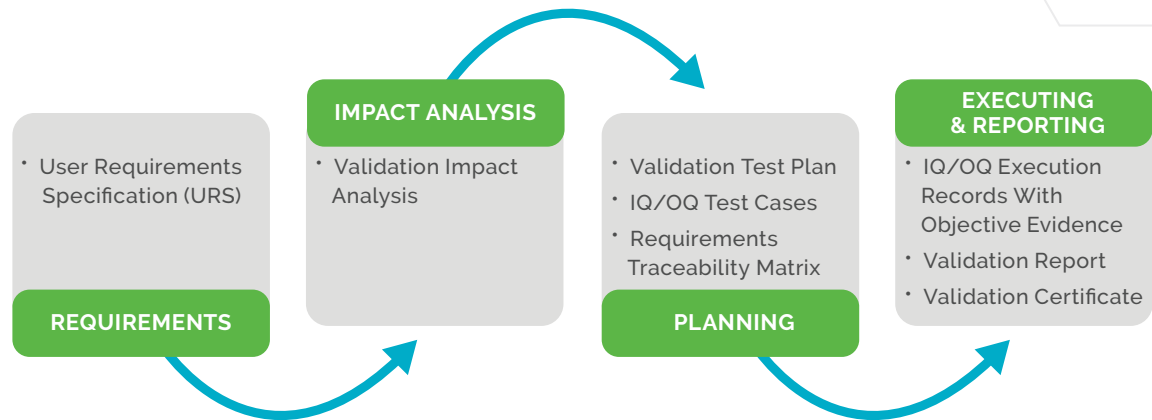
Subject to FDA regulations and ISO standards? Systems you use to design and deliver your products need to be compliant. But, not all solutions are created with regulatory needs and validation in mind. Don't spend more time than necessary on system compliance.

With built-in design controls in Arena's own development cycles, our regulated customers benefit from faster validation of Arena QMS and a simple path to stay current on validation with new releases.

Compliance-Ready Reduces ...

Risks—gaps, uncertainty, time, issues—that threaten your product and company objectives.

Arena Validate Accelerates System Validation



Audit Trail

Arena QMS creates a persistent, automatic history of your product and quality records, including revisions, document versions, approval results (including 21 CFR Part 11 requirements), and actions.



Security

Arena is architected to address every layer of security to protect our customers' information. We have a risk-based approach and utilize industry-standard protocols and mechanisms throughout our solution.



Validation

We embed compliance in our software development process and provide the Arena Validate subscription, a comprehensive validation documentation set for use as objective evidence for your accelerated validation.

Arena QMS: We Make This Easy

With Arena QMS, start with establishing compliant processes, then move beyond to market advantage as you use Arena for all your design control processes—from development to FDA 510(k) clearance, full approval, and production.

We are here for you with the most comprehensive product realization platform on the market. No need to worry about upgrading your solution as you grow.

	Arena QMS
Product Record Control - DMR	✓
Quality Management - DHF, CAPA, CAR, ISO Support	✓
Document Management	✓
Change Management	✓
Regulatory & Compliance	✓
Collaboration	✓
Supplier Quality Management	✓
Project Management	✓
Design Requirements Management	✓
Issue and Complaint Management	✓
Business Insights	✓
3D Visualization	\$
Training Management	\$
Security Controls	✓
Arena Validate	\$
Information Sharing	API, Import, Export, Data Extract
Integration Products	\$
Automations	\$
Onshape CAD Connection	✓
Infrastructure	Unlimited Storage** 8 Workspaces

\$ 3D Visualization - Additional fees apply.

\$ Training Management - One license included for every Write Read or Read Only license purchased. Additional licenses available for a fee for corporate-wide training needs.

\$ Arena Validate - Additional fees apply.

\$ Integration Products - Additional fees apply. For more complex customer needs, Arena also provides MCAD, EDA, ERP, and other enterprise integration solutions.

\$ Automations - includes 5 Automations. Each additional 5 Automations is available for a fee.

** Subject to Arena's Fair Use Policy.

Licensing for Your Team

Choose options to match the way your team works.

Purchase the licenses you need for each type of player on your full product realization team, including partners and suppliers.

License Options <small>Billed Annually</small>	Team
Write Read Empower teams to collaborate on all things	VPs, CTO, Engineering, Ops, QA, Engineers, Document Management, Sourcing & Procurement
Read Only Everyone should know what's going on	CEO, SVPs, Manufacturing, Purchasing
Supplier Easily have partners participate in the product processes	Supplier Mechanical Engineer, Electrical Engineer, Manager, Sales Rep
Training Ensure training compliance across teams company-wide	All team members with training compliance requirements; e.g., Engineering, Quality, Operations, Field Service, Customer Service



Your Success Is Our Success

Our Cloud model means we thrive when you do.

We want you to be wildly successful with Arena and grow with us year after year. To that end, everything we create and all we do is focused on helping you achieve your product dreams.



Your Customer Journey

When you choose Arena, you benefit from the best customer experience. From onboarding activities to scheduled customer success check-ins and customer share opportunities, together we work to ensure your Arena platform has strategic impact on your business.



Deep Domain Success Team

We work with companies of all shapes and sizes. Our expert customer success team understands your business. With 1,300+ successful customer implementations, Arena's proven methodology and value-based pricing give you maximum ROI in record time.



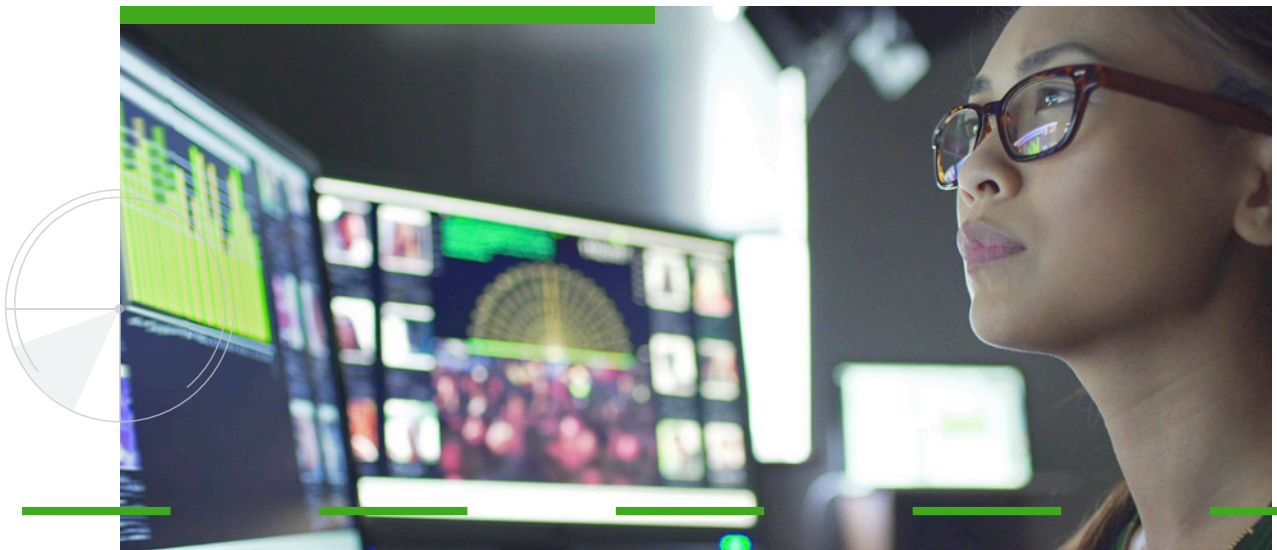
A Platform Elegantly Designed

We created Arena QMS from a design-for-deployment approach, much like you design your products for manufacturing and serviceability. The result is a smart, flexible product realization platform that ensures regulatory compliance, quality, and continuous improvement.



Training & Community Resources

Learn from the comfort of your desk with online training classes and in-application help videos, or join our instructors for classroom training at your site or ours. Make use of Customer Resources for all the help you need, from documentation and video training to best practices.



Your Product Realization Platform for Today and Tomorrow

Arena offers the most comprehensive approach to help you innovate and deliver safe and effective products. Arena's product-centric QMS solution enables complete control and traceability throughout the new product development and introduction (NPDI) process with unified quality and product record management. This ensures every team is on the same page throughout the development and quality process.

To find out how you can join this community of innovative customers, contact arena-sales@ptc.com

