Product Realization Group®

MedTech Solution

QMS*go*™

"QMSgo let us focus on our device and was easy for us to use."
-- Head of Development & Quality, ventilator device company

Contact Us

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Get Your Quality System Right, Out of the Gate

Getting started with Arena QMS is seamless with the QMS*go* solution from PRG

Product Realization Group (PRG) has teamed with Arena Solutions, a trusted partner, to provide the services you need to better leverage your QMS platform:

- SOP templates and services are designed to complement Arena QMS, and address common quality and compliance needs. We understand that creating and maintaining standard operating procedures (SOPs) requires significant effort, and can distract you from focusing on important product or quality needs.
- Performance Qualification (PQ) services help you confirm that your QMS software has been tested to verify it performs as expected under simulated real-world conditions, per your user requirements specification.

PRG provides the hands-on experts to help you customize, implement, and manage these critical procedures.

QMS*go* Features

1. **Preconfigured SOP templates** for best practices. SOPs are compliant with FDA 21 CFR 820 and ISO 13485 requirements
2. **Learn-as-You-Go** and get training only for the components you need
3. **Flexible & Scalable** – we tailor templates to your requirements to:
   - Manage your product data
   - Support regulatory submissions
   - Transfer design to manufacturing
   - Eliminate concerns about audits
4. **Real world expertise** in simulating real-world conditions for PQ

As your development proceeds, QMS*go* SOPs can be added in a cost-effective manner until you have a complete quality management system for document control, design control, and risk management. Product Qualification and additional services to supplement your in-house capabilities are available when you need them.

Product Realization Group®

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The QMS*go* solution supports you throughout the product development cycle

Design and Development Quick-Start	Pre-Production	Production Ramp

Summary of activities per stage

• Access to templates in the SOP Resource Center for the phase(s) you need • Customization of SOP templates • Controls implementation • User training	• Additional SOPs for validation, verification, and supplier quality • Transfer & input of your existing records into the Arena QMS system • Training for your staff to assume this role • Initial Performance Qualification	• Full Performance qualification • Gap analysis, system review, and additional training • Audit preparation

Detailed Quality Management Element delivered per stage

• Document Control
• Record Control & Change Control
• User Training (Arena)
• Design Controls:
  • Requirements Management
  • Design Reviews
  • Verification
  • Software Life Cycle
• Risk Management:
  • Requirements Management
  • Risk Controls and Acceptance
	• Training for staff (FDA requirement)
	• Design Control – Software Verification & Validation
	• Design Control - Validation
	• Non-Conformance Management for NCR
	• Supplier Quality
	• Initial Performance Qualification
		• Quality Control for Verification Builds
		• Manufacturing Process Quality
		• CAPA Management
		• Complaint Management
		• Full Performance Qualification
		• Audit preparation and Gap Analysis

PRG's team fills specific resource gaps to move your product to a development milestone, submission, launch, or acquisition. We can provide quality engineers, supply chain experts, regulatory specialists, and project managers to work side-by-side with your team.

QMS*go* packages can be tailored to fit your needs and can include any of the elements above.

Arena QMS helps innovative medical device companies design, produce, and deliver great products fast, while complying with ever-evolving regulations.

PRG is an Arena Business Expert Partner whose services are offered on an independent basis.

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