

## QMSgo™

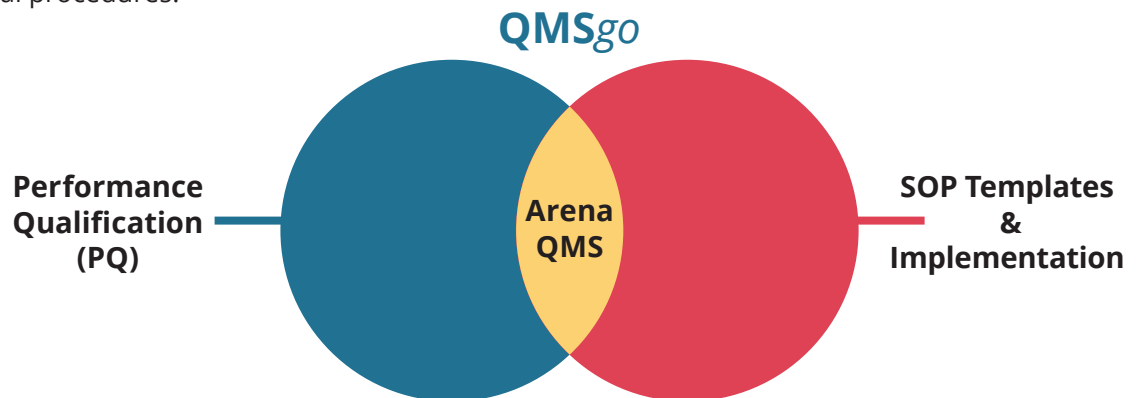
### GET YOUR QUALITY SYSTEM RIGHT OUT OF THE GATE

#### Getting started with Arena is seamless with QMSgo services from Product Realization Group!

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.



### QMSgo 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

SOP Templates and PQ are available for each stage of device development:



As your development proceeds, **QMSgo** 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.

## QMSgo IS AVAILABLE IN THREE LEVELS:

Quality Management Element	Package 1	Package 2	Package 3
<b>Design &amp; Development</b>			
Document Control	☑		
Record Control & Change Control	☑		
User Training (Arena)	☑		
Design Control – Requirements Management	☑		
Design Control – Design Reviews	☑		
Risk Management – Requirements Management	☑		
Design Control - Verification	☑		
Design Control – Software Life Cycle	☑		
Risk Management – Risk Controls and Acceptance	☑		
<b>Pre-Production</b>			
Training for staff (FDA requirement)		☑	
Design Control – Software Verification & Validation		☑	
Design Control - Validation		☑	
Non-Conformance Management for NCR		☑	
Supplier Quality		☑	
Performance Qualification (initial)		☑	
<b>Production</b>			
Quality Control for Verification Builds			☑
Manufacturing Process Quality			☑
CAPA Management			☑
Complaint Management			☑
Performance Qualification (full)			☑
Audit preparation and Gap Analysis			☑

### QMSgo Package 1 Design & Development QuickStart (4 to 6 weeks):

- **Access to templates** in the SOP Resource Center for the phase(s) you need
- **Customization** of SOP templates
- **Controls** implementation
- **User training**

### QMSgo Package 2 Pre-Production (6 to 10 weeks):

- **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
- **Performance Qualification** (initial)

### QMSgo Package 3 Production Ramp (6 to 10 weeks):

- **Performance qualification** (full)
- **Gap analysis**, system review, and additional training
- **Audit** preparation

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.

**QMSgo** 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.*