



**Product  
Realization  
Group®**

## **MedTech Solutions**

*"We realized just how much PRG could help us leverage our team and get to market."*

*-- CEO, emerging medical device company*

# Accelerated Delivery of Medical Devices to Market

Developing new products in the competitive and highly regulated world of medical devices is challenging for large and small companies. Tight schedules, limited resources, greater product complexity and changing regulations along with risky supply chains – all of these factors cause companies to lose focus on innovation and challenge a traditional model of taking medical devices from the lab to full market scale.

PRG offers you a comprehensive set of services that enables you to make the transformation from engineering lab to first Engineering Verification and Clinical Validation (V&V) build through full scale manufacturing or acquisition while managing for risk, and operating under FDA compliant processes.

PRG offers market tested solutions like QMSgo along with access to a group of trusted hands-on professionals experienced in commercializing products for a broad spectrum of medical applications such as monitoring equipment, surgical devices, imaging and wearable devices.

## **PRG Solutions to MedTech Challenges:**

**"Our product is in development and we need help with FDA regulatory compliance..."**

Regulatory decisions are highly strategic which you can leverage to create a competitive advantage. PRG has deep FDA regulatory expertise to set your product's regulatory compliance strategy as well as manage the activities and interface with FDA to gain full compliance for your product.

**"Our processes are not fully compliant and slowing down our product development and increasing costs..."**

PRG's integrated QMSgo delivers an automated database system along with a ready set of standard operating procedures (SOPs) templates and work instructions that are pre-configured to meet FDA 21, CFR 820 and ISO 13485 requirements.

**"We need to set up a supply chain that supports our product..."**

To support your business transition from engineering development to the first V&V (engineering verification and clinical validation) build, PRG provides supply chain expertise that can set a resilient and compliant global supply chain strategy that is in line with your products level of complexity, cost, reliability and volume manufacturing needs.

**"We need to meet tight development schedules..."**

We help you to manage the transition from the lab into full scale commercialization. Working in tandem with you on Program Management, we enable you to develop under process controls and feedback across the development team, streamline execution and reduce execution risk.

### **Contact Us**

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