



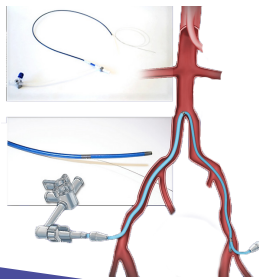
**Product
Realization
Group®**

Success Story

Med-NPI IMPACT Enables FDA Compliance & Full-scale Manufacturing for Debut Product

What we did:

Product Realization Group helped RAM Medical navigate from prototype to full scale manufacturing, while maintaining a robust, FDA compliant medical device Quality Management System (inclusive of SOPs, Work Instructions and Forms).



Results:

Med-NPI IMPACT enabled RAM Medical to focus their limited resources and expertise to more critical parts of their business, so that they could start quickly making an impact with patients in the interventional cardiology space.

Company: RAM Medical Innovations

Headquarters: Springfield, Ohio, USA

What they do:

RAM Medical Innovations is a medical device company that specializes in vascular sheath technology that facilitates endovascular interventions in hostile anatomy.

Challenge

To meet regulatory requirements, RAM Medical needed to rapidly deploy a 21 CFR 820 FDA-compliant electronic Quality Management System (QMS) to manage product development and contract manufacturing transfer activities for a successful market launch. Additionally, they were seeking the right contract manufacturing partner to scale their business.

Solution

Product Realization Group, via the Med-NPI IMPACT solution, delivered hands-on expertise to help RAM Medical manage the transition from a lab prototype into volume manufacturing for their medical device and avoid the many pitfalls of product commercialization. Expertise delivered included:

- Initial product / process assessment and identification of key project needs, gaps, risks and opportunities
- Technical Program Management throughout the engagement
- Contract Manufacturer (CM) Identification, selection and contract finalization
- Implementation of an eQMS system (using PRG's QMSgo IMPACT solution), as well as FDA regulatory compliance and submissions support

From assessment to action

PRG's team of hands-on experts helped RAM Medical to successfully bring their product to market and delivered the following results:

- Implementation customization of eQMS system
- CM identification, selection and ongoing management
- FDA regulatory submissions strategy, guidance and support

Strategic support

Strategic support from PRG was vital for the product launch. PRG continued to provide the interface with the contract manufacturer and helped RAM Medical work through critical program elements. A series of product changes led to the development, filing and successful clearance of a Special 510(k). The supply agreement had to be renegotiated to support First-In-Man testing and early sales that laid the milestone framework for RAM Medical's successive round of fundraising.

Key benefits of engagement with PRG

- Product development best practices and hands-on support
- FDA fully compliant eQMS system implementation to support operations, communication, and the company's growth
- A contract manufacturing assessment and action plan that allowed RAM to select the right strategic partner
- Accelerated time-to-market via leveraging established relationships and supply chain expertise
- FDA regulatory support to help meet compliance objectives

Med-NPI IMPACT enabled RAM Medical to rapidly implement a compliant, scalable and easy-to-use quality system, QMSgo. This solution allowed our team to remotely and effectively operate our medical device business in regulatory compliance and with confidence. The customized deployment to our needs was key to helping RAM Medical transition to the next stage of our growth."

— Mubin Syed MD,
CEO, RAM Medical Innovations

The right systems, processes and relationships

Getting operations resources in place was key to managing the product launch process and identification of contract manufacturers.

Significant contract manufacturing efficiencies

One of the most valuable assets that PRG brought into the engagement was its supply chain expertise and relationships. PRG's Supply Chain & Operations expert mapped out an actionable supply chain strategy for RAM Medical, including detailing a short list of suppliers based on prior track record and the company's strategic requirements.

Product and Process Management

PRG played a key role in implementing the electronic quality management system (eQMS) and managing the system through production transfer and ramp for RAM Medical. Many companies will get bogged down operating these systems. Engaging PRG allowed the RAM Medical team to focus critical resources on the most urgent issues knowing that the quality system was being properly maintained and enforced. A common complaint from management is that system overhead can cause the team to lose focus and miss achieving key business goals. PRG helped to keep the team and project focused on creating the most value for the company.