

**Product
Realization
Group®**

Med-NPI IMPACT

*"Med-NPI IMPACT
gave us the
framework that
allowed us to scale
our product in time
for the market need."
-- VP Product Management,
Medical Device company*

Contact Us

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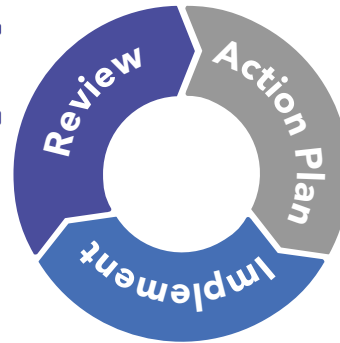
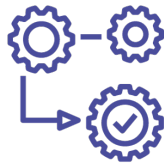
Med-NPI IMPACT



Accelerate your product through critical milestones with Med-NPI IMPACT

The Product Realization Group (PRG) team of seasoned medical device experts help your company navigate change in this complex, competitive and highly regulated environment. With Med-NPI IMPACT we deliver a comprehensive plan and the on-demand resources you need to address the key elements for success in this unforgiving industry.

1. We conduct a review of your medical device to determine the required activities



2. We design a compliant plan for your medical device and a cost-effective strategy for the future



3. PRG works with you to complete the Action Plan

Sample Focus Areas within a Med-NPI IMPACT Engagement

The goals for this comprehensive program of review, recommendation and implementation can include:

- A project development framework, planning and implementation to meet business goals
- Product-market fit, usability and risk mitigation strategies
- Regulatory strategy, planning and execution (to FDA, ISO standards)
- Clinical requirements and planning
- IP planning and strategic positioning
- Reimbursement analysis and revenue model validation
- Business-enabled quality planning, systems and support
- Product Sustaining/Re-engineering Strategies and Implementation
- Product Supply Chain Strategies and Management
- Scientific, advisory and BOD development
- Fundraising planning and support



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The PRG Med-NPI IMPACT process

Review

- Perform a strategic and tactical review of business and regulatory needs.
- Collect all available documentation and plans for review.
- Work with you to understand your current resources and gaps.
- Interview your team to broaden an understanding of your business and its goals.

Action Plan

- Create a full gap/opportunity analysis report, discuss findings and ways forward.
- Document potential risks to the business.
- Develop and agree upon Med-NPI IMPACT preliminary roadmap and resourcing needs.

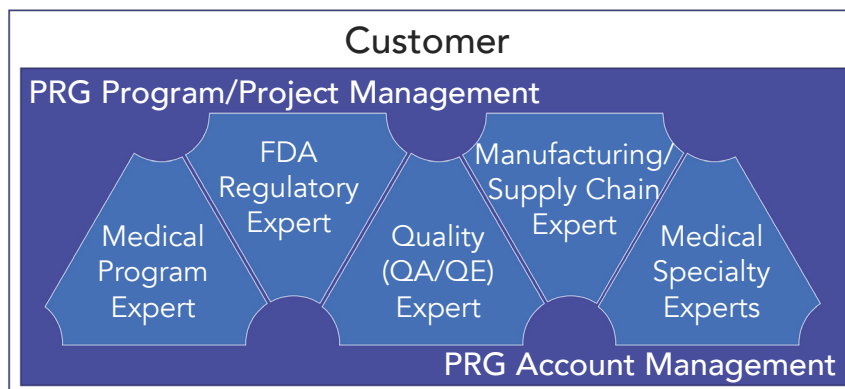
Implement

- Establish project delivery team.
- Create and manage full project plan; meet weekly to update on progress.
- Bring in PRG experts as required to fill temporary gaps in staffing/expertise.
- Guide you through the demanding approvals processes to a product you can sell.
- Assist in hiring additional permanent internal team members as needed.

Additional Strategic benefits with Med-NPI IMPACT

- Due diligence to support professional investors.
- Product launch and transition support, pre/post-Merger & Acquisition (M&A).
- Quality audits and investigations.
- Reorienting product development efforts to align with critical business costs and schedules.

The PRG Med-NPI IMPACT Team



We provide you the resources you need to fill gaps in your team as needed. PRG allows you to quickly staff up in areas of expertise to expedite your NPI process. As you grow, our team can continue to support you or allow you to transition the work to your own team.

Learn more about how you can benefit from end-to-end control of your product lifecycle with Med-NPI IMPACT. Contact us today.