

YOU THINK IT, WE'LL DEVELOP IT.

Too often, great ideas are left on a napkin because companies and development entrepreneurs don't have the capacity or capability to bring them to life. At NAGL MedTech™, we offer fully integrated product development services – from concept to commercialization – bringing to life ideas, mitigating development risks, and elevating the opportunity for commercial success

Using Quality Management Systems (QMS), we drive product development and document every step of the process to ensure all customer expectations and regulatory requirements are met.

THE NAGL MedTech™ PRODUCT DEVELOPMENT PROCESS

Our extensive product development process addresses all elements needed for your project to succeed.

Phase A – Proof of Concept – The First and Critical Step

Identify the strategic considerations for product development beyond the product itself - clinical, regulatory, reimbursement, production, packaging, etc. - to help create a blueprint for success.

Phase 1 – Definition and Feasibility – The Blueprint for Project Success

Fully defining your product and providing that the design is feasible by passing all product specifications.

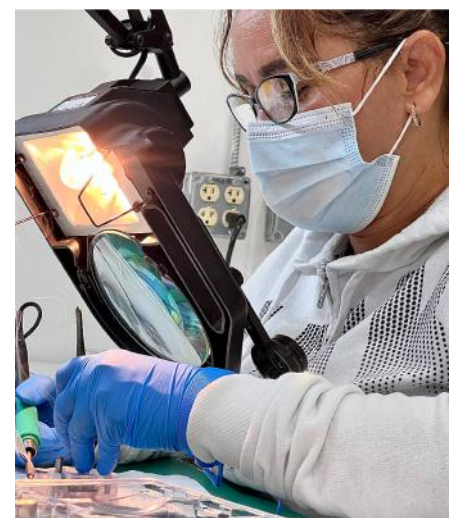
Phase 2 – Design and Development – Optimizing Every Design Detail

Implement product design and development while continually refining and verifying product design details to optimize success. For Class II products, NAGL MedTech™ will prepare and submit 510k documentation and data to the FDA.

Phase 3 – Validation – Essential to Success

Ensure the final design meets intended needs along with all safety, regulatory, and technical requirements. In addition, certify that scale-up manufacturing processes are clearly defined and qualified to consistently meet established production quality specifications.

NAGL MedTech™ can also support the initial or long-term production phase of your device commercialization process through our Contract Manufacturing ELEVATOR™.



SUPPORT FROM CONCEPT TO COMMERCIALIZATION

Clients use NAGL MedTech™ product development services for support across three critical areas:

Equipment Services

NAGL MedTech™ offers state-of-the-art design technologies including expert CAD as well as product prototyping and 3-D printing capabilities. All work is done at our integrated facilities which include ISO Class 8 compliant cleanrooms, QA testing labs, inspection, packaging, labeling, storage, and more.

Systems Services

NAGL MedTech™ utilizes extensive business and quality management systems to ensure document quality, core development process tracking, ongoing client communication, asset review and disposition, information security, and IT systems.

Workforce Services

NAGL MedTech™ provides access to an in-house team of medical product development specialists so that from design to production, you can be sure that the people on your project carry the expertise required to complete your project efficiently and effectively.

NAGL MedTech™ SUCCESS – THE PROOF IS IN THE PRODUCT



Oryon Aspiration Cateter & Smartpump - Poseydon Medical



Hourglass Embolization Plug – EMBolic Acceleration

NAGL MedTech™ DRIVES YOUR DEVELOPMENT

With NAGL MedTech™, you're adding a level of project accountability and process expertise that will increase product quality and consistency resulting in faster market launch at a lower cost. All clients are assigned a dedicated project manager who will work with you to develop a timeline of deliverables by project phase and take full responsibility for keeping everything on time and on budget. Speaking of budgets, NAGL MedTech™ prides itself on delivering accurate, transparent budget projections – we carry a -7% average deviation from budget across all project milestones. A major reason for our accurate budgets is because we manage all required product development activities in-house, without the use of any third-party suppliers. Finally, this is your project which is why we provide a project dashboard with real-time updates along with weekly status reports.

DEVELOP WITH CONFIDENCE

For concept to commercialization, or any stage in between, our goal at NAGL MedTech™ is to minimize your financial risk, optimize your financial return, and, ultimately, ensure device development success.

**NAGL
MEDTECH**

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For more information on partnering with NAGL MedTech™, please call 954.607.3266 or visit nmddo.com.

SPEC DEVELOPER ELEVATOR®

