Marc Graham, Ph.D.

Somerville, MA 02143 – (617) 461-6272 – polo@alum.mit.edu
Website: https://new.express.adobe.com/webpage/k9FaEHzWM84nQ

CORE COMPETENCIES

- Product Development & Engineering Leadership: End-to-end development, NPI, DFMA, clinical trials
- Systems Engineering: Integration of mechanical, electrical, optical, and software systems
- Program & Project Management: Strategic planning, execution, and risk mitigation
- Team Building & Leadership: Cross-functional collaboration, mentorship, and culture-building
- Medical Devices & Regulatory Compliance: FDA, ISO, IEC standards, design control, risk management
- Intellectual Property Strategy: Customer- and market-driven patent portfolio development
- Market & Roadmap Planning: Landscape analysis, gap identification, and strategic roadmapping
- M&A Technical Assessment: Product fit, tech maturity, IP assets, and integration evaluation
- Technical Proficiency: CAD, documentation, data and resource planning tools
- Languages: Fluent in English; Basic Spanish and French

EXPERIENCE

Vantage MedTech – Moonachie, NJ (Remote) – Present

Program Management

Provider of comprehensive design and manufacturing services, supporting the advancement of medical technologies from concept through to product realization.

- Lead and manage cross-functional design and development teams through concept, design, and verification phases
- Develop and implement tools and processes to manage program schedules, budgets, and resource allocation effectively
- Track and report program progress, risks, and mitigation strategies to senior leadership and other key stakeholders
- Oversee manufacturing transfer activities, including process validation, documentation, and ramp-up for production
- Manage ongoing production support and continuous improvement initiatives in collaboration with operations and quality teams
- Lead strategic planning and development efforts aligned with business objectives and emerging market needs

- Define product requirements by engaging with customers, while monitoring evolving industry trends
- Drive the creation of impactful and differentiated product solutions that expand the customer's intellectual property portfolio
- Evaluate new device technologies and assess feasibility, cost, and fit with customer needs and corporate strategy
- Collaborate with internal and external partners to identify and pursue opportunities for innovation and portfolio growth
- Ensure compliance with regulatory standards and quality systems throughout the product lifecycle

Gener8 – Wilmington, MA – 2020 - 2025
Senior Director
Provider of engineering services, including product design and development, prototyping, manufacturing, and supply chain management.

- Directed global programs and high-value projects, overseeing cross-functional teams of managers, engineers, and individual contributors across multiple sites
- Partnered with business development to secure new contracts and expand existing accounts through phased program growth
- Led end-to-end design and development of complex life sciences equipment and consumables including continuous bioprocessing systems and single-use bioreactors, cell handling platforms, medical lasers, prefilled applicators and autoinjectors, and PCR diagnostic devices, from compiling customer requirements through pilot manufacturing
- Built and scaled New Product Introduction (NPI) capabilities for East Coast clients, including system architecture, design execution, and readiness for volume production
- Instrumental in achieving certification and validation of on-site BSL-2 lab, significantly enhancing the organization's ability to win and execute new business opportunities

Other roles: Director

OmniGuide – Lexington, MA – 2012 - 2020
Director, R&D
Provider of precision laser and ferromagnetic surgical systems and instrumentation.

- Directed national product development initiatives, leading R&D across multidisciplinary teams including mechanical, electrical, software, firmware, and optical engineering
- Oversaw the full product lifecycle for CO_2 laser systems, flexible fibers, and advanced handheld and robotic instruments, contributing to design, development,

manufacturing, marketing, and sales strategies
- Designed a comprehensive portfolio of handheld devices for minimally invasive laser surgeries, tailoring each solution to specific clinical needs through direct engagement with key opinion leaders, operating room observations, and workflow analysis
- Improved surgical efficiency by integrating multifunctional features such as tissue manipulation, dissection, and RF cautery, into single instruments, reducing instrument exchanges, shortening procedure times, and enabling new applications like minimally invasive, laser-assisted myomectomy
- Drove revenue growth from $12M to $27M (2012–2015) by completing the instrument–fiber–laser ecosystem, delivering a fully integrated, user-centric energy platform from patient interface to power source

Other roles: Senior Principal Engineer, Principal Engineer, Staff Engineer, Senior Mechanical Engineer

Massachusetts Institute of Technology – Cambridge, MA – 2000 - 2019
Engineering Design Instructor
Top ranked university for engineering, science, and mathematics.
- Designed and taught comprehensive curricula on deterministic design and its real-world applications across multiple MIT engineering programs and courses
- Mentored and advised hundreds of students through hands-on, project-based learning, guiding the development of innovative solutions from consumer products to autonomous and remotely operated systems

Stryker – Waltham, MA – 2006 - 2011
Senior Design Engineer
Leading medical technology company offering products and services in medical and surgical, neurotechnology, orthopedics and spine.
- Led the mechanical design and development of implantable devices for type 2 diabetes treatment, serving as the principal engineer from concept through prototyping
- Delivered novel delivery systems for synthetic adhesive biomaterials used in hard tissue regeneration
- Established advanced R&D laboratories, managed machine shop operations, and oversaw CAD system administration, significantly expanding engineering and prototyping capabilities
- Designed and fabricated custom surgical tools for in vivo studies and created high-fidelity prototypes to support rapid iteration and pre-clinical testing
- Directed and coordinated pre-clinical trials in the U.S. and abroad, ensuring compliance, efficiency, and alignment with regulatory and research protocols

Corning – Wilmington, NC – 1996 - 2001
Mechanical Design Engineer
Provider of materials science technologies.

- Supported the design and optimization of laydown, consolidation, and draw processes to improve optical fiber production efficiency and consistency
- Partnered with cross-functional teams to advance the development of a continuous fiber tower, contributing to long-term strategic manufacturing goals
- Oversaw vendor relationships and coordinated internal contractors to maintain fully operational manufacturing stations and minimize downtime
- Mentored new engineers, promoting skill development, technical onboarding, and knowledge transfer across the team

EDUCATION

Massachusetts Institute of Technology – Cambridge, MA – 1995
B.S, Mechanical Engineering

Massachusetts Institute of Technology – Cambridge, MA – 1997
S.M., Mechanical Engineering

Massachusetts Institute of Technology – Cambridge, MA – 2006
Ph.D., Mechanical Engineering

- Jointly created and investigated a design and development process to optimize team collaboration and productivity via a framework that facilitates heightened contributions from all team members, particularly those who may have otherwise been isolated, such as women, minorities, non-native speakers, and introverts. The study was conducted over five years within undergraduate engineering design courses and STEM outreach programs at MIT.

PATENTS

- Oct 23, 2023 US 11,801,477 Cell Retention Device; Marc Graham, Flora Liu, Andrew Banchieri
- Dec 3, 2019 US 10492876 Devices and Methods for Laser Surgery; Marc Graham, Charalambos Anastassiou, Vladimir Fuflyigin, Noam Josephy, Thieu L. Le, Arnaz Singh Malhi, Robert Payne, Lori Pressman, Jesse Rusk, Gil Shapira, Max Shurgalin, Crystal Simon
- Oct 1, 2019 US 10,426,546 Laparoscopic Handpiece for Waveguides; Marc Graham, Arnaz Singh Malhi, Vladimir Fuflyigin, Courtney Manthei Sienkowski, Flora Liu
- Feb 19, 2019 US 10,206,744 Waveguide Locks and Counterbalances for Waveguide Conduits; Marc Graham, Max Shurgalin

- May 29, 2018, US 9,980,775 Waveguide Locks and Counterbalances for Waveguide Conduits; Marc Graham, Max Shurgalin
- Oct 28, 2014, US 8,870,808 Pyloric Valve Devices and Methods; Marc Graham, Buket Grau, David Robert Gale, Sam Anne Musgrave, George McGee Perkins, Mark Jeffrey Edhouse, Christopher Kadamus
- Sep 16, 2014, US 8,833,606 Device and Method for Mixing and Applying Biomaterials; Marc Graham
- Nov 26, 2013, US 8,591,452 Systems and Methods for Treating Obesity and Type 2 Diabetes; Marc Graham, Attila A. Priplata, Joseph P. Errico, John T. Raffle, Jonathan David Gardiner
- Nov 12, 2013, US 8,579,849 Pyloric Valve Devices and Methods; Marc Graham, Buket Grau, David Robert Gale, Sam Anne Musgrave, George McGee Perkins, Mark Jeffrey Edhouse, Christopher Kadamus
- Aug 27, 2013, US 8,517,972 Pyloric Valve; Marc Graham, Buket Grau
- Jul 24, 2012, US 8,226,593 Pyloric Valve; Marc Graham, Buket Grau
- May 22, 2012, US 8,182,442 Pyloric Valve Devices and Methods; Marc Graham, Buket Grau, David Robert Gale, Sam Anne Musgrave, George McGee Perkins, Mark Jeffrey Edhouse, Christopher Kadamus
- Mar 27, 2012, US 8,142,385 Pyloric Valve Devices and Methods; Marc Graham, Buket Grau, David Robert Gale, Sam Anne Musgrave, George McGee Perkins, Mark Jeffrey Edhouse, Christopher Kadamus
- Jan 24, 2012, US 8,100,850 Pyloric Valve Devices and Methods; Marc Graham, Buket Grau, David Robert Gale, Sam Anne Musgrave, George McGee Perkins, Mark Jeffrey Edhouse, Christopher Kadamus