



Global Commercial
Partner



MAE Group LLC



We Bring Lifesaving Products to Global Markets

MAE Group is the capstone between the inventor and investor. We offer a full bespoke suite of commercialization services to early-stage companies. Our teams will efficiently get through the commercial process, maximize the inventor's exit strategy, and de-risk the investor's funding exposure. We bring medical device and in vitro diagnostic device technology to global markets, allowing the inventor to focus on science and technology and the investor on portfolio management and ROI.

- Manage the Commercialization Pathway
- De-Risk Investment
- Successful Exit Strategy



SERVICES

Strategic Development:

We work with you to develop key strategies, including Business Development, IP Roadmaps, Technology Due Diligence, Regulatory, Clinical, Reimbursement, and Sales Channel Management.

Tactical Implementation:

- IP FTO Assessment
- Regulatory Approval
- Clinical Study Management
- Project Management
- Quality System
- Product Development: Software, Hardware
- Target Product Launch

Post-Market Support:

- Product Expansion
- Global Expansion
- Vigilance
- Next-Generation Developments
- Exit Strategy





MAE Group was founded in 2013. We began by providing global regulatory affairs, clinical affairs, quality management, and reimbursement services to medical device, bioscience, and life science companies to commercialize products in target markets. MAE Group provides these services to SME (Small and Medium Enterprises) and to large blue-chip companies.

In 2017, we expanded our services to partner with early-stage medical device and in vitro diagnostic companies by providing a full suite of commercialization expertise. MAE Group helps clients navigate through the commercialization continuum to successful market launch.

SOLUTIONS

Focus Enterprises:

Early Stage Enterprise: Pre-revenue, early stage funded

Small Enterprise: One device through development, need regulatory support to gain clearance

Medium Enterprise: One device in initial market, expand in other target market or next generation

Blue Chip: Adjunct to your staff, gap assessment and remediation

Innovation Centers & Accelerators: Technology commercialization resource to entrepreneurs

Our Expertise:

- Extremely knowledgeable in product development and manufacturing, regulatory, quality systems, clinical, reimbursement, project management, and initial product launch
- Flexible service, committed to you and your products
- Strong global network of professionals
- Dedicated team of professionals for personalized service and consistency to successful project completion



PROGRAM OVERVIEW

Commercialization Projects:

We navigate the commercialization pathway to successful product approval and initial target launch.

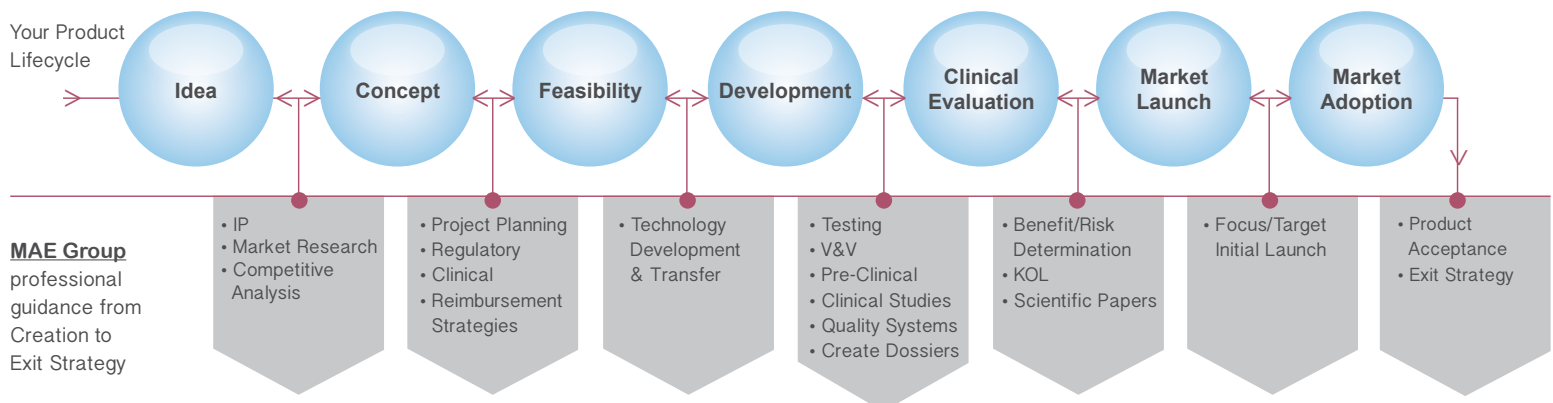
Discrete Projects:

Based on your requirements, we can provide services à la carte, to suit needs and investment-phase commercialization pathway to successful product approval and initial target launch.



Delivering an Integrated Approach that Drives Market Success

COMMERCIALIZATION PATHWAY





KEY SERVICE DETAILS

Regulatory

- 510(k), PMA Documentation
- Technical Documentation, Design Dossier
- Documentation
- Gap Assessment & Remediation
- Liaison with Government Agencies

Quality System

- Quality System Management
- Quality System Implementation
- FDA QSR & ISO 13485 Mock Audits
- Gap Analysis & Remediation
- Due Diligence Assessments & Training

Clinical

- Manage Multicenter Studies (Global)
- Develop Protocols & Study Documents
- Develop Contracts & Budgets
- Monitor Clinical Studies
- Post-Market Studies
- Adjudication Meetings

Product Development & Manufacturing

- Design Verification & Validation
- Software Verification & Validation
- Network Security
- Cybersecurity
- Contract Manufacturing Selection



MEDICAL SPECIALTIES

- Anesthesiology
- Cardiovascular
- Combination Products
- Endoscopy/Laparoscopy
- Gastroenterology
- Hematology
- Imaging
- Immunology
- Infectious Diseases
- In-vitro Diagnostics
- Neurology
- Oncology
- Orthopedics
- Pain Management
- Radiology
- Robotics
- Urology
- Women's Healthcare
- Wound Care



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