Boston MedTech Advisors

More Experience ▸ Better Results

BOSTON | GERMANY | ISRAEL

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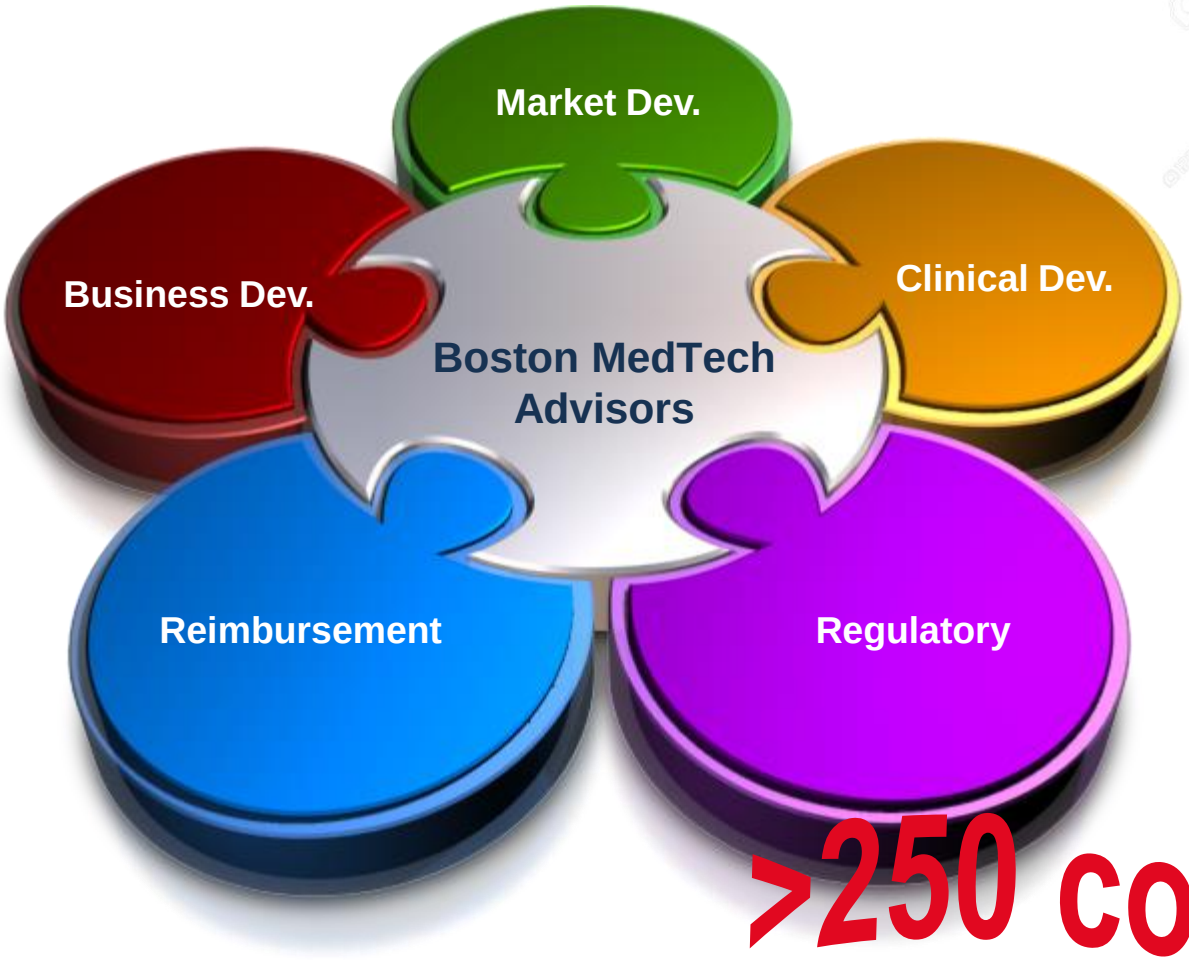

>250 companies

Our Mission, Business and Operating Principles

Mission

Assist medical technology companies and healthcare providers to achieve their business goals by offering ethical, result-oriented, professional and cost effective advice and services.

Business

Support our clients to commercialize new products and services and to increase their market adoption, by addressing their unique and inter-dependent regulatory, clinical, reimbursement, marketing and business development requirements.

Operating Principles

- **Provide optimal solutions** that recognize the multi-faceted aspects of today's healthcare markets and the client's unique business needs.
- **Maximize value** by delivering high quality services at a reasonable cost.
- **Establish ongoing relationships** by aligning our incentives with those of our clients and partners.

Relevant Experiences Driving the Value to Our Clients

- Principals of Boston MedTech Advisors are entrepreneurs, founding own medtech and healthcare service companies, leveraging their extensive general management, product development, marketing, reimbursement, regulatory, clinical affairs and business development.
- We support diverse range of companies, including start-ups, pre- and post-revenue, VC-backed and public entities, enterprises based in the US, Europe, Israel and Asia, and multi-nationals.
- We provide access to an extensive network of industry, healthcare providers, academia, investors and business partners.
- We have hands-on working experience within the US and European medical technology and healthcare systems.
    - Broad industry experience, spanning over diverse and broad medical disciplines.
    - Excellent submission and communication history with the FDA and other regulatory agencies.
    - Successful record of strategizing and implementing reimbursement solutions.
    - Developing and executing marketing and business plans for new technologies and clinical services.
    - Financing of early-stage companies.

Engagements *(partial list)**

Aesthetic Medicine	*Allergy*	*Ambulatory monitoring*	*Anesthesiology*	*Biologics*	*Brain / Neurosurgery*	*Cancer Therapies*
Cardiology	*Critical Care*	*Cryosurgery*	*Dermatology*	*Diabetes*	*Drug Delivery / Combination Products*	*Durable Medical Equipment*
Emergency Medicine	*Gastroenterology*	*General Surgery*	*Health IT*	*Hepatology*	*Home Care*	*Hypertension*
Interventional Cardiology	*In-Vitro Diagnosis*	*Interventional Radiology*	*Neurology*	*Orthopedic*	*Pain*	*Patient Monitoring*
Pulmonary	*Radiology / Imaging*	*Rehabilitation Medicine*	*Renal*	*Robotics*	*Sleep Medicine*	*Spine Surgery*
Surgical Simulation	*Telemedicine*	*Transfusion Medicine*	*Urology*	*Vascular Medicine*	*Wellness / mHealth*	*Wound Care*

* Including advisors' prior relationships

Engagements *(sample)**

- Start-ups through Fortune 500 companies
  - Diagnostic, therapeutic and monitoring technologies
  - Medical device, DME, combination products, biopharma, biologics, mHealth, HIT
  - Healthcare providers - medical practices, clinics and hospitals
  - Consumer medical products and services
- Technology incubators, technology transfer and licensing offices
- Investors (private, institutional)

* Including advisors' prior relationships

When Working with Boston MedTech Advisors…

- You benefit from active involvement by an experienced US and European team, dedicated to helping your company to successfully develop and execute its plans.
- You receive comprehensive support, tailored to the specific needs of the organization, whether an early-stage or an established medical technology company.
- You can recognize significant efficiencies by working with a single entity offering vertically integrated strategy development, planning and execution services.

Expertise, practical solutions and execution in the following areas:

- Regulatory Affairs
- Clinical Trials and Evidence Development
- Technology Assessment, Market Analysis and Business Strategy
- Reimbursement and Contracting Strategy
- Business Development
- Business Plans and Financing Support

Regulatory Affairs

Regulatory Affairs

Quality Assurance

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Analyze the impact of FDA regulatory guidelines on product development, clinical studies and marketing plans.
- Develop rational regulatory strategies and plans, addressing short and long term corporate objectives.
- Solidify regulatory strategies by conducting pre-submission review meetings with the FDA and other regulatory agencies.
- Prepare and facilitate regulatory filings, including 510(k), PMA and IDE applications. Provide an overall management and oversight in order to reduce time-to-approval.
- Coordinate and harmonize FDA and CE efforts in order to increase efficiencies of regulatory activities.
- Serve as a registered ‘US Agent’ for foreign medical device manufacturers.
- ‘Legal expert’ services on regulatory matters.

Quality Assurance

Regulatory Affairs

Quality Assurance

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Develop plans for compliance with FDA's quality system regulation (QSR) requirements.
- Perform quality system audits of medical device manufacturers, suppliers and subcontractors.
- Provide training on compliance with QSR and internal company procedures.
- Advise management on the response to adverse regulatory findings.
- Negotiate with regulatory agencies and formulate timeline and nature of corrective actions required following adverse regulatory actions.
- Assist management in developing comprehensive plans for emerging from operations under consent decree.
- Represent companies in discussions with regulatory agencies concerning compliance with QSR requirements.

Clinical Trials Planning and Evidence Development

BMT CRO Group is a full-service provider, offering a suite of services carefully customized to meet the unique requirements of the clinical trial sponsor.*

* www.bmtCROgroup.com

- Develop clinical study plans and protocols in support of regulatory submissions, marketing and reimbursement activities
- Identify and screen potential clinical sites and principal investigators
- Negotiate study agreements
- Prepare enrollment plans and IRB documentation
- Provide technical, clinical and management oversight during clinical studies
  - ✓ Project / trial management
  - ✓ Clinical site and patient monitoring
  - ✓ Database development, data acquisition and analysis
  - ✓ Logistical and operational support
- Manage Data Safety Monitoring Board (DSMB)
  - ✓ Recruit members
  - ✓ Create policies and establish charter
  - ✓ Facilitate meetings and coordinate communications
  - ✓ Serve as liaison between DSMB and sponsor
- Data processing and statistical analysis
- Prepare summaries of clinical trials for presentation to regulatory agencies, customers, business partners and investors.

Reimbursement and Contracting Strategies

Regulatory Affairs

Quality Assurance

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Review pertinent reimbursement codes and coverage guidelines for new products and services.
- Analyze reimbursement impact on product design, sales, marketing and business strategy.
- Develop a strategy and plans for solidifying new reimbursement codes, favorable coverage policies and adequate payments for new technologies and corresponding clinical procedures.
- Evaluate the multi-facet effects of regulatory, clinical evidence and marketing initiatives on reimbursement and identify steps to mitigate the effects of payment barriers.
- Manage the application process for new reimbursement codes and/or expansion of coverage guidelines.
- Develop reimbursement support services for end-users.
- Provide guidance for contracting with third-party payers.

Technology Assessment, Market Analysis and Business Strategy

Regulatory Affairs

Quality Assurance

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Assess market potential for new technologies and services.
- Conduct competitive market research and analysis.
- Analyze clinical and technical requirements, regulatory and reimbursement environments for new technologies, products and services.
- Identify new market opportunities for medical technologies and services, and identify optimal clinical applications for ‘platform’ technologies.
- Evaluate marketing strategies and develop marketing plans – pre and post launch.
- Evaluate new markets for existing products and services.

Business Development

Regulatory Affairs

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Business Development

Business Plans and Financing Support

- Identify complementary business opportunities and potential strategic partners.
- Analyze alternative sales channels.
- Initiate and facilitate business relationships, supporting product development, marketing and financing.
- Create early US or European presence, including marketing and business development arm for emerging companies.*
- Introduce larger companies seeking to augment their product or technologies portfolio to appropriate early stage players.

* In collaboration with Boston MedTech Advisors' strategic partners.

Business Plans and Financing Support

Regulatory Affairs

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Clinical Trials and Evidence Development

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Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Work with entrepreneurs and management teams to develop ‘fundable’ business plans and to optimize financing campaigns.
- Introduce entrepreneurs to VCs and private investors active in the healthcare field.
- Identify prospective strategic partners, prepare companies to appropriately explore opportunities and support all phases of the process.
- Support fundraising activities.
- Conduct due-diligence evaluations of new technologies and services.
- Develop valuation models.

Team

David Barone, Principal

30 years experience including general, technical and operations management, strategic planning, marketing and business development. Current activities focus on advising and assisting US and off-shore medical technology organizations, ranging from start-ups to Fortune 500 companies, in areas ranging from opportunity analysis, marketing strategy and market development, reimbursement strategies, business development and financing. Prior to co-founding Boston MedTech Advisors, David held senior management positions in a number of medical device companies and has founded, financed and developed a number of healthcare companies. B.Sc., Electrical Engineering, Technion, Israel Institute of Technology, M.Sc., Bio-Medical Engineering and Master, Business Administration, both from Rensselaer Polytechnic Institute, NY.

Zvi Ladin, PhD, Principal

Over 20 years of experience in the medical industry, government and academia, focusing on developing and managing clinical, regulatory affairs and reimbursement initiatives. A co-founder of Boston MedTech Advisors, focusing on establishing regulatory strategies for therapeutic and diagnostic medical device companies, submission of regulatory applications, including 510(k) and PMAs for products in Class I-III and drug-device combination products and representing companies in negotiations with the FDA and other regulatory agencies. Dr. Ladin taught mechanical and biomedical engineering at MIT and Boston University and served as a scientific advisor to the FDA. B.Sc., Aeronautical Engineering and M.Sc., Biomedical Engineering, Technion, Israel Institute of Technology; Ph.D., Medical Engineering, MIT-Harvard Medical School Division of Health Science and Technology.

Michael Imhoff, MD, PhD, Senior Advisor

Board certified in surgery and intensive care medicine, with over 18 years of clinical experience in large medical centers and 20 years of strategic consulting for leading companies in the global medical technology markets, as well as start-ups in the US and Europe, focusing on technologies and clinical applications for the ICU, CCU, OR and ED. Research areas include trauma surgery, intensive care medicine, patient monitoring, clinical data management, artificial intelligence in medicine and health economics, leading to over 300 publications and scientific presentations. Dr. Imhoff is a professor in Medical Informatics and Statistics at Ruhr-University Bochum, Germany, and currently Board Member of the German Association of Biomedical Engineering (DGBMT), chairman of the Section Patient Monitoring. He is editorial board member and reviewer for several international biomedical journals, MD, Universities of Bochum and Munster, Germany; PhD, Ruhr-University, Bochum, Germany. 1991 Recipient of the Lederle Prize for Research.

Team *(cont.)*

Zohar Zephrani, PhD, Senior Consultant

Dr. Zephrani has extensive research background in the fields of neuroscience, cognition, sensory, perception and other. She worked and managed large-scale projects focusing on discoveries that enhance understanding of the neural bases of human behavior projects at major academic and medical centers, including Columbia Medical Center, Cornell University and Brown University. Zohar's prior experiences also include work in the biotech industry, teaching, as well as leading and managing research teams using advanced imaging technology. Ph.D., Psychology, Brown University, RI.

Denise Clarke, Senior Consultant

Over 15 years of experience in clinical research and development of new products in the medical device sector. Prior to BMTA, Denise worked in central research administration for Boston University, overseeing grants, contracts and agreements for a large portfolio of departments. She has also worked in research management roles at Brigham and Women's Hospital, Harvard Medical School and the VA Boston Healthcare System, and as a Certified Clinical Research Associate (CCRA) at Philips Respironics, designing and overseeing research projects to evaluate new technologies. Denise currently serves on the program committee for the Boston chapter of the Healthcare Businesswomen's Association (HBA) and is past president of the New England Chapter of the Association of Clinical Research Professionals (ACRP). B.Sc., Social Psychology and Sociology, University of Ulster; MBA Health Sector Management, Boston University.

Malavika Raju, Analyst

Background in biochemistry. Prior experience includes drug discovery research, and quality and regulatory affairs positions at biotech and pharmaceutical companies in India and the U.S. Malavika has leadership experience with numerous student organizations at University of California, Los Angeles, including chairperson of the Student Media Board of Directors.
B.Sc. Biochemistry, University of California. Los Angeles.

Team *(cont.)*

Andrea Nadai, Director of Operations

Seasoned health care professional with expertise in clinical study operations, reimbursement analysis and market research. Licensed physical therapist and instructor of continuing education programs. Prior experiences include the development of corporate compliance program, risk management, grant writing, searching state and federal regulations and supporting accreditations. Oversaw support services in sponsored clinical studies, managed rehabilitation clinic therapy operations and provided care to patients with neurologic and orthopedic disorders in outpatient, inpatient and home-based settings. B.Sc., Physical Therapy, State University of New York; Master, Health Professions, Northeastern University, MA.