




# Boston **MedTech** Advisors

More Experience ► Better Results

BOSTON | GERMANY | ISRAEL

[www.bmtadvisors.com](http://www.bmtadvisors.com)

[www.bmtCROgroup.com](http://www.bmtCROgroup.com)



Founded in 2004, **Boston MedTech Advisors** has worked with more than 400 medical technologies and life sciences companies.

# About Boston MedTech Advisors



## Our Mission

We assist medical technology companies and healthcare providers to achieve their business goals, offering ethical, result-oriented insights that recognize the multi-faceted aspects of today's healthcare markets and the client's unique business needs.



## Our Business

We support our clients to commercialize new products and services and increase their market adoption, by addressing their unique and inter-dependent regulatory, clinical evidence, reimbursement, and marketing and requirements and strategies.



## Our Operating Principles

**Provide optimal solutions.** Recognize the multi-faceted aspects of today's healthcare markets and the client's unique business needs.

**Maximize value.** Deliver high quality services at a reasonable cost.

**Establish ongoing relationships.** Align our incentives with those of our clients and partners.

# Driving Value to Our Clients



## Our Expertise

Principals of Boston MedTech Advisors are entrepreneurs, founding their own medtech and healthcare service companies, leveraging their extensive management, product development, marketing, reimbursement, regulatory, clinical affairs and business development capabilities.



## Our diverse Clients

We support **start-ups**, private and public companies, not-for-profit organizations, investors and multi-nationals.



## Our extensive network

We provide access to an extensive network of industry, healthcare providers, academia, investors and business partners.

## Our Hands-On Experience

We have hands-on working experience within the US and European healthcare systems.

- Broad industry experience, spanning diverse medical specialties.
- 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.

# The Benefits of Working with Boston MedTech Advisors

- Active involvement by an experienced team, dedicated to helping your company successfully develop and execute its plans.
- Receiving comprehensive support, tailored to the specific needs of each organization, whether an early-stage or an established company.
- Recognizing significant efficiencies by working with a single entity offering integrated strategy development, planning and execution services.



## Experiences *(partial list)*

Aesthetic Medicine	Allergy	Ambulatory Monitoring	Anesthesiology	Biologics	Biomarkers	Brain / Neurosurgery	Cancer Therapies
Cardiology	Cellular Therapies	Critical Care	Cryosurgery	Dermatology	Diabetes	Digital Health	Drug Delivery
Drug / Device Combinations	Durable Medical Equipment	Emergency Medicine	Endoscopy	Gastroenterology	General Surgery	Health IT	Healthcare Services
Hematology	Hepatology	Home Care	Hypertension	Hyperthermia	Interventional Cardiology	In-Vitro Diagnosis	Interventional Radiology
Light-Based Therapies	Neurology	NICU	Ophthalmology	Orthopedic	Pain	Patient Monitoring	Pathology
Pulmonary	Radiology / Imaging	Rehabilitation Medicine	Renal	Robotics / Navigation Systems	Sleep Medicine	Speech Therapy	Spine Surgery
Surgical Simulation	Telemedicine	Transfusion Medicine	Urology	Vascular Medicine	Wearable Devices	Wellness / mHealth	Wound Care



# 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

# Regulatory Affairs

## Regulatory Affairs

Quality Assurance

Clinical Development /  
CRO

Reimbursement

Technology Assessment,  
Market Research and  
Business Strategy

Business Development

Investment Support

Expert Opinion

- 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 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.



# Quality Assurance

Regulatory Affairs

## Quality Assurance

Clinical Development /  
CRO

Reimbursement

Technology Assessment,  
Market Research and  
Business Strategy

Business Development

Investment Support

Expert Opinion

- Develop plans for compliance with FDA and CE quality systems requirements.
- Represent companies in discussions with regulatory agencies concerning compliance with 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 corrective actions to adverse regulatory actions.
- Assist management in developing comprehensive plans for emerging from operations under consent decree.

# Clinical Development / CRO

Regulatory Affairs

Quality Assurance

**Clinical Development /  
CRO**

Reimbursement

Technology Assessment,  
Market Research and  
Business Strategy

Business Development

Financing Support

Expert Opinion

- 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.
- Data processing and statistical analysis.
- Prepare summaries of clinical trials for presentation to regulatory agencies, business partners, investors and customers.
- Provide technical, clinical and management oversight during clinical studies.
  - Project / trial management
  - Clinical site monitoring
  - Database development, data acquisition and analysis
  - Logistical and operational support
- Manage Data Safety Monitoring Board (DSMB).
  - Recruit members
  - Create policies and charter
  - Facilitate meetings and coordinate communications
  - Serve as liaison between DSMB and sponsor

*BMT CRO Group ([www.bmtCROgroup.com](http://www.bmtCROgroup.com)) offers a suite of services carefully tailored to meet the specific requirements of the clinical trial sponsor.*

# Reimbursement

Regulatory Affairs

Quality Assurance

Clinical Development /  
CRO

**Reimbursement**

Technology Assessment,  
Market Research and  
Business Strategy

Business Development

Financing Support

Expert Opinion

- 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-faceted 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 Research and Business Strategy

Regulatory Affairs

Quality Assurance

Clinical Development /  
CRO

Reimbursement

**Technology Assessment,  
Market Research and  
Business Strategy**

Business Development

Investment Support

Expert Opinion

- Assess market potential for new technologies and services.
- Analyze clinical and technical requirements, and regulatory and reimbursement environments for new technologies, products and services.
- Conduct competitive market research and analysis.
- 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

Quality Assurance

Clinical Development /  
CRO

Reimbursement

Technology Assessment,  
Market Research and  
Business Strategy

**Business Development**

Investment Support

Expert Opinion

- Identify complementary business opportunities and potential strategic partners.
- Analyze alternative sales channels.
- Initiate and facilitate clinical and business relationships, supporting product development, marketing and financing activities.
- Create early US or European presence, and assist in the marketing and business development activities.
- Identify early stage and emerging technologies for companies seeking to expand their product portfolio.

# Investment Support

Regulatory Affairs

Quality Assurance

Clinical Development /  
CRO

Reimbursement

Technology Assessment,  
Market Research and  
Business Strategy

Business Development

**Investment Support**

Expert Opinion

- Work with entrepreneurs and management teams to develop ‘fundable’ business plans and to plan financing campaigns.
- Introduce entrepreneurs to healthcare VC’s, angels and other private investors.
- Identify prospective strategic partners and prepare companies to appropriately explore opportunities.
- Assist companies to identify and pursue non-diluting sources of capital.
- Support fundraising activities through the due diligence process.
- Conduct due diligence research and evaluations of investment opportunities sought by private and institutional investors.



# Expert Opinion

Regulatory Affairs

Quality Assurance

Clinical Development /  
CRO

Reimbursement

Technology Assessment,  
Market Research and  
Business Strategy

Business Development

Investment Support

Expert Opinion

- Develop expert opinions in disputed arbitrations.
- Support legal teams during pre-trial discovery and deposition phases.
- Provide expert testimony in litigated cases.
- Generate fairness opinions.
- Develop research-based valuation models.
- Prepare expert opinion reports on issues related to:
  - Regulatory affairs
  - Quality systems
  - Clinical trials
  - Reimbursement practices and policies
  - Economic and valuation estimates

## Senior Team

David Barone, Principal 



Over 35 years experience including management, technical and operations, 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 BMTA, David held senior management positions in a number of medical device companies and has founded, financed and developed a number of healthcare companies.

M.Sc., Bio-Medical Engineering and M.B.A., Rensselaer Polytechnic Institute, NY.

Zvi Ladin, PhD, Principal 



Over 35 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 BMTA, focusing on establishing regulatory

strategies for therapeutic and diagnostic technologies, 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. Zvi taught mechanical and biomedical engineering at MIT and Boston University and served as a scientific advisor to the FDA.

Ph.D., Medical Engineering, MIT-Harvard Medical School Division of Health Science and Technology, MA.

## Senior Team *(cont.)*

Michael Imhoff, MD, PhD, Senior Advisor 



Board certified in surgery and intensive care medicine, with 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. Michael is a professor in Medical Informatics and Statistics at Ruhr-University Bochum, Germany, chairman of the section for patient monitoring of the German Association of Biomedical Engineering (DGBMT), and editorial board member and reviewer for several international biomedical journals. He is also Medical Director of the qtec group, Lübeck, Germany, where he leads a team of scientists and medical writers responsible for clinical evaluations of medical devices according to EU MDR, and design and planning of pre-clinical and clinical studies for regulatory approval.

M.D., Universities of Bochum and Munster, Germany; Ph.D., Ruhr-University, Bochum, Germany.

Andrea Nadai, Director 



Seasoned health care professional with expertise in market research, reimbursement analysis and clinical trial management. Andrea analyzes the health economic and reimbursement landscape to assist clients in pursuing the optimal path for market introduction of new products. She also manages global operations for BMTA. Andrea is a licensed physical therapist and clinical trial monitor. Prior experiences include the development of corporate compliance program, risk management, grant writing, searching state and federal regulations, supporting accreditations and clinical teaching. 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.

M.H.P., Health Professions, Northeastern University, MA.

Zohar Zephrani, PhD, Director 



Zohar has extensive research background in the fields of neuroscience, cognitive science, sensation and perception. She worked and managed large-scale projects at major academic and medical centers. Zohar works closely with the client's executive team to formulate efficient regulatory strategies, in line with business objectives and reimbursement needs, and co-manages regulatory projects with the company's cross-functional team. She capitalizes on rigorous scientific training to analyze clinical data and published evidence for the determination of clinical and regulatory strategies that lead to obtaining timely approvals. Notable experience with wearable devices, Artificial Intelligence/ Machine Learning based applications, Software as a Medical Device (SaMD), surgical robotics/ navigation, imaging and diagnostic devices. 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.  
Completed Regulatory Affairs Certificate: Medical Devices and Pharmaceuticals.