BOSTON MEDTECH ADVISORS

More Experience ▸ Better Results

February 2024 Newsletter

Boston MedTech Advisors (BMTA) in 2023

BMTA continued to collaborate with companies developing technologies supporting a wide variety of medical specialties. Activities included:

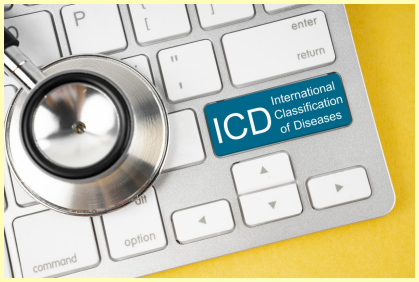
- Successful submissions of FDA 510(k), De Novo, Breakthrough Device Designation, and pre-submission applications for new technologies and clinical indications.
- Supported initial commercialization activities, including serving as U.S. Agent and FDA-registered Importer for offshore manufacturers.
- Development of pivotal and post-marketing clinical study protocols.
- Effectively managed a major multi-site clinical research study.
- Analysis of clinical evidence supporting FDA submissions and reimbursement activities.
- Assessed opportunities and developed business strategies for novel technologies (including market research, competition analysis, expert interviews, business assessment, etc.).
- Developed third-party coverage plans for new technologies and applied successfully for new CPT codes.
- Assisted early-stage companies to raise funding.

Recent Webinars

Sara Little, Ph.D., BMTA Senior Consultant participated on a panel session on Data Management and Monitoring in MedTech Clinical Studies. The webinar discussed the critical nuances of successful clinical trial monitoring and data management, as well as addressed best practices, common pitfalls, and the evolving landscape of remote vs. on-site monitoring.

David Barone, Principal of BMTA, conducted several webinars to non-US companies on topics including "Introduction to the U.S. healthcare system, the largest and most complex market" and "Reimbursement as a driver of valuation, and why developing reimbursement strategy is critical for MedTech companies." For copies of the slide decks of any of these webinars contact info@bmtadvisors.com

New BMTA Blog



Industry News

Inconsistent access to telehealth services. In the wake of COVID-19 most patients lack access to out-of-state telehealth providers. In 2023, several states updated their telehealth policies to address limitations and reduce barriers to medical and behavioral virtual services, including from out-of-state providers. Yet a number of reports (e.g., Cicero Institute) advocate a more universal telehealth policy, as

The Transition Towards ICD-11: The World Health Organization's (WHO) ICD-11 revision contains considerable updates that will affect medical documentation and billing processes. WHO member countries are presently adopting ICD-11 with implementation in the U.S. expected by 2028.

About Boston MedTech Advisors

Since 2004, BMTA's multidisciplinary team of highly experienced consultants has supported more than 400 medical technologies and life sciences companies around the world to achieve their business goals. BMTA offers valuable, ethical, result-oriented, professional, and cost-effective insights that recognize the multi-faceted aspects of today's healthcare markets and the client's unique business needs.

- Market Analysis and Business Strategy
- Business Development
- Regulatory Affairs and Clinical Trial Management
- Reimbursement and Contracting Strategies
- Financing Support
- Other Services

Boston MedTech Advisors provides practical business services to:

- Established and growing medical technology companies
- Healthcare providers
- Startups and entrepreneurs
- Private and institutional investors

most states lack a reciprocity law that would apply to all providers. Companies developing telehealth solutions must stay informed on the continuing developments of such laws to understand how they impact their market access plans. To learn more, please contact BMTA.

Off-label marketing of medical devices could be illegal. The importance of adhering to FDA regulations concerning marketing of a medical device was demonstrated recently with the criminal convictions of two former executives of Acclarent (a subsidiary of J&J) for introducing adulterated and misbranded medical devices into interstate commerce in the U.S. The two executives were personally fined $1 million and $500,000, respectively, while Acclarent agreed to pay $18 million to resolve the allegations. Boston MedTech Advisors is helping companies navigate regulatory requirements beyond the initial FDA approval, to ensure that their marketing complies with the appropriate regulations. To learn more, please contact BMTA.

FDA new rule requires medical device manufacturers to comply with ISO 13485:2016. On February 2, 2024, FDA issued a final rule amending the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation, requiring manufacturers of medical devices registered with FDA and manufacturers that export devices to comply with ISO 13485:2016 [Medical devices—Quality management systems—Requirements for regulatory purposes]. Until this rule becomes effective on February 2, 2026, manufacturers must comply with the current QS regulation. Manufacturers should familiarize themselves with the new regulation and update procedures, processes, and policies as appropriate. To learn more, please contact BMTA.

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You can also contact us by phone at 781-407-0900, or email
info@bmtadvisors.com

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