

# Office Hours for MedTech Startups

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## Addressing the Outcome Studies Challenges for New Medical Technologies

Tuesday, February 9, 2010

Boston University School of Management

5:00 – 7:00 p.m.

Boston, Mass.

Proof of effectiveness and outcome benefits is increasingly important for market adoption of new medical technologies. Beside safety and efficacy required for regulatory approvals, providers and payers now often request outcome studies before starting to use the new technology. In addition, often clinical studies are required for 510K approval. These developments are universal in all developed countries and present new challenges to developers of new medical technology, requiring an integrated regulatory, reimbursement and marketing strategy.

In the workshop, we will discuss challenges and strategies for addressing outcome studies, using a number of real life examples, analyzing potential risks, respective solutions and successful implementation.

You will have the opportunity to consult with the experienced staff of Boston MedTech Advisors. Boston MedTech Advisors has generously sponsored this event to assist the MedTECH IGNITE program increase the number of viable medical technology start-ups in Massachusetts.

### AGENDA

5:00 p.m.

Registration

5:10 p.m.

Current Outcome Challenges for New Medical Technologies

**Michael Imhoff, MD, PhD, Managing Director, Boston MedTech  
Advisors Europe**

Board certified in surgery and intensive care medicine, with over 15 years of clinical experience in large medical centers and strategic consulting for leading companies in the global medical technology markets, as well as start-ups in the US and Europe. Research areas include trauma surgery, intensive care medicine, patient monitoring, clinical data management, artificial intelligence in medicine and health economics. Dr. Imhoff is an associate professor in Medical Informatics and Statistics at Ruhr-University Bochum, Germany, a reviewer for the German Research Foundation, a member of the editorial boards of and reviewer for several international biomedical journals, and author of over 300 publications and scientific presentations.

**5:40 p.m. Q & A with MedTech Advisor Team**  
**6:30 p.m. Networking**

All attendees must be preregistered and must be affiliated with a medical device start-up. For additional information please contact Amy Fredrick, [Fredrick@massmedic.com](mailto:Fredrick@massmedic.com).

To register for this meeting please send an email to [info@massmedic.com](mailto:info@massmedic.com)

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[Directions](#)

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