

News Release

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TCG workshops provide insider advice on entering the US market

In February 2010, TCG conducted workshops in Cambridge, England, and Frankfurt, Germany, sharing insights and advice on how medical device and pharmaceutical companies can successfully launch in the United States. The workshop in England was co-sponsored by ERBI Ltd., a non-profit organization for international life science and healthcare companies.

Approximately 70 people representing 40 European medtech companies attended the workshops led by Dr. Robert C. Keefer, TCG managing partner, and Dr. Reinhard Merz, TCG director of European operations. Other presenters were Steve Lang, president of Argo Consulting; Kurt G. Waldthausen, president of Waldthausen & Associates, Inc.; Albrecht Windelband, CEO of Abtswinder Naturheilmittel GmbH & Co. KG; and Maureen Garner, president, and Glenn Neuman, director, of New World Regulatory Solutions, Inc.

Keefer opened the sessions with support that demonstrates why the United States is the biggest market opportunity for healthcare product companies: A \$120+ billion medical device market growing 6.1% annually and an expanding \$360 billion pharmaceutical market. He emphasized that the first critical step for companies planning to enter the United States is to assess the market, including geographic differences that influence the best sales channels, the role of Key Opinion Leaders and reimbursement issues. Keefer ended his presentation with several case studies.

In their presentations, "Finding Partners and Negotiating with Americans," Lang (in Cambridge) and Waldausen (in Frankfurt) outlined the cultural nuances and structural options for dealing with a US-based entity. They reviewed the pros and cons of licensing, partnerships, and the ease of forming a US subsidiary with the right expertise. They emphasized that even when negotiators speak the same language, differences in negotiation styles rooted in cultural differences must be considered to be successful.

Garner and Neuman presented “How to Manage Regulatory Issues and get FDA Approvals.” They provided answers on FDA submissions for medtech products, compared to the lengthier drug approval process. They stressed the importance of selecting a regulatory strategy tied to a company’s immediate marketing goals and discussed how costs and timing impact the success of a US product launch.

Windelband, former marketing/sales head of Curasan AG, presented a case study of a US medtech product launch from the initial planning in 2004 to the successful 2008 acquisition by Riemser Arzneimittel AG.

TCG will conduct more workshops this year on entering the US market, including an overview session at the EuroMedtech 2010 in June in Leipzig, Germany. Details are posted on the TCG website at www.tcgmedtech.com on the News and Events page.

Technology Commercialization Group (TCG) is an international business development strategy and implementation firm that works with CEOs and other senior executives to develop markets and operations in the medical device, pharmaceutical, biotechnology and other healthcare industries. TCG is headquartered in Research Triangle Park, North Carolina. The company’s European office is in Heidelberg, Germany.

For more information on TCG go to www.tcgmedtech.com or call the US office at 1-919-941-0700 or the European office at 49-6221-27262.