

Marketing your Medical Technology in the US:

Dos and Don'ts

DRAFT

A Business Primer and Workshop in
Boston, MA and Minneapolis, MN
USA
7-11 April 2008

- An invitation to the members of the Medtech clusters in Norway to gain new and critical knowledge on how to market your medical technology or device in the US, the world's largest healthcare market.
- An interactive program with networking and knowledge sharing with experts from the leading US Medtech clusters in Massachusetts and Minnesota.

In collaboration with:

Who should attend?

Company intent on developing a US market entry strategy for a device or technology intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. In vitro diagnostic and information technology companies with products for the US healthcare sector in general are also invited to attend.

What will you learn?

The US regulatory landscape and the rules and regulations for sales and marketing of your medical device:

- The process of obtaining a 510(k) clearance or a PMA and developing a regulatory strategy

US reimbursement fundamentals: Stakeholders, coding requirements, payment systems:

- The process of obtaining reimbursement and developing a reimbursement strategy for your medical device

The US legal environment:

- Issues relating to liability, partnering, contracts, incorporation, employment, etc.

The process of obtaining clinical acceptance for your device or technology:

- Developing good clinical trials

Doing sales and distribution in the US through strategic partner, distributors or own sales force:

- Implications of different sales and distribution models and developing a sales and distribution strategy for your company

How to raise capital at home and in the US:

- Developing an investor pitch for your compelling business case

Needs based innovation driving your company and the essentials of a good business plan and value proposition:

- How to develop and use your business plan

How will you learn?

- Up to date lectures given by a faculty of industry specialists
- Interactive case studies and workshop moderated by succesfull serial medtech entrepreneur
- Networking sessions
- Scheduled and ad-hoc one-to-one meetings between participants and the faculty and other companies/parties

Registration and travel arrangements

Innovation Norway in Oslo will handle all registrations and travel arrangements for hotels and flights in collaboration with ViaTravel. Please contact Knut Larsen for registration and your travel needs:

Knut.larsen@invanor.no

Telephone: 90 03 02 20

Registration deadline is: Thursday 10th January 2008.

The registration fee is NOK 9500,- per person and payable upon registration. This Innovation Norway subsidized fee covers advertised lectures and workshops, ground transportation in the US, networking lunches and networking dinners. Hotels and all airtravel are not included. Registrations are final and fees non-refundable. For the benefit of the Faculty and other interested parties each participating company will be asked to provide a one page profiler of their company. A template will be provided.

Requests for more information and/or for setting up company meetings in Boston and/or Minneapolis

We can help set up meetings for you and your company in Boston and/or Minneapolis with the Faculty or companies/parties that you have identified before or during the event.

Please contact:

Sander John Tufte, Director, Innovation Norway, Boston	Email: satuf@invanor.no	Phone: +1 617 369 7871 Cell: +1 617 818 3900
Linda Pederson, Vice Consul, The Royal Norwegian Consulate, Minneapolis	Email: linda.pederson@mfa.no	Phone: +1 612 332 3338

Program details

BOSTON 6th April 2008

Sunday: Arrival from Norway

BOSTON 7th and 8th April 2008

Monday: Boston University School of Mngmnt + Excursion to Waltham and Natick

Agenda: The Essentials of Business Development in Medtech- What you need to know

08:30 Welcome to Boston
Innovation Norway Boston

08:40 The US Medtech market - its size, value and opportunities
MassMEDIC <http://www.massmedic.com>

09:00 Regulatory and price reimbursement strategies for Medtech

- *The regulatory environment: How to comply with the FDA*
- *Reimbursement planning*

The Maelor Group
MDCI Medical Device Consultants Inc. www.mdcicom.com
Boston Healthcare www.bostonhealthcare.com

12:00 Networking Lunch at Boston University

14:30 US venture capital investing in early stage medtech companies
Polaris Venture Partners (Waltham) www.polarisventures.com

15:30 Strategic investments in medtech companies
Boston Scientific Corporation (Natick) www.bscicom.com

17:00 End of Day 1.

19:00 Networking Dinner in Boston

Tuesday: Massachusetts Institute of Technology

Agenda: Innovation from Converging Cutting Edge Technologies

The Essentials of Selling Medtech in the US

09:00 Trends in integration of medicine and innovative technology

Center for Integration of Innovative Technology (CIMIT)

<http://www.cimit.org>

10:00 The future is here - opportunities for innovations in medtech

MIT Langer Labs <http://web.mit.edu/langerlab/langer.html>

11:00 Business incorporation, partnering and contracting in the US

Wiggin&Dana LLP www.wiggin.com

12:00 Networking Lunch at Legal Seafoods, Cambridge

13:00 Selling to the Physician community in the US - dos and don'ts

Axis-Shield Inc.

Medtronic Inc.

Imatis Inc.

15:30 End of Boston program

Evening Departure for Minneapolis

MINNEAPOLIS 9th and 10th April 2008

Wednesday: Fredrikson and Byron PA

Agenda: *Recipe for Success in the US - the Case of EnteroMedics and Others*
Interactive session moderated by: Dr. Mark Knudson, CEO, EnteroMedics
and Venturi Group www.venturigroup.com

09:00 Welcome to Minnesota
Rolf W.Hansen, The Norwegian Consul General in Minnesota

09:15 Market driven innovation in practice - short overview
Mark Knudson, Enteromedics www.enteromedics.com

09:45 Developing new products based on clinical needs: The Case of
EntereoMedics
Mark Knudson, Tim Conrad and physicians

10:45 How we structured the business
Mark Knudson

11:30 How we got FDA approval in the US?
Linda Alexander, Alquest, www.alquest.com

12:15 Networking Lunch

13:15 How we performed a "good" clinical trial? Abroad and in the US
Linda Alexander, Alquest, www.alquest.com

14:00 How we raised venture capital
Ivar Sorensen, The M&A Group, www.themergergroup.com

15:15 How do we get paid for our product?

Mark Stultz

19:00 Dinner at the Residence of
the Norwegian Consul General, Rolf W. Hansen

Thursday: Fredrikson and Byron PA

Agenda: Developing your Business Plan

Full-day interactive workshop and clinics moderated by: Ivar Sorensen, The M&A Group and Kermit Nash, Partner, Fredrikson and Byron, www.fredlaw.com

09:00 Presentation of the University of Minnesota and Norwegian Links
Robert Elde, Dean, College of Biological Sciences, University of Minnesota

09:45 **Interactive Workshop Part1: Revising your Business Plan**
How have the last days' lessons affected Your business plan? It is time to start revising Your business plan: Each company to prepare an updated 10 minute slide presentation on their company including details on a US market entry strategy. Your elevator pitch!

12:00 **Networking Lunch with Faculty and Invited Guests including Representatives from Medtronic and Medistim**

13:30 **Interactive Workshop Part2: Presenting your Revised Business Plan**
Companies to present their revised business plan through 10 a minute pitch to the Faculty and other invited parties.

15:30 Scheduled and ad hoc one-to-one meetings with Faculty or other invited parties to answer Your specific questions on business strategy and planning.

Evening Social Event hosted by Fredrikson & Byron

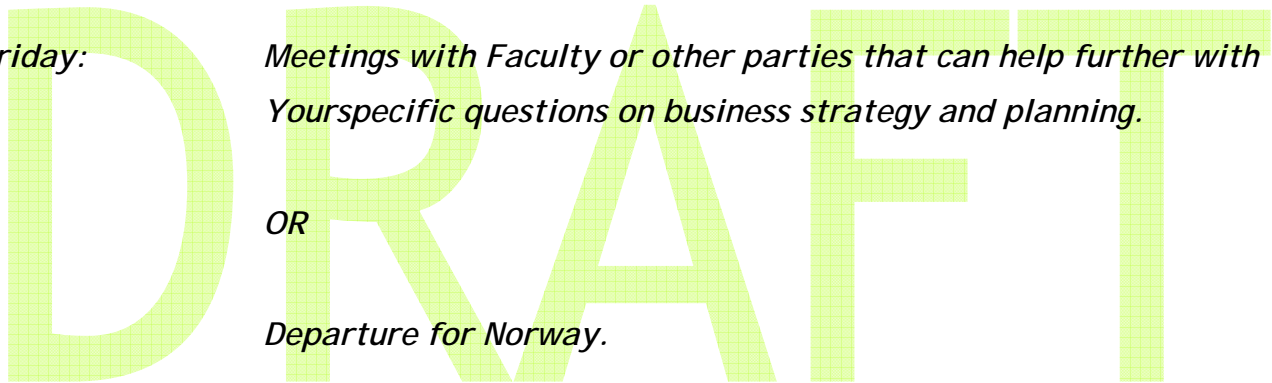
MINNEAPOLIS 11th April 2008

Friday:

Meetings with Faculty or other parties that can help further with Yourspecific questions on business strategy and planning.

OR

Departure for Norway.



Background for proposed event

Clusters of Norwegian medtech companies are emerging most notably around Trondheim and Oslo. The member companies are at very different stages of their development in terms of product and commercial developments. Also, the technologies applied in their inventions are diverse and sometimes the result of convergence. These trends are not unique to the Norwegian medtech scene but global. However, for most medtech companies of the world be they from Trondheim to Tangiers, the US is by far the main market in terms of size and value. As such, Norwegian medtech companies must early on in their life cycle, address the US market opportunity and hurdles and have a clear strategy for entering this market. Innovation Norway in Boston in collaboration with the Royal Norwegian Consulate General in Minneapolis, KITH and SINTEF invite you to Boston and Minneapolis to explore the implications of marketing your medtech products in the US.

Despite the homogeneity and open inner market of the United States of America, getting into this unified market poses some distinct and peculiar challenges. These challenges stem from how health services are produced, distributed, rendered, consumed, controlled, legalized and paid for in the US. The underlying driver is capitalistic and the willingness to pay drives supply and demand of many products and services. It is critical for any medtech company entering the US to understand the drivers at work in the US market place and what the market and 'what is in it' for its stakeholders in finance, regulatory, academia and industry. This study trip through a very practical oriented program in Boston and Minneapolis proposes to address these issues and thereby better equip the aspiring Norwegian medtech companies in their efforts in the US. Massachusetts and Minnesota are natural choice for learning about the do's and don'ts of commercializing medtech in the US.

Massachusetts harbors several of the world's most prominent universities, such as Harvard, Massachusetts Institute of Technology (MIT), and Boston University, are located in the Boston area, along with some 60 other colleges and universities. Bank of Boston reported some years ago that students from MIT have founded 4,000 firms which, in 1994 alone, employed at least 1,1 million people and generated \$ 232 billion in revenue. Since then the high tech sector with spin offs from Universities has continued to grow and play an important role in the US economy. The life science industry is a prominent feature of the Massachusetts industry-university collaboration: there were approximately 300 biotechnology companies in Massachusetts in 2005, and about 150 medical device companies. The industry employs over 30,000 people in the state of Massachusetts. Some of the world's largest medtech companies are found in Mass. including Boston Scientific Corporation, Covidien and Philips Medical Systems.

Likewise, the medtech industry of Minnesota is recognized worldwide for being at the forefront of innovation. Between 2001 and 2005 about 2,500 medical device related patents were registered to Minnesota companies. Minneapolis and St. Paul, the twin cities (TC) of Minnesota harbor 400-500 small and mid-sized medtech companies. In addition, world giants like Medtronic, 3M and St.Jude have their HQ in the twin cities. In 2004 the med tech. industry was employing approximately 24,000 people in Minnesota, with a growth rate of more than 40 percent. The University of Minnesota, Twin Cities (UMTC) is one of the most prestigious universities in the US, in particular on med. tech. and devices development. They have in total approx. 40.000 students more than 4000 scientist in academic and research positions and have established close partnerships with national and international business communities.

Sunday 6th April	Monday 7th April	Tuesday 8th April	Wednesday 9th April	Thursday 10th April	Friday 11th April
Boston	Boston	Boston	Minneapolis	Minneapolis	Minneapolis
	Welcome to Boston <i>Innovation Norway Boston</i>	Trends in integration of medicine and innovative technology <i>Center for Integration of Innovative Technology (CIMIT)</i> http://www.cimit.org	Welcome to Minnesota <i>Rolf W. Hansen, The Norwegian Consul General in Minnesota</i>	Presentation of the University of Minnesota and Norwegian Links <i>Robert Elde, Dean, College of Biological Sciences, University of Minnesota</i>	<i>Meetings with Faculty or other parties that can help further with Your specific questions on business strategy and planning.</i>
	The US Medtech market - its size, value and opportunities <i>MassMEDIC</i> http://www.massmedic.com	The future is here - opportunities for innovations in medtech <i>MIT Langer Labs</i> http://web.mit.edu/longerlab/longer.html	Market driven innovation in practice - The Case of EntereoMedics <i>Mark Knudson, Enteromedics</i> www.enteromedics.com	Interactive Workshop Part1: Revising your Business Plan	
	Regulatory and price reimbursement strategies <i>The Maelor Group</i> <i>MDCI Inc. www.mdc.com</i> <i>Boston Healthcare</i> www.bostonhealthcare.com	Business incorporation, partnering and contracting in the US <i>Wiggin&Dana LLP</i> www.wiggin.com	How we structured the business <i>Mark Knudson</i> How we got FDA approval in the US? <i>Linda Alexander, Alquest,</i> www.alquest.com		
	Networking Lunch	Networking Lunch	Networking Lunch	Networking Lunch	
	US venture capital investing in early stage medtech companies <i>Polaris Venture Partners (Waltham)</i> www.polarisventures.com	Selling to the Physician community in the US - dos and don'ts <i>Axis-Shield Inc.</i> <i>Medtronic Inc.</i> <i>Imatis Inc</i>	How we performed a "good" clinical trial? <i>Linda Alexander, Alquest,</i> www.alquest.com How we raised venture capital <i>Ivar Sorensen, The M&A Group,</i> www.themergergroup.com	Interactive Workshop Part2: Presenting your Revised Business Plan	
	Strategic investments in medtech companies <i>Boston Scientific Corporation (Natick)</i> www.bsci.com		How do we get paid for our product? <i>Mark Stultz</i>	Scheduled and ad hoc one-to-one meetings with Faculty or other invited parties to answer Your specific questions on business strategy and planning.	
PM Arrive Boston	Networking Dinner in Boston	PM Departure for Minneapolis	Networking dinner at the Residence of the Norwegian Consul General, Rolf W. Hansen	Social Event hosted by Fredrikson & Byron	AM/PM Depart Minneapolis