

MANNHEIM MEDICAL TECHNOLOGY CLUSTER PRESENTS AN
EDUCATIONAL WEBINAR

**SUCCESS FACTORS FOR
MEDICAL DEVICE COMPANIES
EXPANDING IN EUROPE**

When: Thursday, June 21st, 2012
5:00 pm CEST
(Mannheim, Frankfurt, Paris, Brussels)
11:00 am EDT, 8:00 am PDT

Duration: 30 minutes

1. Business Environment
2. Sales Execution
3. Clinical & Research Environment
4. Strategic Summary

Moderator



James Greer
European Business
Development Initiative
North Carolina Biotech Center

Panelists



Elmar Bourdon
Manager
Mannheim Medical
Technology Cluster



Prof. Norbert Gretz, M.D.
Managing Director
Institute of Medical Technology,
Mannheim



Dr. Jan Stallkamp
Director
Fraunhofer Institute, Project Group
Medical Device Production & Automation,
Mannheim

Business Environment

Personal relationship building with senior management is critical.

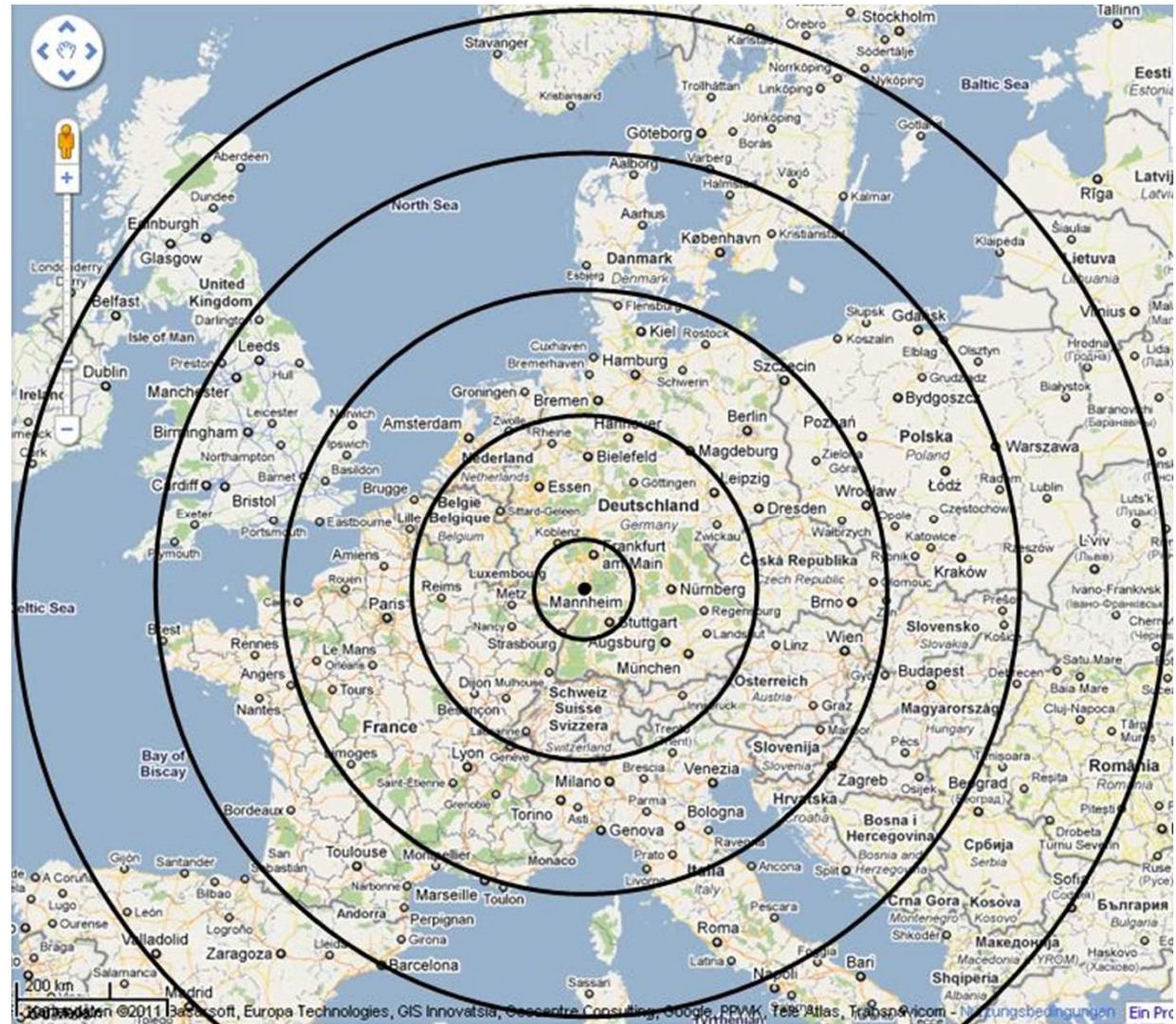
Hospital and Group Purchase Organisation sales much more subject to personal relationship with senior management vs US.

Sales force is “high-maintenance” vs US. Requires more people management.

MANNHEIM provides optimal hub for time-saving and efficient business travel, e.g.

31 minutes to Frankfurt Airport
Worldwide hub for direct flights to US, EMEA, ASPAC and ROW.

High-speed ICE trains
2:58 hrs to Munich
3:09 hrs to Paris



Your fast track to get connected with US, EMEA, ASPAC and ROW

Leveraging your resources is critical.

MANNHEIM provides you quick access to a broad environment of global medical device industry partners that can help you leverage your own resources and capabilities.

In Mannheim and 1 hour car drive around, e.g.

Abbott Diagnostics
Abbott Medical Optics
Abbott (AbbVie) Pharma
Admedes
Angioslide
Bausch & Lomb Medical
BD
Bruker Nano
C.R. Bard
Datascope
Dentsply
DFine Europe
Fresenius Medical Care
GE Healthcare
Heraeus Medical

Hitachi High-Technologies
Johnson & Johnson DePuy
Johnson & Johnson LifeScan
Leica Microsystems
LeMaitre
MAQUET
Merck Pharma/Merck Serono
Nestlé Healthcare
Pfizer Pharma
Roche Diagnostics
Sanofi Aventis Pharma
Siemens Healthcare
Sirona
St. Jude
Terumo

Your fast track to medical device industry partners

Physician training is critical.

Large number of small and medium size hospitals. Varying standards of care.
Accelerated market access through CE and, thus, limited guidance through RCTs.

Physician training is key to launching medical devices, and to drive adoption and diffusion of new medical technologies.

MANNHEIM provides you with quick access to simulator centers dedicated to physician training in surgical and transcatheter therapies

- CatHi Simulator Training Center (Mannheim City)
- VRmagic Simulator Training Center (Mannheim City)
- CardioSkills Simulator Training Center (50 miles from downtown Mannheim)

Your fast track to Simulator Training Centres

Financial performance is critical.

Financial performance and compliance according to your US standards present key metrics for managing your business.

Four worldwide leaders in business consulting run offices in MANNHEIM, and provide finance, taxation, accounting, and expatriate payroll services to you.

- Ernst & Young
- Deloitte
- KPMG
- PriceWaterhouseCoopers

Your fast track to commercial excellence

Skilled medical device labour is critical.

People make the difference. Investing and growing your business goes along with an increasing demand for skilled medical device labour.

Staff and workforce in general less prepared to relocate and assume new roles vs US.

MANNHEIM provides quick access to leading academic institutions dedicated to providing a ready pool of graduates for medical device R&D, Operations, Supply Chain, QA, Regulatory, Marketing, Sales and Distribution.

The following shortlist presents just a sample of academic institutions in Mannheim City:

- University of Applied Science (Medical Engineering)
- Medical Faculty Mannheim of Heidelberg University (Medicine)
- Mannheim University (Business)
- DHBW University of Applied Science (Electrical/Medical Engineering, Business)
- Graduate School RN (Life Science & Healthcare Management)
- University of Applied Management Studies (Business)
- Vocational colleges for nurses and nurse-technicians

Your fast track to skilled medical device labour

Safety in numbers is critical.

Beyond achieving net sales growth, today's medical device market environment requires solid management of both, your gross profit from operations, and your income from customers.

Located in the MANNHEIM, you are able to benefit from competitive labour cost and taxation schemes that help you drive bottom line growth.

Your fast track to drive bottom line growth

Competitive Labour Cost is critical.

The EU Labour Cost Index includes salaries, social insurance charges for employers, and labour-related tax deducting labour-related subsidies.

EU Labour Cost Index Q3/2011

UK	104.9
Germany	105.5
Netherlands	106.4
France	107.3
Italy	109.2
Belgium	110.7

Source: Eurostat – The Statistical Office of the European Commission

http://epp.eurostat.ec.europa.eu/portal/page/portal/labour_market/labour_costs/main_tables

Competitive Local Business Tax is critical.

Local Business Tax is charged by all territorial authorities. Its key indicator forms the so-called Gewerbesteuer-Hebesatz %.

Local Business Tax comparison for major german commercial areas 2011

Berlin	410%
Mannheim	430%
Duesseldorf	440%
Frankfurt	460%
Hamburg	470%
Cologne	475%
Munich	490%

Source: Federal Chamber of Commerce

<http://www.dihk.de/themenfelder/recht-steuern/steuern/finanz-und-haushaltspolitik/realsteuer-hebesaetze>

Competitive Corporate Income Tax is critical.

The Corporate Income Tax does not include other taxes, like local business tax, and other comparable taxes of federal and territorial authorities.

Corporate Income Tax comparison of european industrial countries 2011
standard tax rates in %

Germany	15,0
Netherlands	25,0
United Kingdom	26,0
Italy	27,5
Belgium	33,0
France	33,3

Source: Federal Ministry of Finance

http://www.bundesfinanzministerium.de/Content/DE/Downloads/Broschueren_Bestellservice/wichtigste-steuern-vergleich-2011.pdf?__blob=publicationFile&v=6

Competitive Company Tax is critical.

The Company Tax includes local business tax, corporate income tax and other comparable taxes of federal and territorial authorities.

Company Tax comparison of european industrial countries 2011
tax burden of incorporated companies (nominal) in %

Netherlands	25,00
United Kingdom	26,00
Germany	29,83
Italy	31,40
Belgium	33,99
France	34,43

Source: Federal Ministry of Finance

http://www.bundesfinanzministerium.de/Content/DE/Downloads/Broschueren_Bestellservice/wichtigste-steuern-vergleich-2011.pdf?__blob=publicationFile&v=6

Sales Execution

Risk reduction and P&L leverage is critical.

The initial set-up of your German/EU direct sales organization may present a significant challenge to both, your P&L as well as your risk profile and management resources.

Keep your dedicated/allocated commercial cost and your overhead staff low at that stage.

In MANNHEIM, you will be able to just hire your own local sales force, and focus 100% on customers & taking market share.

The Ready-to-go Sales Office may take care of the rest, i.e.:

- regulatory/legal status of „Inverkehrbringer“ acc. to german medical device law MPG
- customer service / order taking / order processing / local warehouse
- shelf life / consignment stock management
- local recall management
- invoicing / accounts receivables management
- accounting, forecasting, reporting

You'll be charged according to actual workload/sales. Either continue in this mode or transfer this service in a controlled fashion once your business is mature. The Ready-to-go Sales Office team provides experience in partnering with US medical device companies, and understands your standards of performance, reporting, forecasting, and business code of conduct.

Your fast track to sales force effectiveness

Targeting is critical.

When setting up your legal entity in MANNHEIM you'll be provided a tailored starter-package that includes:

- Contacts of TOP-50 german in-patient accounts ranked by procedural volume of your targeted disease/therapy
- Contacts of TOP-20 german Key Opinion Leaders of your targeted disease/therapy
- Contacts of TOP-20 german Group Purchase Organisations (control up to 80% of hospital sales)
- Advice on suitable recruiting profiles for your business model in the german market (farmers vs hunters, rep vs clinical, talents vs pros)
- Support to find the appropriate recruiting partner

Your fast track to sales force effectiveness

Access to Emerging Markets is critical.

Germany has always been a natural gateway to emerging markets in Eastern Europe, particularly following the German reunification in 1990.

Located in the MANNHEIM you benefit from established political and commercial relationships facilitating your access to emerging markets in Poland, Russia, Czech Republic, Hungary, Turkey, Slovakia, Romania, and the Baltics.

Incremental german export growth to emerging market countries 2000-2007
in billion Euro

Poland	21,68
Russia	21,50
Czech Republic	13,30
Hungary	7,00
Turkey	6,73
Slovakia	5,18
Romania	5,27
Baltics	3,79

Your fast track to emerging markets in eastern Europe



Learning from best practice models is critical.

DFINE, Inc. founded in 2004, based in San Jose, California.

Privately held medical device company.

Minimally invasive therapeutic devices used to treat pathologies of the vertebrae.

Flagship product: StabiliT[®], Radiofrequency-Targeted Vertebral Augmentation[™] for treatment of vertebral compression fractures.



DFINE Europe GmbH in MANNHEIM
Headquarter of their european sales & distribution
Established 2008
25 sales force in Germany
Enjoy significant growth



<http://www.dfineinc.com>

<http://www.dfine.eu>

Best Practice Model: DFINE Inc.

Clinical & Research Environment

A collaborative R&D ecosystem is critical.

MANNHEIM aims to provide access to a powerful ecosystem of collaborative clinical research and product R&D.

A sample of leading applied and basic research institutions in Mannheim and its metropolitan region involved in medical device and diagnostics R&D

- Baden-Wuerttemberg Cooperative State University Mannheim
- Central Institute of Mental Health
- European Laboratory for Molecular Biology EMBL
- Fraunhofer Group for Automation in Medical Engineering and Bioengineering
- Freudenberg New Technologies GmbH
- German Cancer Research Center DKFZ
- Heidelberg University Medical Center
- Institute of Medical Technology
- Mannheim University Medical Center
- Mannheim University of Applied Sciences
- Max-Planck-Institute for Medical Research
- National Tumor Center NCT
- Roche Diagnostics Research Center Mannheim

Your fast track to a clinical research and product R&D ecosystem

Access to clinical high-volume practice is critical.

Feedback from clinical routine practice and quick access to key opinion leaders is critical to launching medical devices, and to drive market penetration.

MANNHEIM provides you quick access to key opinion leaders in high-volume centres in Mannheim City and 10 miles around.

Mannheim University Hospital (1.400 beds)
Heidelberg University Hospital (1.600 beds)
Mannheim Theresien-Hospital & St. Hedwig (660 beds)
Mannheim-Speyer Diakonie Hospital (530 & 440 beds)
Ludwigshafen Hospital (940 beds)
BG Ludwigshafen Trauma Surgery Center (415 beds)

Your fast track to a clinical research and product R&D ecosystem

Clinical data is critical.

Whether you are conducting a clinical study or are managing a product life-cycle, MANNHEIM includes CROs dedicated to support you. The following shortlist presents just a sample of CROs in Mannheim:

- Advanced Medical Services
- CONET Clinical Operations Network
- CRS Clinical Research Services Andernach
- FORIM
- IST Clinical Research
- KKS coordination center for clinical studies
- PharmaLex
- PRA International
- QUINTILES Innovex
- Scope International

Your fast track to a clinical research and product R&D ecosystem

Access to innovation is critical.

Clinical and procedural knowledge, engineering excellence and understanding of product development in medical devices are key factors to be first-to-market, and to meet your expectations for return on investment.

MANNHEIM provides quick access to medical technology research units, focused on the development of medical technologies for commercialisation.

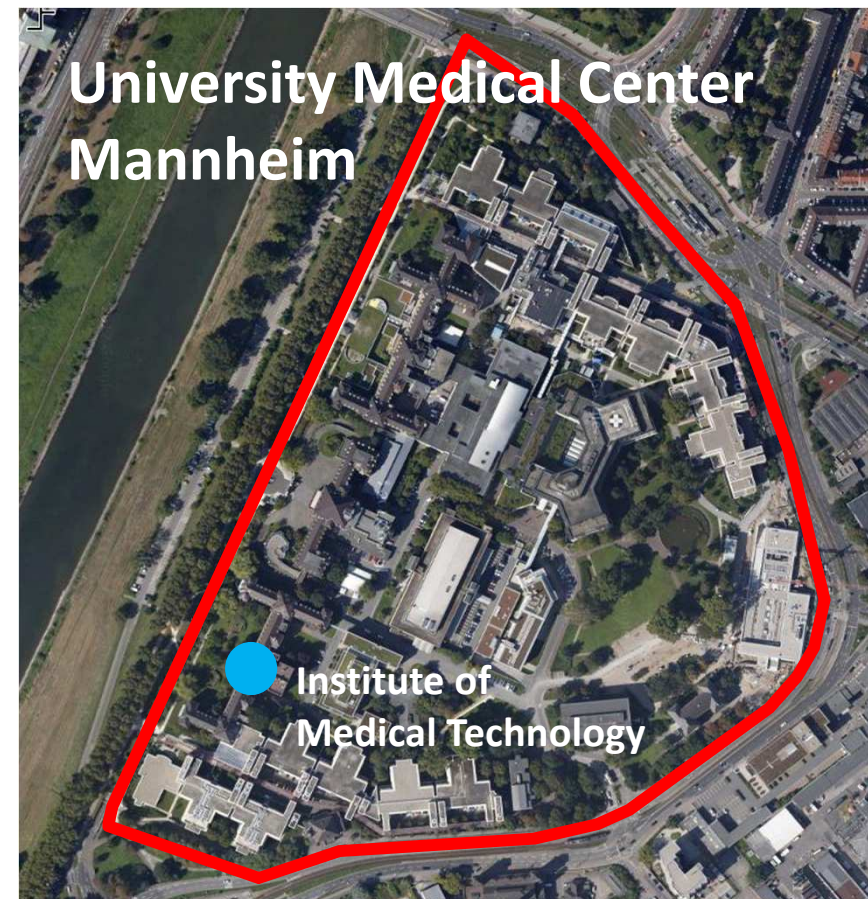
- **Institute of Medical Technology**
- **Fraunhofer Project Group for Automation in Medical Engineering and Bioengineering PAMB**

Your fast track to medical technology applied research units

Access to innovation is critical.

Institute of Medical Technology

- Successful interdisciplinary cooperation between academic hospitals and biotechnology, biomedical engineering as well as business management on one campus
- Direct access to patients
- Access to animal facilities
- Facility providing a combined intervention room as well as "biolabs" (under construction)
- BSc and MSc course: medical device industry enrolled in teaching
- Research training group: photonics
- Enrolled in international networks
- Experience in grant acquisition (European & national level, e.g. BMBF)

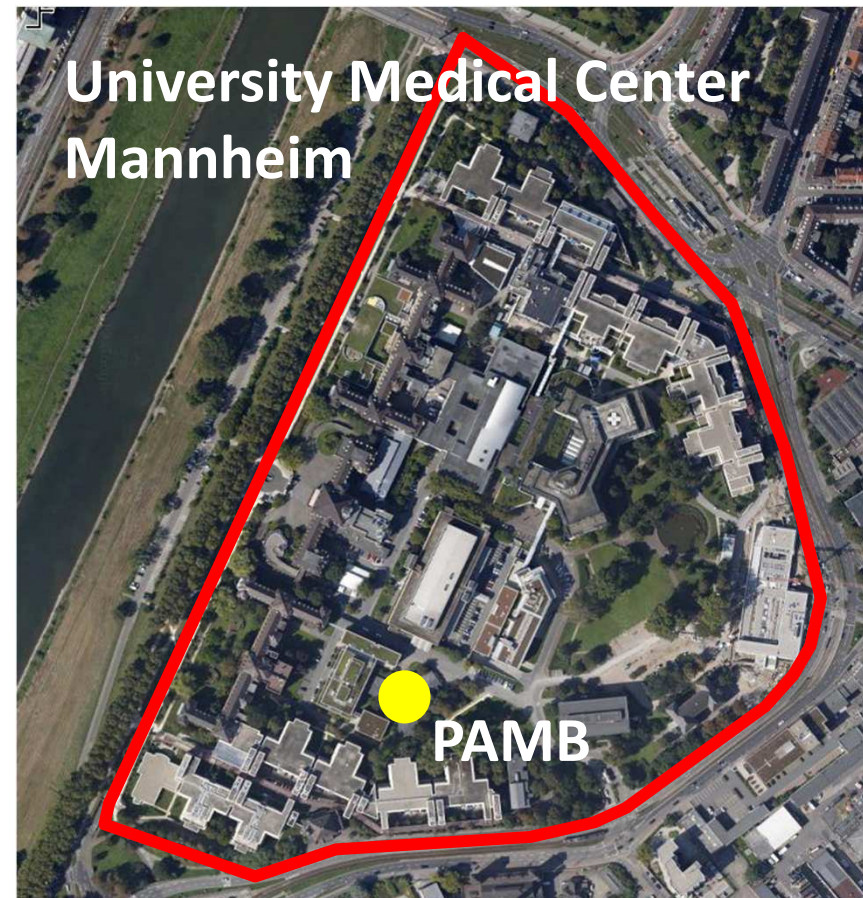


Your fast track to a clinical research and product R&D ecosystem

Access to innovation is critical.

Fraunhofer Project Group for Automation in Medical Engineering and Bioengineering PAMB

- Fraunhofer Institute: Largest organization for applied research in Europe, ~18 000 employees, ~1.65 billion € budget, >60 institutes
- Contract research based on >15 years experience
- Development of automation solutions for (bio-) production and Instruments & devices for diagnosis and intervention
- Cross-linked with medical and biotech facilities in greater Mannheim area and worldwide



Your fast track to a clinical research and product R&D ecosystem

**Bridging the gap is critical.
From R&D to commercialisation. From BioTech to MedTech.**



PAMB Bioproduction Technologies

- Automated Cell Culture
- Automated Tissue Culture
- Biomedical Technologies
- Screenings



PAMB Technologies for Diagnosis and Intervention

- Assistant Systems,
- Intelligent instruments
- Inline-Measurement devices
- OP-Networks
- Implants

Your fast track to a clinical research and product R&D ecosystem

Strategic Summary

There are critical success factors for US medical device companies to be considered when expanding in Europe.

Based out of MANNHEIM you'll be able to address those success factors using the unique commercial, clinical, skilled labour and research environment – with safety in numbers.

Contact us today:

www.mannheim.de/en/medtech