

FROM SCIENCE TO INNOVATION

Monday Sept 7, 10.30am – 5.30pm

11th International
Congress of the IUPESM

**MEDICAL
PHYSICS AND
BIOMEDICAL
ENGINEERING**

**WORLD
CONGRESS
2009**

For the benefit
of the Patient.



Forum



VDE | DGBMT

Deutsche Gesellschaft für Biomedizinische Technik im VDE

From Science to Innovation

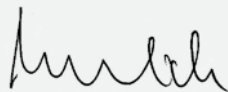
On September 7 at the World Congress 2009, the VDE I DGBMT and the Forum MedTech Pharma will offer a platform for a number of continuing education courses. The courses are specially tailored for the national and international public from research institutions and small and medium enterprises (SMEs) and to foster the innovation process.

These courses are designed to improve cooperation among research institutes, SMEs and industry. They are directly based on the study conducted by the German Ministry for Education and Research on identifying obstacles to innovation in medical engineering. The topics that are detailed in the study, published in November 2008, will be covered in the courses to convey know-how that is both practical and relevant to the daily work of the participants.

We look forward to seeing you in Munich.



Hartmut Gehring
Chairman of DGBMT



Michael Nerlich
Chairman of the Executive Board
of the Forum MedTech Pharma

The Courses

Medical Device Directives – Pharmaceutical Regulation

Which one applies to my new ideas?

Ulrich M. Gassner, Institute of Medical Devices Law, University of Augsburg
Andrea Weiland-Waibel, Explicat Pharma GmbH, Hohenbrunn
Hans-Albert Schultz, MPC International S.A. Luxemburg, Luxemburg

Risk Management Assessment

No approval procedure for medical devices without it

Johannes Dehm, VDE Initiative MikroMedizin, Frankfurt/Main
Michael Bothe, VDE Institut, Offenbach
Peter Knipp, qcmcd Quality Consulting Medical GmbH, Aachen

Standards and Standardization

How knowledge can protect your ideas and innovations

Klaus Neuder, DKE Deutsche Kommission Elektrotechnik Elektronik Informationstechnik im DIN und VDE, Frankfurt/Main

Patents and Intellectual Property Rights

From investigation of alien ideas to protection of your own thoughts

Alfred Schillert, PROvendis GmbH, Mülheim/Ruhr
Kordula Kruber, PROvendis GmbH, Mülheim/Ruhr
Cornelius Bobbert, Bobbert & Partner Patentanwälte, München
Richard Schlötter, Reed Smith, München

Health Technology Assessment and Clinical Studies – from development to reimbursement: Basic knowledge for innovators

Marc O. Schurr, Novineon Healthcare Technology Partners, Tübingen
Hubertus Rosery, AiM GmbH-Assessment in Medicine-Research and Consulting, Schopfheim

Reimbursement for Medical Devices

Basic knowledge for successful innovation

Jan Hacker, EconoMedic AG, Bayreuth
Olaf Pirk, Health Economics & Outcomes Research, IMS Health GmbH & Co. OHG, Nürnberg
Frank-Ulrich Fricke, Health Economics & Outcomes Research, IMS Health GmbH & Co. OHG, Nürnberg

IT-Networks Incorporating Medical Devices

Trends, standards and procedures

Jörg A. K. Ohnsorge, Orthopädische Klinik der RWTH Aachen
Björn Bergh, Zentrum für Informations- und Medizintechnik, Universitätsklinikum Heidelberg
Thomas Norgall, Fraunhofer Institut für Integrierte Schaltungen – (IIS), Erlangen

Medical Device Directives – Pharmaceutical Regulation

Which one applies to my new idea?



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MPC International S.A. Luxembourg,
Luxembourg

Medical products and pharmaceuticals must be approved before they may be sold in the European Union. Basically, the type of effect and intended use of such products or pharmaceuticals determine whether they are subject to the Medical Device Directive or the Pharmaceutical Regulation. However, such categorization isn't always that simple, since there are combination products or medical products that also contain an active pharmaceutical substance.

To help out in such situations, the course provides an overview of the European Directives on various categories of medical products and on the Pharmaceutical Regulation. The course offers aids for determining which Directive is relevant, explains the conformity assessment procedure and the phar-

maceutical marketing authorization application, and introduces the participating institutions for medical devices and pharmaceuticals.

The course explains the differences between the conformity assessment procedure and the pharmaceutical marketing authorization application, as well as the procedures necessary for a combination of a medical device and a medicinal product, or for medical devices incorporating a medicinal substance having an ancillary action. Questions regarding the special requirements of pharmaceutical guidelines for combination devices will be answered: What has to be taken into consideration in the development phase, during routine production, and during the marketing phase? What documentation is needed? The course also provides an overview of the quality management system ISO 13485 (medical devices) versus EU-GMP (pharmaceuticals).

The course addresses the importance of taking the approval process into account early in the development stage, and discusses typical timelines. Several case studies illustrate the theoretical information and participants can apply their new knowledge in specific examples.

 **explicat pharma GmbH**
Consulting and Development

Risk Management Assessment

No approval procedure for medical devices without it



Johannes Dehm

VDE Initiative MikroMedizin,
Frankfurt/Main



Michael Bothe

VDE Prüf- und Zertifizierungsinstitut GmbH, Offenbach



Peter Knipp

qcmed Quality Consulting Medical GmbH, Aachen

A full risk assessment is part of the approval procedure for medical devices! Every manufacturer of medical devices and in-vitro-diagnostics is required to establish the process specified in the EN ISO 14971:2007 as a measure to comply with international medical device approval requirements. Risk Management is explicitly required by all three European directives covering medical devices, which are the Active Implantable Medical Device (AIMD) Directive - 90/385/EEC, the Medical Device Directive (MDD) - 93/42/EEC, the In Vitro Diagnostic Device Directive (IVD) - 98/79/EC. The same applies to national FDA approval in the U.S. and in many other legislations.

Risk assessment not only includes an analysis of design, applied materials, energy flows, biocompatibility, contamination and infection risks and many other product/system properties, but also assesses the process, how product/ system risks are managed within the organization. The measures have to be implemented in all phases of the product's life cycle. This also means that university institutes, research organizations and SME's doing basic research or contributing work for medical device manufacturers should as well implement risk management as an integral part of their services.

Participants will learn how to implement risk management as an intrinsic part of the development process for medical devices, which is prerequisite to successful approval procedure according to the European, U.S. and other worldwide regulatory systems. The course will present hands-on risk management methods and procedures including FMEA (Failure Mode and Effect Analysis) and a bi-directional TOP-DOWN-TOP FTA (Fault Tree Analysis) method. The course will conclude with the application of risk management in case studies submitted by the audience.

Standard and Standardization

How knowledge can protect your ideas and innovations



Klaus Neuder

DKE Deutsche Kommission Elektrotechnik Elektronik
Informationstechnik im DIN und VDE, Frankfurt/Main

Standards play an important role for users, research institutes and medical device manufacturers in protecting their innovation activities. They have to know state-of-the-art standards as well as future standards being developed. This is especially important for meeting the criteria of the European Directives and the FDA regulations, for ensuring usability/interoperability, and for using scale effects for production.

The EU Commission mandates the European Standards Committee, CEN/CENELEC, to develop standards for proving the compliance of products/systems with the essential requirements of the Directives. If these requirements are met, the Commission publishes a reference to the standard in the Official Journal of the European Community, giving the standard the status of a harmonized standard. It is presumed that manufacturers who observe the harmonized standards will ensure that their products are in compliance as well. Since harmonized standards are still voluntary, whenever

manufacturers do not apply them, they must document the alternative solutions adopted to meet the essential requirements of the European Directives.

Participants will learn about the essential requirements of the directives and the judicial importance of standards as a measure for proper technical actions. The course will describe the most important standards (product and horizontal standards) for the development and approval of medical devices, as well as the standardization bodies that prepare them. Knowing how to interpret standards and whom to ask questions about them is useful for all those working in the medical device and instrumentation field.

Patents and Intellectual Property Rights

From investigation of alien ideas to protection of your own thoughts



Alfred Schillert,

PROvendis GmbH, Mülheim/Ruhr



Kordula Kruber,

PROvendis GmbH, Mülheim/Ruhr



Cornelius Bobbert,

Bobbert & Partner Patentanwälte,
München



Richard Schlötter,

Reed Smith, München

Life sciences in general and medical devices in particular are areas where IP rights are highly appreciated and necessary. To protect your ideas, you need a basic knowledge of the procedures involved in the European market. For example, the rights and titles of third parties that may impact current or projected activities of an individual, company or organization should be identified as early as possible. The process involved in patent search and the differences and similarities in international IP procedures are described in this course.

The course also describes patent marketing agencies and their services for both universities and companies, and provides useful information – ranging from whom to contact to contract issues – on how these parties cooperate.

Once the relevant patents or patent applications are identified, different options exist for acquiring or licensing the necessary rights from the patent owner. The course discusses these options and all related issues. In cases where such a “friendly” approach may not appear promising – due to reluctance of the owner to license or unacceptable license fees – we discuss the possibilities of trying to prevent the issuance of “adverse” patents and what options are available to pursue after the patent grant. The course also provides information on litigation procedures and potential threats, ranging from injunctions to damages.

Health Technology Assessment and Clinical Studies – from development to reimbursement: Basic knowledge for innovators



Marc O. Schurr,

Novineon Healthcare Technology
Partners, Tübingen



Hubertus Rosery,

AiM GmbH-Assessment in Medicine-
Research and Consulting, Schopfheim

According to the European Medical Device Directive 93/42/EEC, suitability for intended use must be established for all medical products. This requires the submission of a clinical evaluation based on data from scientific literature, research and testing or clinical studies. Regulatory changes increasingly prefer clinical studies.

The clinical evaluation is part of the technical file, and is submitted to the notified body as part of the official approval process, regardless of the product's risk category. In order to set up a clinical study, experts from the device manufacturer and clinicians have to work hand-in-hand. The first part of the course focuses on basic knowledge about clinical evaluations and clinical studies.

The requirements faced by applicants seeking reimbursement for medical services are becoming increasingly extensive and complex. National databases recording resource consumption as well

as published tariffs are indispensable tools when preparing the mandatory documents for such reimbursement claims, e.g. health cost dossiers, models and pricing reports. The second part of the course focuses on existing public databases relevant to regulatory matters, as well as on the subsequent approval process up to and beyond the CE stage. Participants will learn about basic requirements, set-up, execution and interpretation of the results of clinical evaluations and clinical studies. The course will present precise and detailed information on available databases in order to facilitate the preparation of successful reimbursement documentation, e.g. health technology assessment (HTA) reports, cost dictionaries, HE models and value dossiers.

Reimbursement for Medical Devices

Basic knowledge for successful innovation



Jan Hacker,
EconoMedic AG, Bayreuth



Frank-Ulrich Fricke,
Health Economics & Outcomes Research,
IMS Health GmbH & Co. OHG, Nürnberg



Olaf Pirk,
Health Economics & Outcomes Research,
IMS Health GmbH & Co. OHG, Nürnberg

The success of an innovation not only means that it is worthy and needed, but that a company earns money with it. In Germany there are many different forms of reimbursement for new medical devices, and reimbursement is affected by such factors as the kind of device, the degree of innovation and where the device is used.

The organization of Germany's healthcare system also plays a role in a medical device's success. Since around 90% of the country's population is covered by the statutory health insurance (SHI) system and only 10% is privately insured, the SHI market is by far the more attractive of the two. Moreover, this market is rigorously regulated with collective contracts that apply equally to all SHIs.

The world of the healthcare provider is divided into inpatient and outpatient sectors with different rules governing the payment for medical services – including reimbursement for medical devices.

This course presents an overview of the German healthcare system and the key institutions and mechanisms involved in the reimbursement process. It also offers considerable practical information on how to optimally meet the requirements of the system in all stages of your development or scientific work.

IT-Networks Incorporating Medical Devices

Trends, standards and procedures



Jörg A. K. Ohnsorge,
Orthopädische Klinik der RWTH Aachen



Björn Bergh,
Zentrum für Informations- und Medizintechnik, Universitätsklinikum Heidelberg



Thomas Norgall,
Fraunhofer Institut für Integrierte Schaltungen – (IIS), Erlangen

Medical devices are often operated today as stand-alone devices. By integrating these devices into systems and networking them into a hospital's IT network with a "plug and play" solution, numerous new applications are possible. On the basis of the upcoming norm "IEC 80001: Risk management of networked medical systems," the course describes the current situation in everyday medical practice. Plug and play concepts are needed in order to improve processes and better utilize the full potential of the devices. "Service Oriented Architectures (SOAs)" are currently being developed as the first approach toward providing a solution.

The course participants initially learn about the current situation and possibilities for networking medical devices and IT networks. The second part of the course describes the vision of a plug and play solution with its requisite interfaces and agreements. The course concludes with a discussion of how this vision can be realized and who should work on it.

Registration Fees

Monday courses will be three time blocks of 105 minutes each from 10:30 am-5:30 pm.

Registration fee* for participants of Monday courses

150€ (members)

175€ (non-members)

Member is defined a person who is a member of DGBMT or Forum MedTech Pharma.

*Registration fee includes courseware, lunch and drinks. Registration for World Congress 2009 is not included.

Payment for registration must be made in EUR. The course fee has to be fully paid in advance.

The following methods of payment are accepted:

- By credit card authorization

In case of registration on-site the following methods of payment are accepted:

- Cash payment on-site in EUR (€)
- By credit card authorization

To register for one of the courses please go to www.wc2009.org and click on Monday Courses.

Contact: vde-conferences@vde.com.

Information:

Monday, September 7

10.30 am - 5.30 pm

Check-in starts at 9.30 am

**ICM – Internationales Congress Center München
Messe München GmbH
Messegelände
81823 München**

www.wc2009.org



The Hosts

DGBMT – www.dgbmt.de

German scientists in the field of biomedical engineering are organized in the DGBMT, which was founded in 1972. The Society merged with the VDE in 2001 and now has about 1,900 members including physicians, engineers, scientists and companies.

VDE – www.vde.com

The VDE Association for Electrical, Electronic & Information Technologies currently has over 34,000 members, including a broad spectrum of engineers, scientists and technicians, some 7,000 students and roughly 1,250 corporate and institutional members.

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Forum MedTech Pharma – www.medtech-pharma.de

is a non-profit registered society forming a unique platform for business contacts and knowledge exchange.

We successfully facilitate innovation and co-operation in the medical sector.

The 630 members of the Forum MedTech Pharma include companies, research institutes, clinics, health insurances, regional authorities as well as other actors in the field - from 14 countries out of Europe, America and Asia.

Our thematic working groups cover an extensive agenda on the latest trends in medical technology and pharma.

www.wc2009.org