IHK Lübeck

Lübeck 2012 Summer Academy
"Medical Technology in the Hanse Belt"

# "Regulatory Affairs in Medical Technology"

05.09.2012 – 08:30 – 12:15
Lübeck BioMedTec Science Campus – AudiMax

**Arbeitsgemeinschaft Medizintechnik in Schleswig-Holstein AGMT**
Since 25 years the Study Group Medical Technology in Schleswig-Holstein AGMT is an interdisciplinary forum for manufacturers of medical devices and scientific institutions working in the field of medical technology. Medical devices regulation is a main topic of AGMT.

## Programme and abstracts

**08:30** **Registration, refreshments**

**09:00** **Greeting**
Dr. Raimund Mildner
CEO, Technikzentrum Lübeck, Member of the Board of Arbeitsgemeinschaft Medizintechnik in Schleswig-Holstein – AGMT

**09:10** **Introduction to programme**
Prof. Dr. Horst Frankenberger
Chair of "Forum für Medizintechnik e.V." and Honorary Chair of Arbeitsgemeinschaft Medizintechnik in Schleswig-Holstein – AGMT

**09:15** **Experience with Directive 93/42/EEC (MDD)**
Dr. Peter Gebhardt
Director Regulatory Affairs – Quality & Regulatory Affairs, Dräger Medical GmbH – Moislinger Allee 53-55 – 23558 Lübeck, Germany

**Abstract**
A medical device manufacturer's report of experiences is provided, based on dealing with Directive 93/42/EEC (MDD) over a period of nearly 20 years. It includes experiences from implementation, certification and surveillance by Notified Bodies, pre-market and post-market activities, reforms introduced by Directive 2007/47/EC, and

addresses some problems experienced, deficiencies and benefits found, and gives an outlook to future improvements.

**09:45** **Key note: EU Medical Devices Directive (MDD 93/42/EEC) and the coming EU Medical Devices Regulation – similiarities and expected differences**

Dr. Matthias Neumann
German Federal Ministry of Health, Division 122 „Medical Devices Safety“, Friedrichstraße 108 – 10117 Berlin, Germany

## Abstract

The revision of the European legislation on medical devices is on the way. The expected Regulation on medical devices will combine and supersede the existing Directives 93/42/EEC on medical devices and 90/385/EEC on active implantable medical devices. Similarities and expected differences will be presented in the key note speech.

## 10:30 Refreshments, networking

## 11:00 Panel discussion: European Legislation on Medical Devices – chaired by Horst Frankenberger

### Discussion on

“Experience with Directive 93/42/EEC (MDD)”and
“Key note: EU Medical Devices Directive (MDD 93/42/EEC) and the coming EU Medical Devices Regulation – similarities and expected differences”

### Statement 1: Regulatory Knock Out of Borderline Medical Devices

Dr. Guido Middeler
Head of Medical Devices Services, **Diapharm** GmbH & Co. KG
Maria-Goeppert-Straße 5 – 23562 Lübeck, Germany

**Abstract**

Possible restrictions in the scope of medical devices can cause the exclusion of products placed on the market as medical devices
- with the potential loss of therapeutic options for patients
- without any added value in terms of patient safety
- with substantial influence on jobs in small and medium sized companies

## Statement 2: Clinical evaluation and post market clinical follow up of medical devices

Dr. Heike Wachenhausen
Rechtsanwältin – Lützeler Klümper Wachenhausen Partnerschaft von Rechtsanwälten, Büro Lübeck, An der Untertrave 16 – 23552 Lübeck, Germany

## Abstract

The regulatory framework for the evaluation and post market surveillance of medical devices is still fragmented. Developers and manufacturers of medical devices are often faced with practical and legal hurdles regarding the planning and conduct of clinical studies with medical devices. The diversity of medical devices requires adapted and customized types of studies. Developers, manufactures but also clinical investigators need adequate legal guidance and technical standards in order to achieve patient safety, a constant improvement of medical devices and overall an ethical environment.

## Statement 3: Challenge to Risk Assessment of medical devices

Dr. Poul Schmidt-Andersen
Managing Partner, B.Sc.E.E, B.Comm
DMD – Danish Medical Devices Consulting aps
DK 3520 Farum, Denmark

## Abstract

Performing risk analysis of a medical device during its entire lifetime is an important and challenging task for the manufacturers.

However, getting useful field data from reported vigilance events to aid this process is not possible for the manufacturer within the EU. The European Database on Medical Devices EUDAMED has been set up to service only the EU Competent Authorities. Unfortunately, this means that the EU manufacturer is referred to get this kind of information only from US databases such as the FDA Safety Information and Adverse Event Reporting Program MEDWATCH or other national databases outside EU.

## Discussion on the statements 1, 2 and 3

## 12:15 End of Meeting