Introduction to the programme

Prof. Dr. Horst Frankenberger, Chairman of “Forum für Medizintechnik FFM e.v.” and Honorary Chairman of “Arbeitsgemeinschaft Medizintechnik in Schleswig-Holstein AGMT e.V.”

“Regulatory Affairs in Medical Technology – New Developments in Europe” is the subject of the morning session. In this morning session we will have two lectures and their discussion. Three statements and the discussion of the statements will follow after the break.


The first lecture, presented by Dr. Peter Gebhardt, Dräger Medical Deutschland GmbH, gives an overview about experiences of a medical device manufacturer with the Directive 93/42/EEC.

The second lecture, presented by Dr. Matthias Neumann, Federal Ministry of Health, Division 122 “Medical Devices Safety”, informs about the expected new EU-Regulation on medical devices, a Regulation combining and superseding 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 keynote speech.

The following three statements will be presented:

- Statement 1: “Regulatory Knock Out of Borderline Medical Devices” presented by Dr. Guido Middeler, Head of Medical Devices Services, Diapharm GmbH & Co. KG
- Statement 2: “Clinical evaluation and post market clinical follow up of medical devices” presented by Dr. Heike Wachenhausen, Rechtsanwältin – Lützeler Klümper Wachenhausen Partnerschaft von Rechtsanwälten, Büro Lübeck
- Statement 3: “Challenge to Risk Assessment of medical devices” presented by Dr. Poul Schmidt-Andersen, Managing Partner, B.Sc.E.E, B.Comm, DMD – Danish Medical Devices Consulting aps

Many thanks to the speakers in this morning session, to the audience of this session and to Dr. Hermsmeyer, IHK zu Lübeck, for the organisation of the “Lübeck 2012 Summer Academy” “Medical Technology in the Hanse Belt” including the session “Regulatory Affairs in Medical Technology – New Developments in Europe”.