



## Jens Grothues

*General Manager Germany & Senior Consultant*

Jens Grothues joined the Emergo team in August 2010 as a General Manager and Senior Consultant for Germany. Jens provides strategic direction and oversight for Emergo's activities in Germany, Austria and Switzerland. In his role as Senior Consultant and Lead Auditor, Jens consults for medical devices and in-vitro diagnostic companies on the development and implementation of ISO 13485:2003 and FDA QSR (GMP) compliant quality management systems, and conducts compliance audits against these requirements. He has 17 years of experience in the medical device industry, and has expansive knowledge of European, Canadian, and US FDA regulations for medical devices and in-vitro diagnostics.

### **EXPERIENCE:**

#### **Quality Director, Lohmann & Rauscher GmbH & Co KG – 2006 to 2010**

Lohmann & Rauscher is a leading manufacturer and supplier of dressings and bandaging material in modern and classic wound care. Jens was responsible for the Quality Management System, Quality Assurance, Regulatory Affairs, and Quality Management Representative of the group. Jens was a member of the Management Team, and was involved in strategic planning. He also performed supplier audits worldwide with a focus on Chinese suppliers. As Quality Director, he oversaw 60 people in Germany, Austria and Czech Republic.

Projects Included:

- Regulatory compliance for a new aseptic filling plant
- Implementation of FDA cGMP
- Implementation of SAP in the facilities in Germany, Austria, Czech Republic and France in the role as Global Process Owner for the SAP QA module

#### **Director Certification medical devices, TÜV NORD CERT GmbH (Notified Body) – 2003 to 2006**

Lead Auditor for active and non-active medical devices (QM-systems, product testing and Technical File assessor worldwide). He performed approximately 100 certification audits at medical device manufacturers. He has experience in development and implementation of registration procedures acc. 93/42/EEC, CDMCAS, Taiwan. He trained medical device auditors within TÜV NORD in sterilization methods, risk management, vigilance requirements, and certification requirements in different countries. He was also a member and participant of the NB Med in Brussels.

#### **Authorized Officer, Assut medizinische Produkte GmbH – 2002**

As Authorized Officer, he built up the sales for surgical sutures and micro scalps. He handled all of the business transactions, marketing, purchasing, sales, logistics, finance and customer care. He was also involved in the product development of absorbable surgical sutures.



## **Jens Grothues, continued...**

### **Vice-Director Certification, MedCert GmbH (Notified Body) – 1997 to 2002**

Jens was lead auditor for active and non-active medical devices (QM-systems and product testing worldwide). He performed approximately 180 certification audits worldwide at medical device manufacturers with the focus in Germany and North America. He developed and implemented the registration procedures acc. 93/42/EEC.

### **Regulatory Affairs Coordinator, Angiomed GmbH (C.R. Bard) – 1996 to 1997**

He prepared the registration documentation for US, Europe and Asia for a wide range of products at Angiomed in the field of catheters and endovascular implants (stents). He implemented relevant regulatory requirements for the different markets in the Angiomed quality system. He assisted with improving the quality system management and ensuring it met the requirements of the FDA GMP.

### **Technical Assistant, OMRON Healthcare GmbH – 1993 to 1996**

Jens was the assistant in the technical marketing. He was responsible for the build-up an after sales service, international product introduction, clinical trials, product marketing, quality assurance, and implementation of the requirements of the 93/42/EEC (Production in Japan). Omron Healthcare produced active medical devices in the consumer business, like blood pressure monitors und inhalation equipment.

### **Telecommunication Worker, German Telecom – 1987 to 1990**

Serviced and repaired computing systems and accessories. Jens was the instructor for computing training.

### **EDUCATION:**

- Degree: Skilled Worker, Education for telecommunication worker, 1983-1986
- Degree: Advanced Technical College Entrance Qualification, Technical college Gottingen, 1990-1991
- Degree: Dipl.-Ing. Biomedical Engineer, University of Applied Science, Hamburg, 1991-1996