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Press Release

Training for the SFDA

27 January 2012

Knowledge transfer in Healthcare technology: TÜV SÜD Academy provides training to Saudi Arabian authority

Munich. Nine employees of the "Saudi Food and Drug Authority" (SFDA) have just completed in-depth training on the standards, laws and approval processes for medical devices at TÜV SÜD Academy. The program illustrated the theory behind the testing and assessment of medical devices by including visits to various laboratories.

The SFDA is an independent Authority reporting to the Council of Ministers of Saudi Arabia and is responsible for the safety of food, medicinal products and medical devices. The experts of this authority have to assess and evaluate the manufacturers of medical devices for compliance with quality standards, product safety and intended use. Furthermore, the SFDA experts have to implement standards and must be familiar with the approval requirements in various international markets – a challenging task which demands in-depth expert knowledge.

In order to support SFDA in augmenting the skills and performance of its employees, TÜV SÜD Academy developed and offered a customized training program. The program was tailored to the needs of the SFDA, taking into account the specific questions and issues of the delegates from Saudi Arabia. Primarily it addressed the fundamentals of the European Medical Devices Directive (MDD), the requirements that the technical file of a medical device must fulfil and the processing, review and evaluation of clinical data. The delegates were also familiarized with the provisions of various standards, concerning aspects such as risk management and the special requirements applying to implants. A further important subject treated in the training for SFDA addressed the provisions of the IEC 60601-1, 3rd regarding the safety of electrical medical equipment.

To witness the testing of the approval requirements in practice, the training program included on-site visits to the accredited testing laboratories of TÜV SÜD Product Service where participants gained an impression of the testing and assessment of medical devices. The delegates also visited the testing laboratories of TÜV SÜD SENTON in Straubing, which offer comprehensive services in the fields of EMC and radio testing, environmental simulations and equipment safety testing.

The third laboratory site-visit into the real-life of testing brought the training delegates to Brainlab AG. This innovative manufacturer of medical devices specializes in image-guided surgery and provided the delegates with an insight into internal hard- and software issues.

Birgit Klusmeier, Head of the Medical and Health Centre of Competence, was very pleased with the visit of the delegation from Saudi Arabia and is convinced that international knowledge transfer will become even more important in the future: "The healthcare technology sector is growing in significance throughout the world. International cooperation will play an increasingly important role in this context to ensure long-term patient safety and standard compliance." Zeyad AlKahtani, Head of the Scientific & Technical Evaluation Section of the SFDA confirms this, saying "Intensively learning from each other and enabling regular exchanges of experience and information are of the essence." The feedback from the delegates was very positive. The attendees especially appreciated the technical expertise of the trainers, the approach applied to tuition and the excellent practical focus of the entire course.

As a Conformity Assessment Body (CAB), TÜV SÜD Product Service has now operated an office in Riyadh for over one year, supporting the SFDA in the assessment of medical devices.

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