Quality Assurance and Regulatory Affairs

Günter Weisshaar, Executive Vice President Global Quality and Regulatory Compliance, has news of ISO certification for all Tecan's manufacturing sites.

Standardization and regulatory compliance are of critical importance for Tecan and its customers so, over the last few years, we have concentrated on implementing the newest ISO standards - ISO 9001 and ISO 13485 - into all of our manufacturing sites; in Switzerland, Austria, Tecan SCC in Mainz, Germany, and in Tecan Systems in California. Although all these sites were already certified with local companies, our aim was to reach a universal global standardization with just one notified body. We have now achieved this aim in direct association with TÜV SÜD Product Service, chosen as one of the most common, global notified bodies with a particular expertise in the medical device business and a very strong reputation for high standards.

Many of our customers also use TÜV as their regulatory partner and it makes perfect sense that we work to the same standards and can talk on the same level, especially since TÜV has been given authorization from the United States FDA since 2002 to perform and execute follow-up inspections on its behalf.

Our customers can expect that, with the ISO 9001 quality system regulation, Tecan has met all the elements required and has been audited and proved by a neutral company or party. ISO 13485 deals specifically with additional requirements for medical devices. At the same time, our sites in Switzerland and Austria are also certified according to CMDCAS - Canadian Medical Device Conformity Assessment System – an additional national regulation to ISO 13485 required in Canada and also dealt with by TÜV.

We are delighted with these new implementations and trust that they will give you, our customers, the reassurance of working together with a knowledge-able supplier that is fully compliant with the highest international regulations.

- Tecan Switzerland Ltd.
  Seestrasse 103
  CH-8708 Männedorf

- Tecan Austria GmbH
  Untersbergstrasse 1a
  A-5082 Grödig/Salzburg

- Tecan Software Competence Center GmbH
  Schmalweg 5
  D-55252 Mainz-Kastel

- Tecan Systems, Inc.
  2450 Zanker Road
  USA-San Jose, CA 95131