Sharpening up our market intelligence for mutual benefit

Tecan's Regulatory Affairs (RA) team has invested in a new market intelligence infrastructure that will keep our product development teams, business units and worldwide sales organizations, as well as our customers, fully up-to-date with regulatory information as it changes.

The current regulatory situation in the World today

Medical products companies are striving to increase their baseline sales by meeting the demands of today's fast-growing, competitive global medical device market. Success can be limited by many factors, including new or changed international import and export regulations and/or registration requirements.

We won't be caught out by changes!

Tecan's RA professionals are vigilant and proactive. It is our responsibility to ensure that effective market intelligence is collected for all countries where Tecan is operating, now and potentially in the future. The market intelligence we receive through our new system is continually updated and, as we receive new information, we will perform gap analysis to identify what is necessary to adapt to changing requirements. We react immediately to any new requirements that might hinder Tecan's ability to operate in some countries.

What is our target?

It is our intention to always be one step ahead of our competitors, and to ensure sustainable compliance with all global market registrations and regulations as they relate to the standards with which we must comply. One of RA's goals is to meet the demands of Tecan and our customers.

How do we realize that?

RA's senior management has been very supportive towards our goals and objectives, allowing us to increase our market surveillance activities and to establish a powerful state-of-the-art software database. The database provides regulatory intelligence dossiers organized on a country-by-country basis – currently including 63 countries – which include country-specific reports, forms, and other useful background information. Tecan RA professionals already have unlimited and immediate access to this information. This will keep our product development teams, business units and worldwide sales organizations, as well as our customers, fully up-to-date with regulatory information as it changes.

Are there more things to be considered?

Yes, Tecan RA professionals will also improve the service for you on currently marketed or registered devices.

In addition to the market surveillance tool, a dedicated worldwide device approval monitoring system is currently being introduced. This enables the consolidation of all existing registration information such as:

- product classification
- submission documents
- test certificates
- ISO certificates
- registration certificates and much more country-specific information

What are the benefits?

You will notice real improvements in the response to your regulatory enquiries; we will respond in a faster and more uniform way. In addition, Tecan and customer RA professionals around the world will be able to work more closely together by using the same information source.

We believe that having good quality information is essential for your decision-making process, whether you're releasing a Tecan product into a market for the first time or choosing to purchase a Tecan product. Our new system will help us to achieve our aim of providing you with the best regulatory market intelligence available.