Hot Topics

Patients better protected against faulty or poor quality medical devices thanks to new ISO standard

Thousands of new medical devices enter the market every year. Are they safe? A new ISO International Standard will help to assess better the safety and performance of medical devices and so improve the protection of patients, provide a technical basis for regulation and minimize technical barriers to trade.

ISO 14155:2011, Clinical investigation of medical devices for human subjects – Good clinical practice, will help to improve the quality of medical devices and encourage manufacturers to guarantee that their products do not compromise patient safety.

In 2007, the World Health Organization (WHO) reported that in the United States, more than one million accidents attributable to medical devices occur annually and that, in some developing countries, as much as half of medical equipment is unusable or only partly usable. ISO 14155:2011 addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out on human subjects to assess the safety or performance of medical devices for regulatory and other purposes.

This International Standard specifies general requirements intended to:

- Protect the rights, safety and well-being of human subjects
- Ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results
- Define the responsibilities of the sponsor and principal investigator
- Assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

There are an estimated 1.5 million different medical devices available worldwide and thousands of new and innovative medical devices are introduced in the market every year. At the national level, different tests including clinical investigations on human subjects, are required before a medical device is granted marketing authorization. This process can be very costly if not carried out with the right methodology and constitute a barrier to international trade if not performed at a global acceptable level. ISO 14155 will help to overcome these barriers and to respond to the growing demand for standardized methods of assessment of medical devices available on the market.

Danielle Giroud, Convenor of the Working Group that developed the standard, comment, "The requirements laid out in ISO 14155 are a major step towards global acceptance of clinical data, following these requirements will ensure increased cost effectiveness to reach the global market and help keeping medical devices safe on the market. Applying the standard to any clinical investigation is just good business."

ISO 14155:2011 was developed by ISO technical committee ISO/TC 194, Biological evaluation of medical devices, Working Group 4, Clinical investigations in humans, and is available from ISO national member institutes (see the complete list with contact details). It may also be obtained directly from the ISO Central Secretariat, price 168 Swiss francs through the ISO Store or by contacting the Marketing, Communication & Information department.

Source: www.iso.org