

Quality management systems for the medical device industry

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Ed Kimmelman, convener of the ISO working group that developed the new standard: 'ISO 13485:2003 is intended to serve as a model.'

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ISO has just published a standard to facilitate implementation of quality management systems based on ISO 9001:2000 by the medical device industry.

"The key objectives of ISO 13485:2003 are to maximize the probability that a medical device organization will meet regulatory quality management system requirements worldwide, will provide safe and effective medical devices and will meet customer requirements," said Ed Kimmelman, convener of the ISO working group that developed the new standard.

ISO 13485:2003, *Medical devices – Quality management systems – Requirements for regulatory purposes*, is based on quality management system requirements currently contained in medical device regulations around the world, as well as those appropriate requirements contained in ISO 9001:2000.

In order to clarify the differences between the standard and ISO 9001:2000 and to explain them, Annex B of ISO 13485:2003 contains a "side-by-side", section-by-section comparison of the two documents.

According to Ed Kimmelman, ISO 13485:2003 is intended to be the vehicle for harmonizing quality management system regulations in the medical device sector around the world.

Improvements

"Most of the industrialized countries around the world already have some form of quality management system regulation. For these countries, ISO 13485:2003 should reflect their current requirements and provide them with suggestions for improvements of these regulations. For those countries that are beginning to consider regulating medical device quality management systems, ISO 13485 is intended to serve as a model for such regulation."

The new standard is intended for use by organizations involved in the design, production, installation and servicing of medical devices as well as in the design, development and provision of related services. It can also be used by internal and external parties, including certification bodies, in order to assess an organization's ability to meet requirements.

The new standard, which replaces ISO 13485:1996, *Quality systems – Medical devices – Particular requirements for the application of ISO 9001*, is the work of ISO technical committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, working group WG 1, *Application of quality systems to medical devices*, in conjunction with members of the Global Harmonization Task Force (Study Group 3). ISO 13485:2003 costs 148 Swiss francs and is available from ISO national member institutes (see complete list with contact details on ISO's Web site – www.iso.org) and from ISO Central Secretariat (sales@iso.org).

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