

Revised Quality Management System requirements for medical device organizations: revision of ISO 13485 published

The third edition of ISO 13485 was made available at the end of February 2016 with a publication date of 1st March 2016. This standard defines requirements for a quality management system (QMS) for regulatory purposes for organizations involved in the supply chain and lifecycle of medical devices, replacing the second edition from 2003.

ISO 13485:2016 was adopted as a European standard (EN ISO 13485:2016) with identical requirements, a European Foreword and Annexes that map the conformity assessment requirements from the Directives for medical devices, to the requirements of the standard. The Annexes show when the regulatory requirement is covered, partly covered or not covered and provides information on the extent of the gap in coverage, where such a gap exists. EN ISO 13485:2016 replaces EN ISO 13485:2012, which was identical to ISO 13485:2003 with revised European Foreword and Annexes. The third edition of the standard has been put forward to be harmonized against the Directives for medical devices.

The structure of ISO 13485:2016 is aligned with ISO 9001:2008 and follows the sequence of ISO 9001:2008 with some adjustment to the subclause numbering. This reduces the number of four and five number designations, making it easier to relate audit observations to the appropriate requirement. The structure does not follow ISO 9001:2015 because the two standards were developed in parallel and ISO 13485 is used for regulatory purposes; there was not alignment with regulatory authorities to introduce a major restructure to ISO 13485. Annex B provides cross-reference with the structure of ISO 9001:2015 for organizations that wish to comply with both standards.

The scope emphasizes that the standard can be used by organizations involved in one or more stages in the lifecycle or the supply chain for medical devices. As well as organizations that place medical devices on the market under their own name (aka the 'legal manufacturer'), the standard can be used by organizations that undertake part of the medical device lifecycle, such as design and development or repair and maintenance, or are part of the supply chain such as entities like importers, distributors or authorized representatives or suppliers of raw materials, components, or subassemblies, or services providers such as for contract manufacturer or sterilization, logistics or calibration.

Additionally, changes in the scope clarify that the requirements of standard are applicable irrespective of the size of the organization but certain requirements apply based on the type of medical device covered by the QMS and others do not apply based on the role undertaken by the organization.

Other changes were introduced in this third edition of ISO 13485 to update the requirements in line with current regulatory expectations and foreseen future regulatory requirements. Experience in use of the 2003 edition of the standard was also taken into account. The changes include:

- incorporation of risk-based approaches to safety and performance of the medical device and in meeting regulatory requirements beyond product realization;
- increased linkage with regulatory requirements, and in particular regulatory documentation;
- harmonizing software validation for applications for QMS, process control, and monitoring and measurement;
- emphasis on infrastructure for orderly handling, production of sterile medical devices and validation of sterile barrier properties;
- consideration in design and development of usability, use of standards, verification and validation planning, design transfer and design records;
- emphasis on complaints, reporting to regulatory authorities and consideration of post-market surveillance;
- planning, documenting and implementing corrective action and preventive action without undue delay.

A three year transition period has been agreed for organizations to update their certification to the new edition of the standard. Organizations should discuss their plans for transitioning certification with their Conformity Assessment Body to make sure that they are aligned in their approach to this important transition.