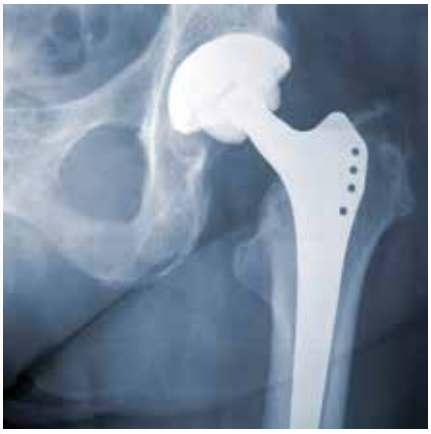
QUALITY

RISK MANAGEMENT



COMPETITIVE ADVANTAGE

EXPERTISE

FURTHER EXCELLENCE

MARKET INTELLIGENCE

REGULATORY COMPLIANCE

SPEED TO MARKET

PATIENT SAFETY

HOW CAN YOU ADOPT A RISK-BASED APPROACH TO YOUR MEDICAL DEVICE QMS?

THE NEW ISO 13485:2016 MEDICAL DEVICE – QUALITY MANAGEMENT SYSTEM

SGS

First issued as a draft international standard (DIS) in February 2015, ISO 13485:2016 has now been finalised, and the new version was released on 1 March 2016.

The new version of ISO 13485, published on 1 March 2016, has evolved. To streamline and improve the quality management of medical device design and manufacture, the standard now encompasses all stakeholder roles within the medical device life cycle. Furthermore, it also requires organisations to adopt a risk-based approach to their quality management systems.

In a market subject to increasing levels of regulation, ISO 13485:2016 also places increased emphasis on meeting regulatory requirements.

STRUCTURE & TERMINOLOGY

ISO 13485:2016 has been structured with three key aims:

- To meet the requirements of manufacturer's and service provider's quality systems
- To ensure that all key stakeholders in the industry are able to demonstrate compliance
- To cover the life cycle of a medical device

The structure of ISO 13485:2016 is very similar to its previous versions. Changes are apparent with the addition of new sub-clauses within key sections.

NOTE: It is important to note that ISO 13485:2016 does not follow the 'Annex SL' structure adopted by ISOs 9001 and 14001. Instead, it retains the same clause structure as its 2003 and 2012 version.

The terminology of ISO 13485:2016 is largely unchanged. New terms appear in the standard's 'Terms & Definitions' section, and reference:

- Additional stakeholders in the medical device industry to whom this standard applies:
  - Authorised Representative
  - Distributor
  - Importer
  - Manufacturer
- Key themes of the new version:
  - Risk
  - Risk Management
  - Performance Evaluation

KEY CHANGES

The emphasis in ISO 13485:2016 is very much on managing risk and compliance with regulatory requirements. It has also expanded its scope to include all stakeholder roles. Furthermore, it provides clarification for design and validation activities (including software validation), as well as for improving supplier control.

To align itself with the forthcoming medical device regulations, ISO 13485:2016 also includes improvements to the feedback processes and clauses surrounding identification and traceability.

Specifically, the changes impact the following ISO 13485 clauses:

- Quality Management Systems
- Management Responsibility
- Resource Management
- Product Realisation
- Measurement, Analysis & Improvement

QUALITY MANAGEMENT SYSTEMS

Changes for this version primarily focus on the General Requirements sub-clauses, including the definition of roles within an organisation, documentation requirements, and demonstrating compliance and control. Key omissions in this clause include the removal of reference to ISO/TR 14969, the removal of references to ISO 13485 following the ISO 9001 format, and the removal of the Notes section.

MANAGEMENT RESPONSIBILITY

Within this clause, the emphasis on meeting regulatory requirements now applies to Customer Focus and Quality Objectives, and there is a formal requirement for clients to document the management review process. References to Statutory Requirements and Safety and Performance of the Medical Device from the 2003 version, have been replaced with Regulatory Requirement and Assessment of Risk in the 2016 version. The nominated person required by national or regional regulations has been replaced, with the new role of Authorised Representative. Similarly, the Management Representative from 2003 has been removed, as this is now included within 2016's clause 8.2.3 Reporting to Regulatory Authorities.

RESOURCE MANAGEMENT

There is additional emphasis in the 2016 version on documenting the process for establishing competency, awareness and training. Infrastructure has additional requirements too, to ensure product mix-up is prevented and documentation relating to the procedures to manage these aspects. In addition, resource management relating to the work environment and contamination control have been updated to prevent contamination in the workplace and to manage contaminated or potentially contaminated products.

PRODUCT REALISATION

In the new version, there are now additions to clause 7.1, Planning of Product Realisation that require documentation of risk management processes. Also, any need for user training must be documented to ensure the safe and effective operation of a device. Customer Related Process and Communication have been updated to emphasise the need to demonstrate communication with regulatory authorities.

In addition, the Design & Development of a product must be planned and controlled, and the design planning must be documented. Records of Design & Development Inputs must be maintained, and the verification methods documented. The Design & Development Validation requirements have also been updated. The purchasing content too has been updated, to help identify risk and product changes.

Design Transfer is a new clause, requiring documentation on the design transfer process, from design centre to manufacturing facility, while the new Design & Development Files clause aims to demonstrate traceability. Other new clauses include:

- Cleanliness of Product
- Servicing Activities
- Identification
- Traceability

The last two points have been called out as separate clauses to clarify and re-emphasise their importance.

Sections on the Validation of Processes and Control of Monitoring and Measuring Equipment have also been updated, to emphasise their importance and update requirements.

Omissions from this clause revolve around the removal of 'NOTES' from the above-mentioned sections, because in the 2016 version their detail has been incorporated within the main body of the text.

MEASUREMENT, ANALYSIS & IMPROVEMENT

Focusing on outcomes and the requirement to document all aspects of feedback within the quality management system, ISO 13485:2016 introduces new sections for Complaint Handling and Reporting to Regulatory Authorities, as well as updates to Feedback, Monitoring and Measuring of Products and the Control of Non-Conforming Product. This defines roles and responsibilities, documentation requirements and the need to use key inputs to ensure device safety when changes are made.

TRANSITION PERIOD TIMING

There is a three-year transition period for ISO 13485:2016, by the end of which all certificates against the 2003 and 2012 versions must have been transitioned, or they will cease to be valid. This three year transition period started on 1 March 2016, the date on which the 2016 version was published.

As of 28 February 2018, certificates against ISO 13485:2003 will no longer be issued. All certification holders are expected to have made the transition to the new version by 31 March 2019.

THE BIGGER PICTURE

ISO 13485:2016 was just the first of several regulatory changes taking place, and the new version was written with these in mind:

- In Europe, release of the new Medical Device Regulation and In-Vitro Diagnostic Regulation is imminent; publication is expected to happen mid-2017.
- In Japan, the PMD Act is now in place.
- At the global level, the Medical Device Single Audit (MDSAP) began its operational phase on 1 January, 2017.

NEXT STEPS

Three years may seem a long time, but organisations currently certified against ISO 13485 should start planning their transition to the new 2016 version as soon as possible. There are a number of steps that should be planned and implemented, in order to achieve a successful and timely transition.

Gap Analysis: organisations need to complete a review of the new version, compare the requirements against their existing quality management systems and identify any gaps.

Transition Plan: taking control of the process is key. A transition plan should be defined, including timescales and milestones, as well as allocating roles and responsibilities.

Resource Identification: it is important to determine any additional resources that may be necessary to complete the transition, and any related costs.

SGS SOLUTIONS

SGS can offer a wide range of services to organisations currently certified against the 2003 and 2012 version of ISO 13485, as they transition to ISO 13485:2016.

Our experts can help clients to understand the requirements of the standard and the new focus on risk-based thinking, through attendance at one of our approved training courses.

SGS is also able to provide expert advice to support clients during the transition/ implementation phase, and finally, to conduct certification audits and assessments against the ISO 13485:2016 standard.

WHY SGS?

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 90,000 employees, SGS operates a network of over 2,000 offices and laboratories around the world.

We are constantly looking beyond customers' and society's expectations in order to deliver market leading services wherever they are needed. We have a history of undertaking and successfully executing large-scale, complex international projects. With a presence in every single region around the globe, our people speak the language and understand the culture of the local market, and operate globally in a consistent, reliable and effective manner.

For an optimal transition towards ISO 13485:2016 contact medicaldevices@sgs.com or visit www.sgs.com/iso13485-2016

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WHEN YOU NEED TO BE SURE

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