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ISO 13485 Certifications

What is 13485 Certifications?

ISO 13485 *Medical devices -- Quality management systems -- Requirements for regulatory purposes* is a voluntary standard, published by International Organization for Standardization (ISO) for the first time in 1996, and contains a comprehensive quality management system for the design and manufacture of medical devices. The latest version of this standard supersedes earlier documents such as EN 46001 (1993 and 1996) and EN 46002 (1996), the previously published ISO 13485 (1996 and 2003), and ISO 13488 (also 1996).

The current ISO 13485 edition was published on 1 March 2016.

Background

Though it is tailored to the industry's quality system expectations and regulatory requirements, an organization does not need to be actively manufacturing medical devices or their components to seek certification to this standard, in contrast to the automotive sector's ISO/TS 16949, where only firms with an active request for quotation, or on the bid list, of an International Automotive Task Force supply chain manufacturer can seek registration.

Reason for use

While it remains a stand-alone document, ISO 13485 is generally harmonized with ISO 9001. A principal difference, however, is that ISO 9001 requires the organization to demonstrate continual improvement, whereas ISO 13485 requires only that the certified organization demonstrate the quality system is effectively implemented and maintained. Additionally, the ISO 9001 requirements regarding customer satisfaction are absent from the medical device standard.

Other specific differences include:

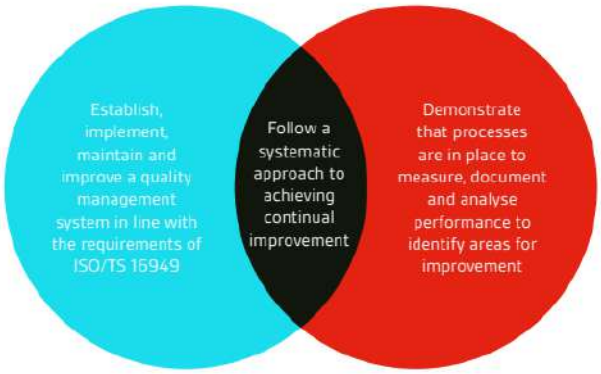
- . the promotion and awareness of regulatory requirements as a management responsibility. Examples of market-specific regulatory requirements include 21 CFR 820, the Quality System Regulation for medical devices sold in the United States, enforced by the U.S. Food and Drug Administration (FDA), or the Medical Devices Directive 93/42/EEC, required for doing business in the European Union
- controls in the work environment to ensure product safety
- focus on risk management activities and design control activities during product development
- specific requirements for inspection and traceability for implantable devices
- specific requirements for documentation and validation of processes for sterile medical devices
- specific requirements for verification of the effectiveness of corrective and preventive actions
- specific requirements for cleanliness of products
    - Compliance with ISO 13485 is often seen as the first step in achieving compliance with European regulatory requirements. The conformity of Medical Devices and In-vitro Diagnostic Medical Device according to European Union Directives 93/42/EEC, 90/385/EEC and 98/79/EEC must be assessed before sale is permitted. One of the major requirements to prove conformity is the implementation of the Quality Management System according ISO 9001 and/or ISO 13485 and ISO 14971. Although the European Union Directives do not mandate certification to ISO 9001 and/or ISO 13485 the preferred method to prove compliance to such standards is to seek its official certification which is issued by certifying organizations known as "Registrars". Several registrars also act as Notified Body. For those medical devices requiring the pre-market involvement of a Notified Body, the result of a positive assessment from the Notified Body is the certificate of conformity allowing the CE mark and the permission to sell the medical device in the European Union. A very careful assessment of the company Quality Management System by the Notified Body, together with the review of the required Technical Documentation, is a major element which the Notified Body takes into account to issue the certificate of conformity to the company product(s).
    - This standard adopted by CEN as EN ISO 13485:2003/AC:2007 is harmonized with respect to the European medical device directives 93/42/EEC, 90/385/EEC and 98/79/EC.
    - ISO 13485 is now considered to be inline standard and requirement for medical devices even with "Global Harmonization Task Force Guidelines" (GHTF). The GHTF guidelines are slowly becoming universal standards for design, manufacture, export and sales of various medical devices. The GHTF has been replaced in the last few years by the International Medical Device Regulators Forum (IMDRF) and is structured differently from the GHTF as only the regulators, that are primary members of the group, get to make many of the decisions. The IMDRF main membership (the regulators) do want to have non-regulators involved without voting rights and in this way, they are hoping to get the process and documents completed quicker than under the GHTF system (regulators & non-regulators were equal in voting rights) that worked reasonably well, but somewhat slow.
    - This standard adopted by CEN as EN ISO 13485:2012 is harmonized with respect to the European Medical Devices Directive 93/42/EEC.
    - Mexico published on October 11, 2012, a national standard as a Norma Official Mexicana (NOM) to control manufacture of medical devices inside the country. NOM-241-SSA1-2012, Buenas Practicas de Fabricación para Establecimientos dedicados a la Fabricación de Dispositivos Médicos. The scope of application is mandatory in the national territory, for all establishments dedicated to the process of medical devices marketed in the country. The Cofepris is the body assigned to its control, verification and to grant the records of compliance to the companies that implement this Standard of Good Manufacturing Practices. This standard is partially in line with ISO 13485: 2003 and ISO 9001: 2008.

- In 2017, The Farmacopea de los Estados Unidos Mexicanos (United Mexican States Pharmacopoeia), medical industrial sectors and Cofepris are working together for updating NOM-241 Standard, putting special attention on managing risks during manufacture and regulating by manufacturing lines some of the most important medical devices manufacturing processes. This standard will be published in August 2018, and 180 days after publication it will become mandatory for the industry.
- In Spain, medical devices are named in ISO-13485 as "Sanitary Products" as Castellano-language translation of ISO-13485, but in Mexico they are known as "Medical Devices" and correspond to those used in medical practice and that meet the definition established by NOM-241 as: Medical device, to the substance, mixture of substances, material, apparatus or instrument (including the computer program necessary for its proper use or application), used alone or in combination in the diagnosis, monitoring or prevention of human or auxiliary diseases in the treatment of the same and of the disability, as well as the employees in the replacement, correction, restoration or modification of the anatomy or human physiological processes. Medical devices include products of the following categories: medical equipment, prostheses, orthotics, functional aids, diagnostic agents, supplies for dental use, surgical, healing and hygiene products. ISO 13485:2016 Certificates meets the requirement of IEC 60601-2-25: 1993 + A1: 1999 safety of Electrocardiograms.

Chronology

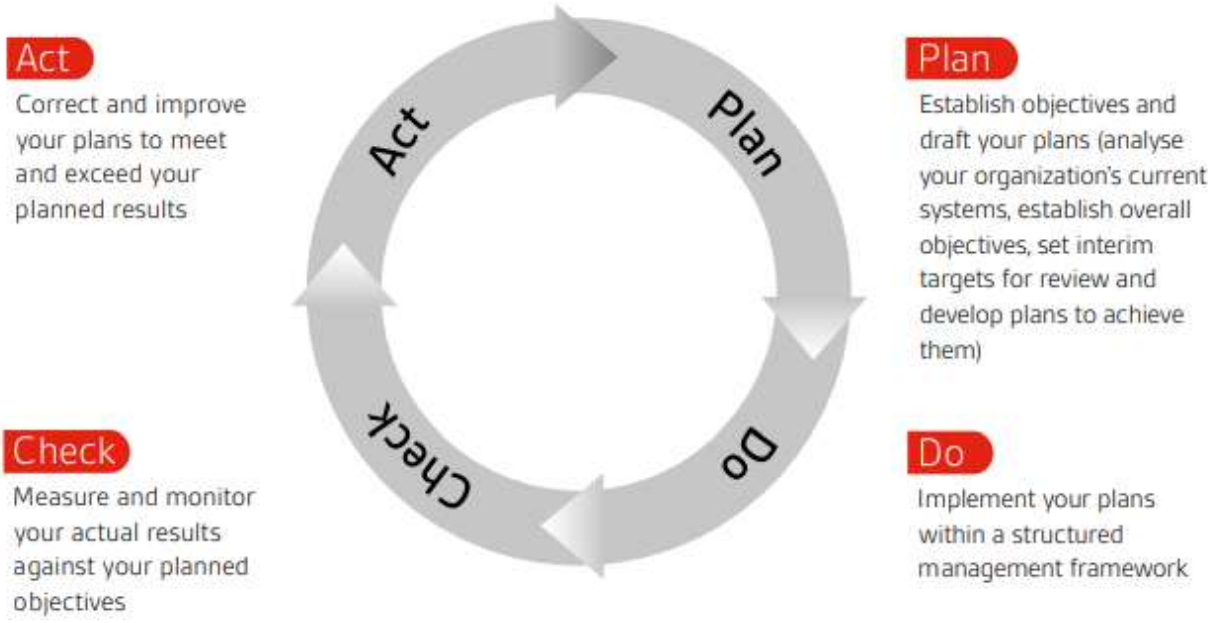
Year	Description
1993	EN 46001 *Quality systems – Medical devices – Particular requirements for the application of EN ISO 9001* is published by the European Committee for Standardization (CEN), forming the basis for developing ISO 13485.
1996	ISO 13485 (1st Edition).
2000	EN ISO 13485 is published by CEN, creating a European Norm version of the international standard, and the previous European standard (EN 46001) is withdrawn.
2003	ISO 13485 (2nd Edition).
2012	EN ISO 13485 is revised so that it harmonizes with the three European directives associated with the medical sector: 93/42/EEC (medical devices), 98/79/EC (*in vitro* diagnostic medical devices), and 90/385/EEC (active implantable medical devices).
2016	ISO 13485 (3rd Edition).

The principal requirements of the standard are illustrated below:



The next few pages of the guide takes you through the Plan-Do-Check-Act (PDCA) methodology, common in all ISO management systems and how DCS can help and support you on your ISO/TS 16949 journey.

Understanding the principles of continual improvement



10 Tips on making ISO/TS 16949 work for you

1. Top management commitment is vital for the system to be introduced successfully. Make sure senior managers are actively responsible, involved, approve resources and agree to the key processes.
2. Make sure your whole business and supply chain are committed to business improvement and engage them with a sound communications strategy.
3. Establish a competent and knowledgeable implementation team to deliver best results, sharing roles and responsibilities.
4. Review systems, policies, procedures and processes you have in place at the moment. Then compare them with what ISO/TS 16949 asks for. Get supply chain and stakeholder feedback on your current quality processes.
5. Adapt the basic principles of ISO/TS 16949 standard to your specific business objectives and environment.
6. Clearly lay out a well-communicated plan of activities and timescales. Make sure everyone understands them and their role in achieving them.
7. Consider using DCS's Entropy™ Software to manage your system which is configured to help you achieve sustained compliance with key ISO/TS 16949 requirements.
8. Train your staff to carry out internal audits, which can provide valuable feedback on potential audits and opportunities for improvement.
9. Encourage your supply chain to become certified to ISO/TS 16949 to benefit from a robust end to end system.
10. Regularly review your ISO/TS 16949 management system to make sure it remains appropriate, effective and delivered continual improvement.

How DCS supports you throughout the implementation of ISO/TS 16949

Speak to someone at DCS to help you understand the process If you are new to management systems then we know this may seem rather daunting at first. But don't worry – just pick up the phone to speak to one of our people. We can turn jargon into English and put you on the right track for success – simply call 02502341257/9322728183

Commit to best practice and start making excellence a habit

Once we have received your application, we will identify the best people to assist you on your journey – those that know your industry sector and will clearly understand your specific challenges. We also have some useful self-assessment tools to help you get started.

Engage your team and the rest of the organization

Success will depend on a team effort so get the backing of your organization by helping them understand how they can contribute to the system. Consider whether people have the necessary skills and if not equip them accordingly.

Get ahead with pre-assessment and identify potential loopholes

Many DCS clients like to get reassurance that they are on the right track before committing to the official stage 1 assessment. At your discretion, DCS will carry out an optional 'gap-analysis' or pre-assessment visit to help you identify any weaknesses or omissions prior to the formal assessment. Call our team on 02502341257/9322728183 to book a pre-assessment

Celebrate the achievement of your official ISO/TS 16949

DCS will assess your management system in two stages. Our 'Stage 1' visit will involve the review of the system against the requirements of the standard. 'Stage 2' is simply a follow-up to check that you have corrected and progressed any issues raised in the first stage. Now is the time to celebrate your success.

Use your certificate to promote your business

Once certified, you'll be able to make your own mark by displaying the DCS Assurance Mark. It's a valuable marketing tool that you can use to promote your organization, differentiate you from your competitors and win new business.

Help for continuous improvement

DCS's support extends far beyond the issue of a certificate. Your certificate is valid for three years however our team will continue to work with you to ensure that your business remains compliant and you strive for continual improvement. If you are interested in additional scheme or integrating your system, DCS can help. Talk to your client manager or call our team on 02502341257/9322728183

We know ISO/TS 16949; DCS shaped the original standard.

DCS

• Shaped the original standard that is now ISO/TS 16949 and continues to lead the development of related standards
• Has the most highly trained and knowledgeable assessors
• Offers the widest range of support solutions in the market place
• Is the number one certification body in the UK, USA and Korea?
• Looks after more than 70,000 global clients
• Has an unrivalled International reputation for excellence