Iso 13485 overview pdf

If you polled a group of people and asked them to define the word “quality,” you would probably get mixed responses. Most people have a good idea of what quality means to them, but it is not as easy to define quality in terms that would include everyone’s interpretation of its meaning. For some words, especially those that deal with abstract concepts, a bit of ambiguity is fine. However, when an assessment or judgment of the quality of a tangible item or activity is necessary, more explicitness is required. Medical devices are probably the most critical electronic systems developed as they are used to preserve or enhance lives. This level of responsibility mandates that these systems adhere to well-defined regulations and standards to ensure they are able to perform their intended functions with no injury to patients. One of the most important of these standards is ISO 13485, which defines how to manage the quality of medical devices throughout their life-cycle. This includes explicit quality management system (QMS) requirements for organizations involved in providing systems and services to the medical device industry. As adherence to the ISO 13485 standard is mandatory, a good understanding of its intent and content overview is necessary. With this information, specific provisions that impact the PCB design and development process can be further explored. ISO 13485 Overview ISO 13485 is an international standard intended to reassure organizations purchasing and utilizing medical devices that the developers and suppliers of these devices have instituted and implemented a QMS that meets certain minimum requirements. Suppliers and developers demonstrate their compliance and commitment to this level of medical device quality by becoming ISO 13485 certified. If a company or entity participates in or provides design and development, production, storage, distribution, installation, servicing or other technical support, their related operations most likely fall under the QMS standard. The major requirements are listed below. ISO 13485 Requirements Overview Section 4: General Requirements 4.1. Establishing your QMS 4.2. Documenting your QMS Section 5: Management Requirements 5.1. Management support 5.2. Customer emphasis 5.3. Quality policy establishment 5.4. QMS planning 5.5. Internal roles, responsibilities and communication protocol 5.6. Management oversight procedures Section 6: Resource Requirements 6.1. Resource allocation 6.2. Personnel allocation 6.3. Infrastructure allocation 6.4. Work environment control Section 7: Product Realization Requirements 7.1. Product realization planning 7.2. Customer requirement assurance 7.3. Design and development requirements 7.4. Purchasing process requirements 7.5. Production and servicing requirements 7.6. Monitoring and measurement control Section 8: Remedial Requirements 8.1. General remedial requirements 8.2. Monitoring and measurement requirements 8.3. Noncorming products control 8.4. Data analysis 8.5. QMS improvements Obviously, ISO 13485 is quite detailed and provides a clear roadmap to be in compliance and obtain certification. PCB Manufacturing for ISO 13485 Compliance Sections 4, 5 and 6 of the ISO 13485 standard deal particularly with how to establish a QMS within your organization and the resource requirements for its operation and management. Section 7, which is probably the most detailed area of the standard, describes the requirements for the design and development process. Successfully complying with the requirements of this section is your responsibility; however, it greatly depends on the level of quality control of your contract manufacturer (CM). Specifically, your CM can support your adherence to ISO 13485 requirements by doing the following: PCB DEVELOPMENT SUPPORT OF ISO 13485 REQUIREMENTS ISO 13485 Section 7 Requirement PCB Development Stage(s) CM Support 7.1 and 7.2 Design You should establish an open, transparent white box relationship with your CM from day one. Communicate openly with your CM and promote the free flow of data and information, especially customer requirement changes. 7.3 Board fabrication, component procurement and PCB assembly Get access to DFM guidelines tailored to CM equipment capabilities. 7.4 Component procurement In conjunction with your CM, institute methods to avoid counterfeit components and component shortages. 7.6 Board fabrication, component procurement and PCB assembly Enlist your CM’s support in tracking materials and components, performing or aiding in testing requirements and collection of pertinent data. Your ability to fully comply with the spirit, as well as the regulations, of the ISO 13485 standard is best supported by the optimization of your board fabrication, component selection and PCB assembly (PCBA), which requires selecting the best CM. ISO standard ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes is a voluntary standard,[1] 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.[2] 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.[3] 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.[4] 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.[5] ISO 13485 is now considered to be inline standard and requirement for medical devices even with "Global Harmonization Task Force Guidelines" (GHTF).[6] 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)[7] 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.[8] Mexico published in October 11, 2012 a national standard as a Norma Oficial 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.[9] 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). See also ISO 14971 Good manufacturing practice List of International Organization for Standardization standards References ^ "FOREWORD - SUPPLEMENTARY INFORMATION". www.iso.org/foreword-supplementary-information.html. ^ "ISO 13485:2016 - Medical devices -- Quality management systems -- Requirements for regulatory purposes". www.iso.org. Retrieved 2016-03-24. ^ "IATF 16949:2016 Automotive Quality Management System - BSI America - BSI America". www.bsiamerica.com. ^ "Understanding ISO 13485". ^ "Summary list of titles and references of harmonised standards related to medical devices - DG Enterprise & Industry. European Commission". Archived from the original on 2009-02-01. ^ "GHTF is no longer in operation". www.ghtf.org. ^ "International Medical Device Regulators Forum". www.imdrf.org. ^ "CENELEC - Standards Development - List of Technical Bodies -". www.cenelec.eu. ^ "NORMA Oficial Mexicana NOM-241-SSA1-2012, Buenas prácticas de fabricación para establecimientos dedicados a la fabricación de dispositivos médicos". www.dof.gob.mx. Retrieved 19 October 2017. External links Guide to ISO 13485 ISO Organisation 13485 page Overview, guidance and regulatory compliance for EU medical device manufacturers CFR - Code of Federal Regulations Title 21, Part 821, Food and Drug Administration's Quality System Regulation Retrieved from "

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