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ISO 9001: 2015 for Medical Device Industry, How it is Different than ISO13485

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A B S T R A C T

1. Under ISO 9001:2015, it would be important for the company to show what it plans to do in order to fulfill the target — to purchase more facilities, to educate more employees, etc. It must then show that these acts had the intended result of helping to accomplish the specified purpose. The ISO 9001:2015 coveres a much wider reach than ISO 9001:2008 in terms of the relation to externally supplied systems, goods and facilities, rather than the previous procurement provision. It further clarifies the conditions for the implementation of the standards. ISO 9001:2015 seeks specifically to set guidelines for a voluntary, generic QMS which satisfies consumer and regulatory requirements and enhances customer fulfillment by processes like quality improvement. The intent of this paper is to explain the discrepancies between these two international standards that are usually followed in medical device design and manual. The ISO 9001-2015 standard reflects on the consistency and rejection control system. The achievement of consistency means product compliance, an awareness of internal and external parties' desires and aspirations about a specifically defined risk-based strategy.

Keywords: Medical, Imaging, Standards, Devices, Health

1. Introduction

The medical device industry is responsible for designing and distributing a wide array of devices for the diagnosis and treatment of diseases and the advancement of patient welfare. Items include imaging machinery, artificial limbs and other implants. Top players in the medical devices sector receive trillions of dollars in sales per year. Since medical devices are critical healthcare instruments, their protection is crucial as they have significant impacts on public health and quality of life. Companies must meet the required medical device production practices in order to produce acceptable results for both participants and avoid device recalls. These requirements help ensure that the consistency needed by patients and health care personnel can be achieved reliably in the development or design process.

The release of ISO 9001:2015 includes some previews for medical device manufactures to upcoming updates to ISO 13485, as changes are likely to follow. ISO 13485 is often compliant with ISO 9001. Although ISO 9001 can be used by any organization in all branch fields, ISO 13845 has been developed especially for medical device businesses. The international quality control standards ISO 9001 and ISO 13485 are among the most widely used today with more than one million accredited organizations worldwide. Several updates have been carried out since their first publication (1987 for ISO 9001 and 1993 for ISO 13485), which match these requirements with the evolving consumer needs. On 25 February 2016, the latest version of the ISO 13485 medical device standard was officially published and on September 2015, the ISO 9001 was announced.

ISO 9001: Which is the general quality control standard. This is not industry-specific, as every company, who would like to introduce a more stringent framework based on a quality management period, will effectively incorporate it. ISO 9001 involves quality control management to help producers make

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internal improvements to minimize costs, increase transparency, promote more rational development and ease regulatory enforcement. The most recent edition of ISO 9001, which was released in 2015, is based on the high level Annex SL directive, using a similar terminology and framework
ISO 9001:2015 will thus assist makers of medical equipment in predicting improvements that are ultimately expressed in ISO 13485. The final ISO 9001:2015 and the DIS 13485 have improved risk representation, for example. Risks are found in all systems, procedures and operations for medical device manufactures delivering life-enhancing goods. This is why risk control is a vital aspect of the operation in the medical device industry, where the safety of patients and customers is paramount.

2. Evolution of the Standards

With the introduction of the different ISO 9001 models, they deviated from the previously mentioned classic documentation model. ISO 9001:2015 has practically no mandatory protocols and applies broadly to "documented information" or "documented processes." In the other hand, as reporting standards were more prescriptive in ISO 9001:2008, ISO 13485:2016 (E) has several unique requirements for a number of recorded procedures. A recorded method or documented knowledge shall not be considered compatible with a documented system for the purpose of this article. This latter includes in addition to the process the provision of scope/applicability/ references/organizations concerned/responsibility etc.
A number of new specifications from the 2008 revision were used in ISO 9001:2015. In comparison, the criteria of ISO 9001:2008 were eliminated in the 2015 study. In ISO 9001:2015, ISO 13485 has specifications for which there are no equivalents, both due to single sector requirements and improvements to the revision ISO 9001. It is up to each company to decide which provisions of ISO 13485 are covered in accordance with the normal operating procedures (e.g. control documentation) and which require additional procedures. And if an appropriate procedure/process leaves it is extremely likely that it will have to add a detailed connection to the medical devices produced

Salient points:

For each type of medical device or family of medical devices, the institution shall create and retain one or more files, either containing or referring documentation produced, demonstrating conformance to and compliance with the specifications of this International Standard. The file(s) contents shall include but are not limited to:

a) Basic definition, intended use/use and marking of the medical device, including any consumer instructions; a)
b) Product specification;
c) Production, packaging, shipping, handling and delivery requirements or procedures
d) Assessment and control procedures;
e) Installation specifications, as appropriate;
f) Operation processes as necessary

3. Contemporary Medical Device Manufacturing Standards

- ISO 9001: Which is the general quality control standard. This is not industry-specific, as every company, who would like to introduce a more stringent framework based on a quality management period, will effectively incorporate it. ISO 9001 involves quality control management to help producers make internal improvements to minimize costs, increase transparency, promote more rational development and ease regulatory enforcement. The most recent edition of ISO 9001, which was released in 2015, is based on the high level Annex SL directive, using a similar terminology and framework
- ISO 13485: Which is the quality control system developed especially for suppliers of medical equipment. The system developed by ISO 9001 is extended and streamlined in order to harmonize regulatory standards. Overall quality monitoring, traceability, process evaluation and risk assessment is supported by complying with ISO 13485. Manufacturers that comply with ISO 13485 get to carry their goods to foreign markets more quickly. Compliance will also simplify the operations and eventually allow you to work more effectively, efficiently and safely.
- ISO 14001: For all manufacturers striving to operate a leaner sector, sustainability is an essential consideration. Implementation of an ISO 14001 compliant environmental management scheme will help manufacturers of medtical devices minimize waste, save resources and reduce their total carbon footprint — significant advantages when dealing with diverse multinational supply chains. The new edition of ISO 14001 is based on the Annex SL structure, including ISO 9001:2015. As a result, implementing ISO 14001 may be reasonably easy if you already have a professional quality control framework in operation. In the dynamic medical device market, your company is best prepared to prosper as the environmental, health and safety criteria and other protocols share.
- ISO 50001: This standard complements ISO 14001 with a special uniform energy management framework. Medical product manufacturers will also reduce operating costs and increase their overall energy performance, thus improving their prestige and promoting regulatory enforcement.
- OHSAS 18001 / ISO 45001: The manufacture of pharmaceutical and medical devices also poses particular occupational hazards, particularly when dealing with advanced technology used in imagery and other items. While it is important to ensure the wellbeing of your staff, it should not be at the cost of efficiency. OHSAS 18001 / ISO 45001 lays out criteria for workplace health and security management programs to minimize vulnerability and enhance transparency in the medical devices sector when positioning the organisation. Using it constantly to reduce injury rates and associated liability problems.

- ISO 27001: With more advanced medical equipment, cybersecurity is a growing issue. Proactive information security requirements are expected for a growing demand for smartphone-based health tracking applications as well as linked devices in the diagnostic field and operating theater. Furthermore, the possibility of a privacy infringement being violated on your precious intellectual property and it is obvious that ISO 27001 has become a vital standard for medical and medical equipment manufactures. ISO 27001 contains tools to better analyze and handle the company's cybersecurity threats. It is based on a range of world-famous best practices that are not unique to any platform or product bundle. With the ISO 27001 accredited, you can react as risks to your business shift and retain stability in case of a cyber safety event.

What is ISO 13485 ?

The ISO 13485 is an independent QMS standard originating from the ISO 9000 quality control standard internationally recognised and approved. For a controlled medical device manufacturing environment, ISO 13485 adapts the previous version of ISO 9001, ISO 9 000:2008 process-based model. Although ISO 13485 is based on ISO 9001's Plan, Do, Check and Act models, it is designed to comply with regulations. This makes it more prescriptive and includes a quality control framework that is more carefully recorded. ISO 13485 was developed to help manufacturers of medical devices in the design of quality control mechanisms that improve and sustain their processes' effectiveness. It ensures that the design, development, manufacturing, implementation and distribution of medical devices which are secure for their intended use is reliable.

4. ISO 9001:2015 vs. ISO 13485:2016 – How are they Similar?

In addition to these structural differences, parallels still occur between ISO 9001:2015 and ISO 13485:2016:

- Risk-oriented approach: Both principles stress the need for a risk-based approach both to development and industry and for critical decisions based on risk analysis.
- Process methodology: All standards use the process approach of the Plan-Do-Check-Act (PDCA).
- Consumer focus: All requirements are structured to ensure consumer expectations are met.
- Architecture: The infrastructure required for business operations must be defined for all requirements.
- Expertise for workers: the two criteria require a company to assess the abilities of employees in order to carry out their mission in compliance with regulatory requirements.
- Agency role: All requirements include the specification of employee positions within the structure of the organization.

5. ISO 9001:2015 vs. ISO 13485:2016 – How are they Different?

Structure

While the composition of the criteria indicates clear variations, overall specifications do not vary. The new framework was created as a common structure for ISO specifications and for the development of condensed language terminology. In order to support Member States, an exception was given to ISO 13485:2016, which does not conform with the common framework.

Required Processes

ISO 13485 retains standards for recording key procedures and documents in a quality manual. ISO 9001 has updated this provision and became more versatile, meaning that the details about paperwork that has to be held will be determined by each company.

Management Responsibilities

ISO 9001 encourages top management to delegate tasks without specifying positions, ISO 13485 requires managers to be defined (s).

Product Realization

ISO 13485:2016 stresses design and production as a central phase of product realization. ISO 9001:2015 moved product realization to product distribution phase recognition. ISO 9001:2015 is more customer-focused than design and construction reports.

Continual Improvement

ISO 9001 focuses on consistent customer loyalty and process development. ISO 13485 maintains the need to concentrate on development programs, continued suitability, adequacy and efficacy of the quality control system and medical product safety and performance.

6. Conclusion

The criteria should be interpreted by the company and to some degree by an inspector. While this report does not guarantee success, it aims to be a useful tool in the strategic processes that the company enters the manufacturing industry of medical devices. Finally, there are a number of further considerations when trying to cross industry borders. The context of the enterprise is discussed in Clause 4 of ISO 9001:2015. Understanding the organisation's organization and its context involves identifying internal and external issues that affect the organization's ability to achieve its intended results and which are relevant to the organisation's purpose. There are numerous ways to identify and improve. Both evaluation outcomes may be evaluated in order to decide where changes are needed or wanted. Policy and goals can then be defined and implemented by means of prevention and improvement

programmes. The producer must demonstrate that 58 places comply with regulatory requirements in ISO 13485:2016. For contrast, the term "regulatory requirements" is only listed 11 times in ISO 9001:2015.

REFERENCES

[1] U.S. Food and Drug Administration [Internet]. Silver spring, MD; 2012 April [cited 2014 Feb 24] Available from: http://www.fda.gov/aboutfda/transparency/basics/ ucm211822.htm

[2] U.S. Food and Drug Administration [Internet]. Silver spring, MD; 2012 Dec [cited 2014 Feb 24] Available from: http://www.fda.gov/%20MedicalDevices/Device RegulationandGuidance/Overview/ClassifyYour Device/default.htm (Cited on 2014 Feb 24)

[3] Poc CENT, point of care Center for Emerging Neuro technologies [Internet]. USFDA; 2014[cited 2014 Feb 24]. Available from: http://www.ece.uc.edu/POC-CENT/funding/ Additional%20Information/fda-classification

[4] U.S. Food and Drug Administration [Internet]. Silver spring, MD; 2013 April [cited 2014 Feb 24]. Available from: http://www.fda.gov/MedicalDevices/DeviceRegul ationandGuidance/Overview/GeneralandSpecialControls/ucm2005378.htm (Cited on 2014, Feb 24)

[5] ISO, What is a standard? [Internet]. Geneva; 2014 [cited 2014 Feb 24]. Available at: http://www.iso.org/iso/home/standards.htm.

[6] ISO, International Organization for Standardization [Internet]. Geneva; 2014 [cited 2014 Feb 24]. Available at: http://www.standards.org/standards/listing/iso_13 485.

[7] Willett N. Quality Magazine. Quality Management: The Need for ISO 13485 [Internet]. 2011 Jan [cited 2014 Feb 25]. Available at: http://www.qualitymag.com/articles/87898- quality-management-the-need-for-iso-13485.