White Paper

MasterControl

Understanding ISO 13485:2016 - A Brief, Yet Comprehensive, Overview

Overview

If you work in the medical device industry, you are aware of the importance of ISO 13485, also referred to as ISO 13485—Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes, and ISO 13485:2016. This white paper provides a brief, yet comprehensive, overview of the standard, and examines how obtaining ISO 13485 certification can open doors to untapped domestic and international business opportunities. It also explains how to avoid becoming a device company that fails to obtain recertification to the new revision due to inadequate manual processes.

What is ISO 13485?

ISO 13485 is a hierarchy series of requirements that help medical device manufacturers develop a quality management system. According to the official ISO 13485 standard, these requirements "can be used by an organization involved in one or more stages of the product and/or service lifecycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of a device, along with the provision of associated activities (e.g., contract manufacturing organizations, engineering support)."[1]

ISO 13485 was recently revised (in 2016) and companies seeking to comply with this latest of standards must fully comply with its contents by March 2019. Until that date, compliance with the 2003 (2012 international) standard will suffice. However, it is important to start preparing for compliance with the standard as early as possible since there are significant changes within the revision. (Please see sub-header below "What are the Major Differences Between ISO 13485:2003 and ISO 13485:2016?")

Although ISO 13485 is a stand-alone document, it is harmonized with ISO 9001, the world's leading quality management standard (although the existing numbering convention remains). However, it is important to note that due to significant changes in the most recent version of the standard it has now become more difficult to harmonize standards 13485 and 9001. Both certifications can still be obtained, however, medical device companies may choose not to do so based on increased ISO 13485 requirements and differences between the formats and intent of the two standards.[2]

How Does ISO 13485 Differ from ISO 9001?

The most fundamental difference between the two standards is that ISO 13485 is tailored specifically to medical device companies, whereas ISO 9001 can be used by any company, of any size, within any industry sector. Additionally, ISO 9001 requires the certified company or organization to demonstrate continual improvement based upon the newly added sections of 9.0 and 10.0. By contrast, ISO 13485 requires ongoing improvement but only as much as

needed to demonstrate that its quality system is effectively implemented and maintained. ISO 9001 requires continual improvement of the effectiveness of the QMS by virtue of the rearranged requirements, planning orientation and formal deployment of the risk and opportunity analysis.

Another principal difference is that ISO 13485 excludes the ISO 9001 requirements regarding customer satisfaction, focusing instead on regulatory requirements for post-market surveillance activity. This newest version requires device manufacturers, as well as their sub-tier suppliers and contractors, to apply risk management with analysis from the product's concept and design phases throughout product realization and servicing. The standard also requires that risk management practices be applied to the processes of the quality management system (QMS) itself as part of the rigorous formality of planning (see section ISO 9001 - 6.0). Prior to the 2016 version, risk management was only required in relation to product planning (ISO 14971) and not to the processes that resulted in its manufacture (e.g.,design control and risk-based quality reviews).

According to a recently released white paper, the ISO 13485 standard is now at a "new level of application," due to the following:

1. "Any actions taken by a business must be measures for controlling risk…"
2. "Critical factors must be evaluated as risk and opportunistic (R&O) driven outcomes."
3. "As a result of 1&2 it is explicitly imperative to make planning a tangible and documented activity with appropriate review and actions at executive level decision making."[3]

Due to these new elements within the 2016 standard, and increased levels of various aspects of quality management (see section header below – "What are the Major Differences Between ISO 13485:2003 and ISO 13485:2016?") some medical device companies may find it in their best interest to comply with ISO 13485 only as opposed to seeking certification with both 9001 and 13485.

However, one thing that is likely to remain the same (despite the changes in the most recent version of the 13485 standard) is that non-medical device companies will often upgrade or migrate from 9001 to ISO 13485 (or maintain both certifications) in order to introduce their existing products for use in medical (device) applications. Additionally, device manufacturers that intend to market their products within the European Union will need to address compliance with the requirements of the applicable Medical Device Directive (MDD) and CE marking process. Some medical device companies will also do the same based on their own unique needs. This has created a whole new positioning of registrars in the regulatory intent of a certification process. (e.g., MDSAP audits).

Applicable Changes to the MDD and CE Marking: How Will ISO 13485:2016 Play a Part?

Even as this white paper is written, there are many moving parts in the "chess game" of the medical device industry's guiding regulations and standards.[4] For example the MDD and the CE mark, the main standards for medical devices in the European Union, are currently in the process of being fully replaced by the new European Medical Device Regulation (MDR) which is already official law.[5] MDD compliance and CE mark will still be recognized for several years but will become extinct soon enough as certifications are a regulatory oriented process. For the purposes of this paper however it is important to recognize that ISO 13485 will remain a critical aid in supporting compliance with the current MDD and other countries who deploy prescriptive systems for quality.

What are the Major Differences Between ISO 13485:2003 and ISO 13485:2016

There are many differences between the 2003 and 2016 versions of the ISO 13485 standard. Listed below are some of the key differences:

1) Risk Management

As mentioned in an earlier section of this paper, risk management plays a central role in the ISO 13485 standard. However, the 2016 version takes risk management standards to an entirely new level. Where in the past, ISO 13485 required the assessment of risk in relation to the medical device itself, risk assessment, analysis and management should now be applied to all QMS processes, especially design control deployment toward the completion of the product.[6] The formality of technical design transfer has become a critical component of this process.

To emphasize the importance of risk management in the new version of the standard even more clearly, a recent white paper states, "Risk is mentioned some 15 times throughout the standard, to account for the specific issues being addressed. Risk is to be considered in outsourcing and supplier controls, along with software qualifications related to risk, and in the training of personnel commensurate with risks inherent in the processes they perform. Risk is to be taken into account in all product planning processes. Risk management activities should also be incorporated during the reviews within the processes for:
-Verification, validation, revalidation
-Documentation of design in product realization
-Monitoring, testing, and traceability
-Risk and opportunity in corrective actions and preventive actions"[7]

2) Software Qualification

The ISO 13485:2016 standard was greatly influenced by the U.S. Food and Drug Administration which places a great deal of emphasis on validation processes and procedures and includes language and definitions similar to those used by the U.S. agency.[8] This influence can be seen in more than one area of the 2016 standard, one of which is the validation of software systems. The new standard requires medical device companies to thoroughly validate all software systems utilized (directly or indirectly) throughout the conceptualization and manufacture of a device. FDA currently has a guidance entitled, Software as Medical Device (SaMD), which is a compulsory document.[9] Other standards such as ISO 62304 – Design and Maintenance Lifecycle of Software – has stipulated the basis of Level of Concern (LOC) as a risk rating. Medical device companies seeking to comply with the 2016 standard should begin planning their validation process (VMP) now (if they haven't already) so that software(s) can be validated by March 2019 if not sooner based upon the LOC designation. In a technology-driven business environment where real-time decision making is now the norm it is competitively demanding on companies at any size to use software based applications for quality-based performance.

3) Purchasing/Outsourcing

Although many medical devices already require criteria, it is now required per ISO 13485:2016 standard to base the criteria on supplier performance to the level of risk of the device components being manufactured for assembly of the product. The purchasing information also needs to include qualified specifications and a quality agreement with the supplier to provide notification of any changes, or events through formal, documented communication. Again, this is not new to many device companies but is now an explicit (vs. implicit) requirement.

Also related to purchasing, the 2016 standard requires that verification activities — such as purchasing criteria — be based on supplier evaluations and proportional to the risk of a given device as it was qualified during design control. What this means in reality is that for many Class II & III medical devices (high risk) it is likely that 100% of the parts being purchased from a supplier must be verified, if not formally validated. And finally, if a purchased part is changed, a medical device company is now required to determine the effects (risk) of the change on the manufacturing process. Change control is explicitly risk-based and requires phased reviews throughout the development lifecycle of the product.

4) Usability Within the Scope of Design Control

Usability is a new requirement (not new to the medical device industry) that has been added to the design control section (7.3) in the ISO 13485:2016 standard. The concept of usability is not new to medical device companies that already have to meet FDA regulations or to those that implement ISO standard 62366 (a standard for usability within the scope of design control).[10] However, usability is now a requirement of the new ISO 13485 standard. The standard stipulates that companies shall create a usability assessment and plan document, address usability as early in the design control as possible, create usability standards documentation, test products in simulated user environments and anticipate expected user scenarios be validated.

In addition to the differences already mentioned, a recently published white paper[11] also describes additional differences between the two standards:

5) Leadership

"The responsibilities of top management are clarified [in the 2016 standard], with explicit requirements for reviews at documented, planned intervals. More emphasis is put on results of activities and effectiveness of the quality system and measurable quality objectives." The relationship of management with higher risk-based conditions of the system may even require direct influence, input and active oversight. It is conceivable, for example, that top management may be the owner of a significant CAPA if an issue were to merit it.

6) Human Resources

"There is more emphasis [in the 2016 standard] on training to quality processes, establishing competence and awareness of personnel duties. The standard now specifies that the organization shall determine any user training needed to ensure specified performance and safe use of the medical device (e.g., use of software in realization). This is much like the qualified persons required in the EU."

7) Facilities

"Facilities must be designed and arranged in order to prevent mix-ups. Manufacturers must ensure control of contamination and particulate matter where needed for aseptic and sterile products, and requirements for documenting the work environment are added."

Current Versions of ISO 13485

There are three current and common versions of ISO 13485. The primary international version is ISO 13485:2016. The variant EN ISO 13485:2012 is the latest European harmonized version of ISO 13485; it replaces the prior harmonized version, EN ISO 13485:2003, which is now considered to be obsolete. EN ISO 13485:2012 is applicable only to manufacturers placing devices on the

market in Europe. Manufacturers can employ ISO 13485 to meet the quality system requirements of the European directives, including European Medical Device Directive (MDR). Confusion frequently occurs when people use the abbreviated ISO 13485 to refer to both ISO 13485:2003 and EN ISO 13485:2012. This leads some to assume that there is a 2012 version of the 2003 standard, which there isn't. As mentioned earlier in this paper the 13485 standard is essential for meeting MDD standards (soon to be MDR standards) when selling devices in Europe.

The third version of the standard is CAMCAS-ISO 13485:2016. Conformance to this standard is necessary to secure a Canadian Medical Device License for Class II, III or IV medical device. Health Canada considers this variant to be the equivalent to ISO 13485:2003 standard.

On a curious note the new MDSAP program (Med Device Single Audit Program) is situated against the Canadian population of certificate-bearing manufacturers and is the driving force for continued harmonization of regulatory bodies participating in the program. Canada has declared the ISO 13485:2016 standard as the regulatory compliance application for manufacturers in that country, which of course, would include companies doing business in Canada.

The MDSAP: How Does It Relate to ISO 13485?

The MDSAP offers medical device companies the opportunity to audit against a single set of conformance standards. Participating regulatory bodies are the U.S., Japan, Australia, Brazil, EU, China and CAMCAS. Other countries are participating in the program as observers and may require medical device companies to participate in the program in the future. For now, Canada is the only country that by law currently requires companies to participate in the MDSAP. Specifically, all medical device companies planning on selling their products in Canada beginning January 1, 2019, will be required to participate in the MDSAP due to current ISO 13485 as the compliance and conformance document. It seems important to note that since MDSAP is almost entirely based on ISO 13485:2016 (and compliance for that standard is due in March of 2019) companies that to work toward meeting the ISO 13485:2016 and MDSAP standards in conjunction with one another will have the advantage of qualification for all countries participating in the program. Only registrars currently used in Canada's process can be qualified to perform such audits.

How is the ISO 13485 Standard Organized?

ISO 13485 comprises the eight original 2008 version sections, which are preceded by an introduction. Sections one through three describe the purpose and harmonization for use of the standard. Sections four through eight contain the conformance conditions of the standard, i.e., the requirements necessary for compliance, so they would be examined individually and collectively as an integrated system. Many items which were implicit before are now explicit in the wording for deployment.

-Section Four (Systemic Requirements): This section defines the general documentation requirements for compliance. It explains how to implement and maintain a QMS for devices; prepare a quality manual, quality policy, and quality objectives; control QMS documents and records; and maintain document integrity. Important to note is the new EDMS requirement for storing and handling of documentation.

-Section Five (Management Requirements): This section defines management's role in the planning (risk based), establishment, maintenance and performance of an ISO 13485 QMS. It requires upper management to actively participate in quality planning, and to ensure that the quality policy is understood throughout the organization. Specific requirements for carrying out periodic (risk established) management reviews of the QMS, including how often reviews should take place with defined roles; what to cover; and expected outputs to planned objectives, are also covered in section five.

-Section Six (Resource Requirements): This section defines the requirements for the provision of resources, including physical resources (e.g, the need for adequate space, tools and equipment); environmental resources (e.g, the environment must suit the type of device being made); and human resources (e.g, how to train and maintain competent personnel). Key topics covered in section six include the importance of defining employee job requirements (like software) and how to keep good training records that verify and validate usability conditions

-Section Seven (Product Realization Requirements): The most extensive section covers everything that is required in order to produce a product, from customer requirements and communication to creating (designing and manufacturing), installing, and supporting a medical device through post-market surveillance. Requirements are given for how to correctly perform the most basic tasks (e.g, processing maintenance; all risk management planning and analysis phases), are also covered in section seven. New items such as rigorous technical design transfer, risk based reviews, deployed change control and the formality of design and development files (i.e. parent/child DHFs) that should be audited during the design control process.

-Section Eight (Remedial Requirements): This final (but explicit) section defines the remedial processes necessary in order to maintain the effectiveness of the QMS. Key topics covered in section eight include handling adverse events and customer complaints; conducting risk-based internal audits; formalities for monitoring and measuring processes and product, including nonconforming product; analyzing data for effectiveness (in management and design reviews); and taking corrective and preventive actions based on explicit risk and opportunity analyses using rigorous statistically developed tools.

The ISO/TR 14969:2004 guidance document for application of ISO 13485 has been replaced by a more extensive 220 page practical guide produced by the standards technical committee (TC210).[11] The additional guidance for implementing a medical device QMS can be obtained from a document provider for a nominal cost. The international Medical Device Regulatory Forum (IMDRF) has a rich library of credible guidance documents that are free and available on the website.[12]

Is ISO 13485 Required?

ISO 13485 is required in Canada (CAN/CSA-ISO 13485:16), at the Japanese Ministry of Health, Labour and Welfare (MHLW) ordinance #169 is based on ISO 13485:2016 and is required in Japan.[13-14] Although EN ISO 13485 is considered to be the de facto standard for the device industry in Europe, it is not technically a requirement. It is, however, the expectation for two reasons: certification to EN ISO 13485 presume compliance with applicable European Directives (making it easier to obtain CE Mark, which is currently mandatory if you want to place a device on the market outside the U.S. and is considered good practice. In the United States, the FDA Quality System Regulation (QSR.), also known as cGMP, is required. Of course, if a U.S. based company wishes to market its medical device products internationally, it must comply with both cGMP and ISO 13485.

Even in countries where adherence to the standard isn't required by law, ISO 13485 is becoming increasingly required by investors, partners and customers. Third-party certification to a particular standard or regulation assures both potential and existing consumers, as well as suppliers and foreign trade officials that your business operations are save and efficient. The MDSAP program was designed to fulfill both regulatory and business requirements.

Why is ISO 13485 Important?

There are many reasons why ISO 13485 certification is important to a medical device company, including:

- Increases customer confidence: Certification establishes a company's commitment to quality, which often leads to increased customer confidence;

- Enhances marketing and promotional opportunities: Once a company has been deemed compliant by a certified ISO 13485 registrar, it will receive a certificate. The company's marketing team will be able to display this certificate on all corporate marketing materials to enhance its credibility in the eyes of customers, employees and other stakeholders;

- Promotes better communication/fewer deviations: ISO 13485 promotes harmonization of regulatory requirements on an international scale. Harmonization allows device manufacturers and other quality experts to communicate using a familiar/standardized vocabulary. This reduces communication gaps and ambiguity that often result in deviations, non-conformances and other quality events that can cause patient harm, regulatory sanctions and significant revenue loss;
- Improves performance and supplier relationships: Using a uniform, widely-accepted system of process control leads to improved products and processes. This in turn often leads to increased customer satisfaction and better relationships with suppliers and partners;

- Enhances brand equity: Improved products and processes help device manufacturers sustain their delivery of high-quality products, and minimize or avoid embarrassing product recalls and costly regulatory sanctions. Ultimately, this leads to increased brand equity, which is an important competitive advantage.

- Increases Speed to Market: ISO 13485 certification allows an organization to meet the quality system requirements of the European Medical Device Directive (MDR), In Vitro Medical Device Directive (98/79/EEC) and Active Implantable Medication Device Directive (90/385/EEC) with less difficulty, which expedites market entry.

What are the Financial Benefits of ISO 13485?

Many device companies fail to realize how much money they could save (or even generate) by developing and implementing a quality management system that adheres to ISO 13485. Although the standard is not designed to make every medical device company equal in talent or ability, it is designed to help management understand how company processes correspond to ISO 13485, and why those processes work in the way that they do. In other words, the standard is designed to make the quality system transparent for business and now between regulatory bodies (MDSAP).

Unclear or vague documentation is often what keeps company processes and ISO 13485 compliance at odds. Once documentation presents a clear and deep understanding of how processes and standards fit together, and why they are designed as they are, it becomes easier to spot errors, avoid costly regulatory sanctions and provide effective employee training.

Clear training and understandable SOPs enable employees to understand their assigned tasks, as well as any deviations or nonconformance events they are responsible for reporting. The end result: confident employees who are more satisfied with the company, and their role within it. When employees are satisfied and productive, deviations "bubble up" through the system faster, and a positive financial impact is all but guaranteed.

According to Quality Digest magazine, there is more than one way to save money by adhering to ISO 13485 standards. "Having a quality management system [based on ISO 13485 standards] at an early stage provides another advantage to these companies [medical device companies]: quicker market access. Many regulatory organizations were involved in the development of this standard. Therefore, requirements in regulatory laws such as the MDR share numerous similarities with ISO 13485. Hence, after a simple update of their systems, these companies can quickly and cost-effectively seek regulatory approvals from a variety of countries."

The same article states "For medical device manufacturers, it is mission-critical to receive such certification [ISO 13485 certification] quickly. They invest in both research and development, and in the product's sales and marketing plans. Particularly in the medical device industry, the longer a product languishes in the review process, the less it returns to the manufacturer's bottom line."[15]

Medical device companies can also save a significant amount of money by automating their quality processes, a concept which will be expanded on in upcoming sections.

How Do I Prepare for ISO 13485 Certification?

Preparing for a third-party accreditation audit can be a long and tedious process. Many device manufactures, particularly smaller firms, simply do not have the time, resources or expertise to assess their entire quality management system to identify and correct all of the potential barriers to certification success. If time is of the essence, or a dedicated internal resource is not available, the company may decide to enlist the services of an experienced ISO consultant or quality management certification expert to liaise with the registration body, also referred to as the registrar.

The certification process is typically divided into five phases. If the company is using the services of an ISO consultant, the consultant will often handle most—if not all—of the phases on behalf of the company. This can save the company a great deal of time and accelerate the process significantly.

Phase One: Inquiry—ISO itself does not perform certification audits or issue certificates. These services are performed by external certification bodies. Choosing a certification body is the first step of the inquiry phase. ISO's website provides some tips for selecting a certification body. For example, ISO recommends evaluating several registrars before making a final selection. It's important that the registrar you select is competent and provides the scope of the certification (i.e., continent, country or product registration, etc.).

The evaluation process typically commences with a fact-finding meeting between the registrar and the company seeking certification. During this meeting, the registrar will attempt to gather background information about the company and its certification needs. The company will want to inquire about the registrar's working philosophy, as well as what to expect during the certification process.

Phase Two: Application—If the fact-finding meeting goes well, the company will be asked to fill out a certification application form, which can be obtained online. The registrar will review the completed application form, as well as the information gathered during the inquiry phase, and provide the company with a quote. Obviously, if the company has chosen to follow ISO's advice, it will be requesting and receiving multiple quotes, from multiple registration bodies. Once a registrar has been selected, the company is ready to advance to phase three.

Phase Three: Documentation Review—At this point in the process, the registrar will begin to assess how the company's documented quality processes compare or comply with the standard. During phase three, the company may opt to conduct a trial audit (often referred to as a pre-assessment) to get a sense of the registrar's auditing style and to see what quality areas, if any, are deficient. Although a pre-assessment in not required, it is highly recommended in light of the transition planning and execution of the ISO 13485:2016 version of the standard.

Phase Four: Final Certification Audit—For certification audits, a Stage 1 and a Stage 2 must be conducted prior to the final certification audit. The combined duration of the audits must comply with the IAF MD9 guidance document. Section 0.3 of ISO 13485 requires auditors to use a "process approach" auditing style, as opposed to a checklist approach. The process approach utilizes the plan-do-check-act (PDCA) cycle.

Phase Five: Ongoing Surveillance—Annual or semi-annual surveillance audits should be scheduled with the registrar in order to monitor progress and correction. These audits should be scheduled well in advance of the company's anniversary date. A complete assessment restarts every three years.

(Editor's note: MasterControl's Quality Compliance Consulting division offers ISO 13485 application/certification services. If you would like to learn more about QCC, visit: http://www.mastercontrol.com/home_page_ads/need-consulting.html?lne=hlnk_needconsult. To learn more about automating your paper-based quality management processes with MasterControl software, and how it can facilitate the certification process, continue reading.)

Is It True That Some Medical Device Companies Fail to Obtain Recertification?

Many small- and medium-sized companies continue to prepare for or maintain ISO registration through manual processes. Imagine the amount of time it takes to key in or type the required quality documents, physically draw process diagrams, create reports and validate data in preparation for a registration audit. Now imagine how many days it takes for internal and external auditors to locate paperwork and manually compare the data to information provided in the application. Time isn't the only disadvantage of manual preparation; expense is also a concern. The article estimates that registrations in manual environments still cost more than $100,000, and take an average of one year of preparation. Moreover, evidence suggests that up to 50 percent of these registration fail at the time of recertification due to a company's inability to maintain and scale manual processes. Automating quality management processes with sophisticated software tools can help manufactures not only obtain certification faster, but also maintain that certification long term. The following section explains how the MasterControl software suite facilitates ISO 13485 compliance.

MasterControl Automates Your Processes for ISO 13485 Compliance

ISO 13485 Requirements	MasterControl Features To Ensure Compliance with ISO 13485
(ISO 13485-Sections 4 and 4.2) Requires establishment of a quality management system for medical devices. A manufacturer must have quality procedures that are documented, controlled, and effectively implemented and maintained.)	MasterControl helps medical device companies comply with ISO 13485 by automating routing, escalation, approval, and delivery of standard operating procedures (SOPs), policies, and other documentation. The software provides automatic revision control to ensure that only the current version of an SOP is available. When a user makes a change to the document or record, the user must enter a reason for the change. The system tracks these changes and makes them available through reports.
(ISO 13485-Section 6.2.2) A manufacturer must ensure that its personnel have the right experience, education, training, and skills. Acceptable levels of competence must be defined. Training needs must be established and assessed. A record of competence must be maintained.	MasterControl helps medical device companies comply with ISO 13485 by automating the assignment and monitoring of training tasks and grading of online exams. The software allows sequencing of training courses so after a prerequisite is completed the next course is automatically launched. It also provides a group sign-off feature for verifying training of large groups of employees.

(ISO 13485-Sections 8.2.3, 8.2.4, 8.3.2 and 8.3.3) A manufacturer must plan how remedial processes will be used to assure conformity. It must use remedial processes to demonstrate conformance. It must establish a nonconforming products procedure; nonconformances must be corrected and documented.	MasterControl helps medical device companies comply with ISO 13485 by integrating the corrective and preventive action process with other quality processes. A CAPA form can be launched directly from another form (e.g., a nonconformance report). The software automatically enters relevant data into a CAPA form, reducing data entry and eliminating errors that result from the manual transfer of information. It also provides customizable reporting capabilities to help managers monitor the entire quality management life cycle.
(ISO 13485—Sections 4.1.2, 4.1.5, 4.1.6 — General Requirements and Sections 7.3.3, 7.3.9, 7.4.1 — Product Realization) A risk-based approach is needed when developing processes. Anything that effects the quality system must be viewed from a risk perspective.	MasterControl helps medical device companies comply with ISO 13485 by allowing users to configure multiple risk types for evaluating different categories of operational risk. Risk assessments can be launched from anywhere within the MasterControl system to analyze hazards associated with any process or activity. MasterControl's best practice process also include risk mitigation and risk assessment. Standardizing risk analysis methodologies and assessment results in a single location saves time, money and valuable resources.
(ISO 13485-Section 5.6.1) Requires management reviews, including examination of product conformity data.	MasterControl is a robust solution designed to help medical device manufacturers comply with ISO 13485 by automating, managing, and streamlining the process for identifying, evaluating, reviewing, and handling of nonconforming materials, components, parts and finished products. The solution's best practice from and five-step process connect all responsible personnel for effective and timely disposition of a nonconformance. In addition, the solutions' scheduled reports enable management to stay on top of product conformity data by simply reviewing their email.

(ISO 13485 -- Section 7.3.1) Design and development documentation must be established. Communication and all forms of interfacing must be managed between all groups involved with the design and development processes. Planning output must also be established.	MasterControl allows medical device manufactuers to comply with ISO 13485 by enabling users to control design documentation, technical dossiers, BOM iterations and all related supplier documentation. The Project Management module also allows MasterControl users to manage all stages of design and development.
(ISO 13485 — Section 4.1) The 2016 standard adds "requirements related to validation of the application of computer software used in the quality management system."	Not only does MasterControl Documents™ allow companies to easily manage all documentation related to validation but also provides IQ,OQ and PQ validation services to assist in validating the MasterControl Enterprise Quality Management System (EQMS) itself. (Note: The EQMS includes the MasterControl Documents module.)

Conclusion

In today's global medical device industry, it's no longer enough to merely comply with FDA requirements. Medical device manufacturers must address the demands of regulators from countries around the world. Achieving ISO 13485 certification is a worthy endeavor since maintaining ISO standards promotes customer, investor, and employee confidence, and builds a system that is ideal for automation and increased productivity.

References

(1) ISO 13485 Official International Standard: Third Edition. "Medical devices — Quality management systems — Requirements for regulatory purposes."

(2) The most recent version of ISO 9001 occurred in 2015.

(3) "ISO 13485: Change – Do I Have To?" White Paper. Published by MasterControl in 2016. Note: In addition to the "new level of application," as already mentioned, "the revised ISO 13485 standard sports the converging alignment with FDA terms, such as establish, implement and maintain documented processes, while clarifying that regulatory requirements include statutes, regulations, ordinances or directives, relative to the safety and performance of the medical device."

(4) This white paper was published in October 2017.

(5) "Europe's new MDR and IVDR Have Become Law." See also: "Top 10 European MDR Questions."

(6) "What's New In ISO 13485:2016?" StarFish Medical.

(7-8, 10) "ISO 13485: Change – Do I Have To?" White Paper. Published by MasterControl in 2016.

(9) "Fostering Medical Innovation: A Plan for Digital Health Devices"

(10) IEC 62366-1:2015 Preview Medical devices -- Part 1: Application of usability engineering to medical devices.

(11) "The Practical Guide to the ISO 13485:2016 Practical Guide".

(12) Library of guidance documents: www.imdrf.org.

(13) "CAN/CSA-ISO 13485:16."

(14) Japanese MHLW Takes Steps Toward Aligning ISO 13485:2016 with Its Own QMS Requirements.

(15) Zwilling, Martin, "How to Start ISO Automation," See also: Ramaley, Grant, "The Beginning of the End for Fake ISO 13485 Certificates." See also: Borsai, Tamas; Dzialas, Gregor; and Ludovico, Brian, "ISO 13485: A Path to the Global Market."

About MasterControl

MasterControl Inc. creates software solutions that enable life science and other regulated companies to deliver life-improving products to more people sooner. MasterControl's integrated solutions accelerate ROI and increase efficiencies by automating and securely managing critical business processes throughout the entire product lifecycle. More than 1,000 companies worldwide, ranging in size from five employees to tens of thousands, rely on MasterControl cloud solutions to automate processes for new product development, clinical, regulatory, quality management, supplier management, manufacturing and postmarket surveillance. MasterControl solutions are well-known for being scalable, easy to implement, easy to validate and easy to use. For more information, visit www.mastercontrol.com.

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