The Differences and Similarities between ISO 9001:2015 and ISO 13485:2016

Can we integrate these Quality Management standards?

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Preface

Both ISO 9001:2015 and ISO 13485:2016 have gone through their first standard review period to be reconfirmed for another 5-year period. These two standards for Quality Management Systems (QMS) have different structures and differences in the definition of risk and other terms. In this paper, we are looking to see how these standards co-exist and what developments are being discussed. The intent of this document is to provide insight into some of the differences and similarities between the standards, to allow organizations to understand how they can continue to work together for organizations that are part of the medical device supply chain, without undue burden to their systems.

Background

ISO 9001 was first published in 1987 and then revised to a second edition in 1994. Meanwhile the initial versions of the QMS standard for medical devices was published as part of the ISO 46000 series which later became the first edition of ISO 13485 (along with ISO 13488) in 1996. In 2000, the third edition of ISO 9001 was published and ISO 13485 was revised in 2003 to align with that revision (ISO 13488 was withdrawn at this time). In 2008, ISO 9001 was again revised and brought in many of the requirements of ISO 13485:2003. It was decided (by international ballot) in the periodic review that no corresponding revision of ISO 13485 was to be done.

The work for the current edition of ISO 13485 was started in 2012 and the revision of ISO 9001 followed. In the meantime, the ISO Technical Management Board (TMB) embarked on an initiative to work on a common structure of Management System Standards (MSS) that came from a previous edition of Guide 72. The High Level Structure (HLS) was developed by ISO to implement this common structure along with several definitions for terminology with simplified language to help organizations implementing multiple management systems (such as those for environment, information systems health & safety or business continuity) to enable this integration by having less work or differences to resolve when using the ISO standards for those systems. Since many Technical Committees (TC) had not been following this guide, they determined to incorporate this into the ISO/IEC Directives, Part 1 as Annex SL to ensure the use of this HLS in the ISO MSS structure. The work on the revision of the HLS is on-going through both ISO Task Force (TF) 14 and 15, in particular with the definition of risk that the HLS brings from the definition of ISO 31000 that is the work of TC 262 (Risk management).

Both ISO 9001 and ISO 13485 have been revised with publication of the fifth edition of ISO 9001 in September 2015 and publication of the third edition of ISO 13485:2016 in late February 2016.

As discussed in the previous version of this white paper, TC 210 (Quality management and related general aspects for medical devices), WG1 adopted a resolution to initiate discussions with the relevant interested parties (e.g. medical device regulators, manufacturers and certification bodies) to review the possible future alignment with the High Level Structure outlined in the ISO/IEC Directive, Part 1, Annex SL and a mapping of this third edition into the High Level Structure in the ISO/IEC Directive was completed to understand the differences and the systematic review of ISO 13485:2016 was accelerated to the end of the transition period (3 years) instead of the ‘normal’ 5-year cycle. This review was initiated in late 2018 by ISO Technical Committee 210 (TC 210) with user surveys and meetings of national bodies to gain perspective on the use of the standard and if any changes should be made. Impacting this review was the regulatory shift in Europe with the transition to the Medical Device Regulation that was released in 2017 with full compliance set for May 2024. Given the burden of that regulatory transition and other world-wide regulatory framework changes, the medical device industry feedback from the relevant interested parties was nearly unanimous that a change in ISO 13485 was not to be made at that time and this resulted in confirmation of ISO 13485 for the standard systematic review.

Following this, TC 176 (Quality management and quality assurance) did their own user surveys to support the systematic review for ISO 9001 in 2020. A key related change happening at this point was the consideration by an ISO Task Force (TF14) on the revision of the High-Level Structure (HLS). Given the high likelihood of changes to that structure and the desire for some stability, the resulting survey feedback and subsequent TC 176 committee ballot resulted in ISO 9001 also being reconfirmed without revisions for an additional 5-year period. However, the leadership of TC 176 continues to monitor these changes and may consider an acceleration of the next review when this update to the ISO HLS in Directive, part 1 is released.

Introduction

It has been more than 6 years now that ISO 9001 has been using the High-Level Structure (HLS) as outlined in the ISO/IEC Directive, Part 1. As outlined in the previous version of this white paper, there have not been any significant problems created by the divergence of the two standards. In this update we will discuss the current activities by both Technical Committees and other activities by the ISO organization and others that could be of significance.

While there are still many people that focus on the differences, it is clear that the standards continue to be used alongside each other without significant issues as there remains no direct conflict between the requirements. Outlined below are the differences followed by the similarities between the two standards. ISO 9001:2015 and ISO 13485:2016 work together to outline a Quality Management System for medical device organizations and those concerned with providing product within the supply chain of medical devices.

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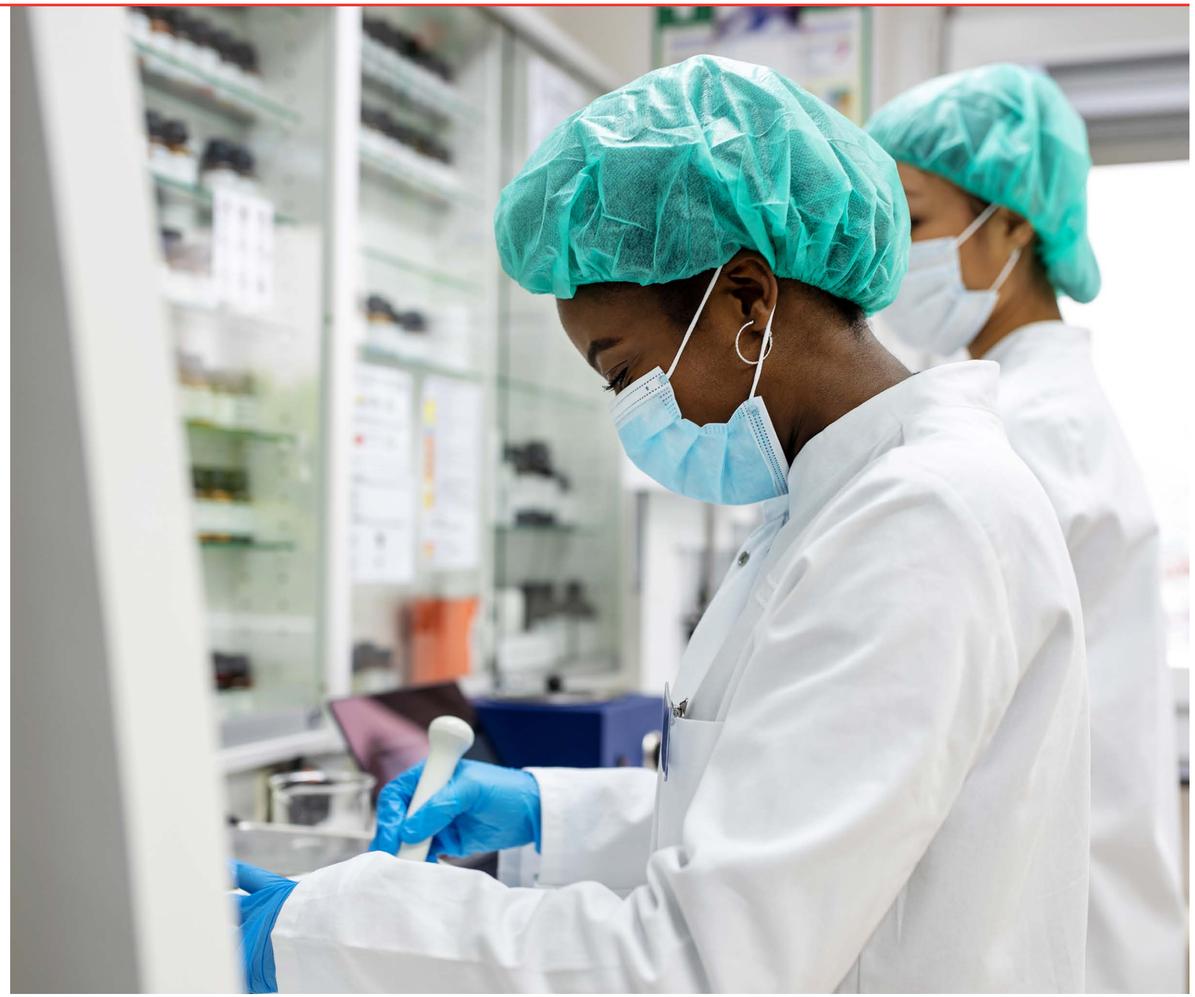

The differences between the two standards

The following is a brief summary of the primary differences between these two Quality Management standards.

Structure

While there are obvious differences in the structures of the two revised standards, this does not lead to distinct differences in the requirements. ISO 9001:2015 uses the structure specified in the ISO/IEC Directive, Part 1 (Annex SL) while ISO 13485:2016 continues with the structure developed in the previous versions. Both regulatory bodies and manufacturers continue to be concerned that any change to the structure and particularly the definitions of ISO 13485:2016 would cause issues within the medical device industry with little or no benefit as most medical device manufacturers have no specific need for those other management systems. Furthermore, the difference in structure has little effect on the requirements of the two standards. As mentioned in the background, users of the standard may refer to Annex B in ISO 13485:2016 which compares the structures of these two standards to identify the differences for cross-reference.

Scope

One of the biggest differences between the two standards begins with the scope statements. The scope of ISO 9001 defines it as a general and generic standard for all quality management systems while the scope of ISO 13485:2016 is specific to the medical device sector and those related services. Specifically, ISO 13485:2016 is aimed at including those quality management system requirements for organizations that provide medical devices and helping organizations concerned with medical devices ensure they meet not only the customer requirements but also the applicable regulatory requirements for the countries and regions where the medical devices are provided. This difference is further emphasized in the documentation requirements in ISO 13485:2016 for the design and development history, management review, medical device files, complaint handling, regulatory reporting and other regulatory focused documentation.

Focus

One big difference between the standards that is driven by the difference in scope is the primary focus of the results. The general nature and industries that use ISO 9001:2015 are driven by customer focus and making the correct risk-based decisions to drive customer satisfaction. Meanwhile, the focus of ISO 13485:2016 is primarily driven by the need to ensure that the medical devices placed on the market by organizations are safe and effective and meet regulatory requirements. This could be a challenge for organizations that are part of the medical device supply chain and choose to maintain certification to both standards. However, the standards do not have requirements that conflict and therefore can be implemented together with proper management focus as customer satisfaction aligns with provision of safe and effective product.

Required Processes

While ISO 13485:2016 maintains the requirements to document key processes and the related documentation in a quality manual and other processes, ISO 9001:2015 has taken a distinctly more flexible approach of allowing an organization to determine the documented information required to be maintained to ensure consistent results without directly stating the required documented information. However, organizations should be cautious of taking action to eliminate these documents as outlined below in the sections on documented information and risk-based thinking, so that they don't take any actions that could increase risk or cause issues in meeting requirements on retaining documented information.

Personnel Identification

The flexibility of ISO 9001:2015 allows top management to assign responsibilities and authorities without defining any required roles. This is similar in ISO 13485:2016 except the requirement to specifically identify a Management Representative is retained.

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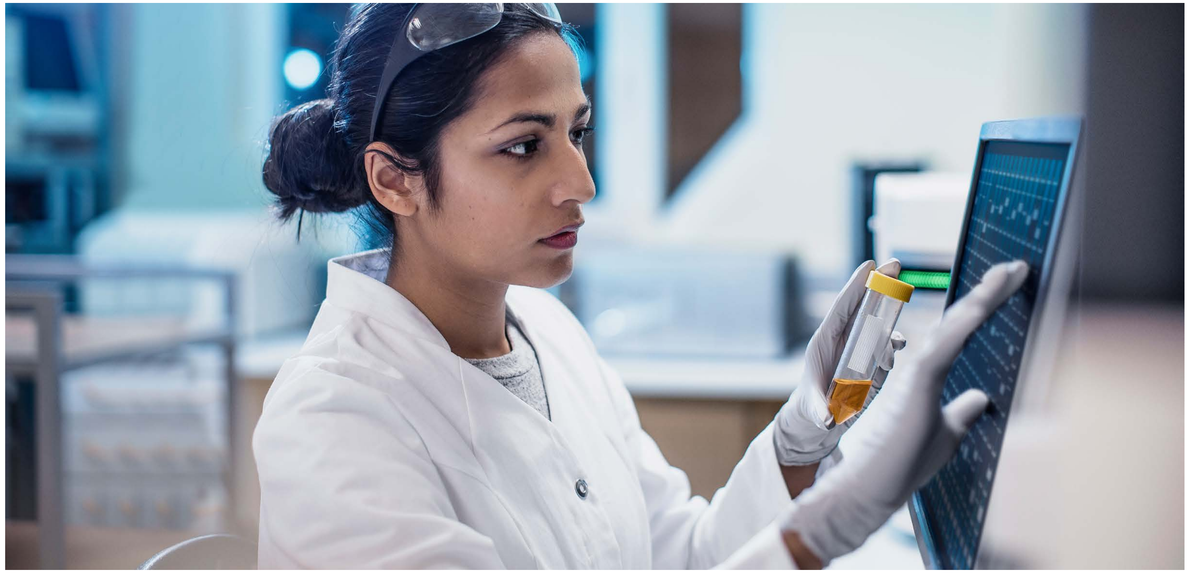
Product Realization

ISO 13485:2016 continues the strong emphasis on design and development as a key process within product realization. However, ISO 9001:2015 shifts this emphasis to the identification of operational processes to deliver product. This slight change encourages organizations to be more focused on their operations to ensure their product or service to meet the customer needs rather than the documentation of the design and development of product.

Continual Improvement

ISO 9001:2015 continues an emphasis on continual improvement to both enhance customer satisfaction and improve the processes of the organization. Meanwhile, ISO 13485:2016 maintains the need for organizations to focus improvement activities on the continuing suitability, adequacy and effectiveness of the quality management system and the safety and performance of the medical device. These differences drive the differing focus and could cause the organization's goals to be slightly different.



Terminology

Process approach – ISO 9001:2015 has added risk-based thinking directly into the Plan-Do-Check-Act (PDCA) concept. This has resulted in a new diagram of a process in ISO 9001:2015 and the new structure has also resulted in an update to the process approach model. By incorporating risk-based thinking in this area, the application integrates preventive action automatically into all processes as the organization must take action to reduce risk within the processes and prevent occurrence of any potential nonconformities through continual improvement.

Required Documentation – In ISO 9001:2015, the terminology used for "documentation" has changed to "Documented Information". In ISO 9001:2008 and in ISO 13485:2016, "documentation" includes "Documents" and "Records". This change was driven by the use of the new High-Level Structure outlined in the ISO/IEC Directive, Part 1 (Annex SL) and comes from the desire to provide a common term across Management System Standards. While this term has been changed in ISO 9001:2015, there is distinct common usage outlined by the word preceding the "documented information" term. When correlating to the term 'document', you will see the words 'maintain documented information' and the correlating use of 'record' has the words 'retain documented information'.

Note: Detailed guidance on 'documented information' is provided by TC 176/SC2/ on their website: http://isotc.iso.org/livelink/livelink/open/tc176SC2public

Relationships – Traditionally, within a quality management system, you have relationships identified between the organizations and their customers and the organization and its suppliers. These relationships have been identified with a more generic term of "interested parties" within ISO 9001:2015. This is due to the desire for more simplified language (not having to distinguish the roles within the standard) for an organization. However, ISO 13485:2016 keeps the previous terms to identify these roles consistently with the way they are designated in many of the medical device sector regulations.

Purchasing – ISO 13485:2016 retains the sub-clause on Purchasing (7.4) with some clarifications on supplier evaluation, selection and monitoring. Meanwhile, ISO 9001:2015 changes the identification of these processes and the associated controls to the use of "externally provided processes, products and services" (8.4). This change of language may allow a more generic look at who the organization considers to be its suppliers which could include relevant suppliers of information and guidance (e.g. regulators).

Top Management – The identification of top management within ISO 9001:2015 changes the name of the clause on Management to Leadership (5.0) to outline the roles of this important group. This change will likely put greater emphasis on the need for leadership engagement in the management of the requirements. Meanwhile, ISO 13485:2016 keeps much of the previous language with some updates to the content of management reviews. While this alignment, in ISO 13485:2016, of the information provided in management review with the improvement outlined in Clause 8 will likely drive better understanding by management of the improvement actions, it doesn't go as far as ISO 9001:2015 in engagement of management in those actions for improvement.

Definitions – Both standards use ISO 9000:2015 as a normative reference. However, ISO 13485:2016 has modified the definitions of the terms: Complaint, Product and Risk to align the definitions with those provided by the Global Harmonization Task Force and the regulatory requirements with a note to entry for each of these definitions within ISO 13485:2016. These more specific definitions in ISO 13485:2016 do not conflict, but organizations should pay attention to the details in those related processes to ensure requirements are met. In particular, the definition of 'risk' is likely one of the areas of greatest concern as the focus on product safety by the medical device sector as a driver. The definition in ISO 9000 (derived from ISO 31000), takes the focus away from the safety of the product by removing the direct connection to harms and could lead to conclusions on acceptability of risk that considers other (business) risks to drive decisions. The international community has to recognize this and continue to work to resolve this definition for all sectors where safety is the paramount concern.

These more specific definitions in ISO 13485 do not conflict, but organizations should pay attention to the details in those related processes to ensure requirements are met.

… and the similarities

While the two standards have some divergence in structure and some terminology, there are no conflicts in requirements and they have several similarities that allow them to work together. This should allow organizations who have or are looking to obtain certification to ISO 9001:2015 to also obtain or maintain a certification to ISO 13485:2016 if they so desire.

Reason for Using—Both standards continue to emphasize that the adoption of a quality management system is a strategic decision for an organization. Management of any organization that decides they want to use a quality management system should integrate the requirements of these standards into their strategic planning and ensure quality objectives are also aligned with the achievement of the organizational objectives.

Role of the Organization—Both revised standards have outlined the need for an organization to determine their role or purpose in the supply chain of delivering a product to the customer. This allows relevant people (interested parties) to understand the scope of the organization and determines the applicable requirements of the standard that apply to the organization.

Customer Focus—Both revised standards start the product realization process with determining customer needs to drive the requirements for the organization's product or service. While there is a small difference in how this is measured, as ISO 9001:2015 seeks customer satisfaction and ISO 13485:2016 asks organizations to demonstrate that customer requirements have been met, this minor difference is still the motivation for organizations to focus on the needs of the customer. In addition, the use of the phrase, "relevant interested parties" can help organizations realize that regulators are part of this customer group.

Methodology—Both revised standards have maintained the use of process approach with the Plan-Do-Check-Act (PDCA) cycle as the core methodology that follows from the quality principles outlined in ISO 9000.

Risk-based—Both revised standards advocate the use of risk assessments as the basis of making decisions along with the application of risk-based controls to the processes of the quality management system. The driver of this approach in both standards is to remove the arbitrary approach that doesn't consider the actual application. ISO 9001:2015 does take this a step further by integrating risk-based thinking as a key concept within the process approach and eliminating the separate sub-clause on preventive action, however this could be adopted to meet the requirements of ISO 13485:2016 for preventive action as well.

Competency—The updates to each of these standards has reflected a shift from the identification of training needs to ensuring the competency of employees. This will likely have the effect that organizations will have to determine the way to show that their employees are able to do the job they are assigned. Again, ISO 9001 takes this a bit further in the new clause (7.1.6) on organizational knowledge, but this also would be a good requirement for ISO 13485:2016 organizations to adopt as a best practice.

Infrastructure —Both revised standards have a renewed emphasis on the determination of the necessary buildings, equipment and other resources (including information technology) that are needed for processes and for ensuring product conformity. This is only further emphasized in ISO 13485:2016 with regard to cleanliness of environment and contamination control required in assembly or packaging of product.

Analysis of Data—Another key concept emphasized in both revised standards is the need to use the appropriate statistical techniques in the analysis of data to drive the actions of the organization.

Both standards continue to emphasize that the adoption of a quality management system is a strategic decision for an organization.

Final Summary

As organizations seek to make strategic decisions on the implementation of a quality management system, they need to understand how the similarities and differences between the two revised standards can affect those decisions. Over the last several years, we continue to see how these standards work together with no direct conflicts within their Quality Management System to achieve the goals and objectives of their organization. Both Technical Committees (TC 176 and TC 210) are keenly aware of the need to ensure these two critical standards will need to maintain this relationship and Top Management of organizations should seek to understand any changes in this context. The next editions of both standards will be undergoing revision in in 2024 or 2025 with key decisions on the structure and definitions in the hands of the ISO organization.

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QRx Partners is focused on helping small to mid-sized companies have the same regulatory and quality systems knowledge as the large medical device companies. Mark is an active member of ISO Technical Committee 210 (TC 210), Working Group 1 (WG1) working on ISO 13485:2016 and also is the liaison member from ISO TC 210 to ISO TC 176/SC2 (the subcommittee for ISO 9001). In addition, Mark is the liaison member for TC 262 (ISO 31000) working on the resolution of the risk management requirements including the definition of “risk”. This work includes discussions regarding the impact of changes in the ISO quality management system standards, the integration of various standards and how to effectively integrate the different management system standards and other regulations into a single quality management system.

Reviewers

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Scott is currently the ISO TC 210 Working Group 1 Convener and responsible for ISO 13485:2016 - *Medical devices — Quality management systems — Requirements for regulatory purposes*. In addition, he teaches as an adjunct professor in St. Cloud State University's Master of Regulatory Affairs and Services program and maintains various global leadership positions promoting convergence of medical device regulations. Previously, he held the position of International Regulatory Affairs and Quality Director in 3M's Health Care Business.

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Paul has worked in the healthcare industry for over 35 years, joining BSI in 2010 to lead the organization in Saudi Arabia where it had been designated as a Conformity Assessment Body. Later, he managed BSI's Unannounced Audits programme. Since October 2015, he has been working with both the Notified Body and Standards organizations looking at how best to use the knowledge, competencies and expertise in both. Previously he held senior RA/QA leadership positions at Spacelabs Healthcare, Teleflex Medical, Smiths Medical and Ohmeda (formerly BOC Group healthcare business). Paul is a member of the Association of British Healthcare Industries (ABHI) Technical Policy Group and Convenor of the ABHI ISO TC 210 Mirror Group. He is Convenor of the BSI Committee that monitors all of the work undertaken by ISO TC 210, and Convenor of the BSI Subcommittee dealing with quality systems. As UK Delegation Leader to ISO TC 210, he is also actively involved in the work of national, European and international standards' committees.

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Eamonn is a technical author, trainer and consultant in a range of life science areas including regulatory compliance, quality management, sterility assurance and standards development. He worked for Johnson & Johnson for 17 years in positions of increasing responsibility for Quality and Regulatory Compliance for medical devices, pharmaceuticals and consumer products, including Vice President of Compliance, Vice President of Market Quality and leading quality implementation for the EU medical devices regulation for J&J's Medical Devices companies. Prior to joining J&J, Eamonn spent 16 years with the UK Medical Devices Agency, including six years as Head of Device Technology and Safety. Eamonn is currently chair of ISO TC 198, 'Sterilization of Healthcare products', chair of CEN TC 204, 'Sterilization of medical devices' and past chair of ISO TC 210, 'Quality management and related general aspects for medical devices'. He received the BSI Wolfe-Barry medal in 2016 for his contribution to standards development.

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Anette has over 30 years' experience in the medical device and pharma industries, as QA, RA, QP and the tasks within the medical fields such as quality and risk management, clinical affairs, toxicology and biocompatibility. She is a member of the Swedish (TK 355) and the international technical (TC 210) committees since 2010. Anette has been a consultant with PREVENTIA since 2003. She holds an MSc in Biomedicine.

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