The differences and similarities between ISO 9001:2015 and ISO 13485:2016

Can we integrate these quality management standards?

Mark Swanson, President and Lead Consultant, H&M Consulting Group

bsi.

...making excellence a habit.™

Preface

Given the recent revisions of two of the most used quality management system standards, there have been many questions about what this means for organizations who have had certification to either or both standards. This is particularly true with the move of ISO 9001:2015 (and other management system standards) to the new ISO/IEC high level structure (HLS) that comes from Annex SL of the ISO/IEC Directives, Part 1.

The intent of this document is to provide insight into some of the differences and similarities between ISO 9001:2015 and ISO 13485:2016, to allow organizations to understand how they can work together for those 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. The first edition of ISO 13485 followed in 1996. In 2000, the third edition of ISO 9001 was published and ISO 13485 was revised in 2003 to align with that revision. 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.

Now, 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 in March 2016. These two standards have always been very closely aligned, as the 1996 and 2003 versions of ISO 13485 were directly based on ISO 9001 (1994/2000). This was readily apparent in ISO 13485:2003 as much of the text is identical to the text from ISO 9001:2000. In this second edition of ISO 13485, the identical text was shown in black standard font and different text was provided in black italic font (blue italic font in electronic versions). In addition, ISO 9001:2008 took on more similarities to ISO 13485:2003.

The fifth revision of ISO 9001 was originally behind the third revision of ISO 13485, but due to some delays in the approval of the draft version of ISO 13485, the revision of ISO 9001 was published first (September 2015). As with all revision work, some of the latest changes published in ISO 9001:2015 were not available to be incorporated into the revision of ISO 13485. In addition, after much deliberation on the design specification for ISO 13485, ISO Technical Committee 210, Working Group 1 (ISO/TC 210, WG 1), the working group responsible for the revision of ISO 13485:2003, decided it was not appropriate during this revision cycle to adopt the formatting and text changes mandated by Annex SL of the ISO/IEC Directives, Part 1 for the HLS for management system standards. Also, being aware of the change in structure and content of ISO 9001, ISO/TC 210, WG 1 decided not to maintain the different font or provide the comparison back to ISO 9001:2008, however a clause structure comparison to ISO 9001:2015 (Annex B) is provided. Furthermore, ISO/TC 210, WG 1 has informed the ISO Technical Management Board (TMB), via resolutions, that it intends to do two things in the short term. Firstly, it has adopted a resolution to initiate discussions with the relevant interested parties (e.g. medical device regulators, manufacturers and certification bodies) to enable future alignment with the HLS outlined in Annex SL of the ISO/IEC Directives, Part 1. This will likely result in a mapping of this third revision into the HLS in the ISO/IEC Directives to understand the differences. Secondly, it will accelerate the next systematic review to the end of the outlined transition period (3 years) instead of the 'normal' 5-year cycle. At that point in time, the working group will again consider the adoption of the HLS for management system standards.

Introduction

With the change of ISO 9001 to the new HLS, the content of the two standards has diverged. While this divergence may cause some concern in organizations where both standards are relevant, the knowledge of the differences (and similarities) will hopefully help you better understand how your organization may react to these new revisions and mitigate these concerns.

While many people may focus on the differences between the two standards, it is the similarities that are more prevalent and the value in how these two standards can be used together that will provide industry with the greatest insight and corresponding strategic direction. Outlined below are the differences followed by the similarities between the two standards. Much of the content of the standards may be in both sections since while there are

Device for designing dental equipment

several differences in the terminology and structure, there are no direct conflicts between the requirements of the two standards. ISO 9001:2015 and ISO 13485:2016 work together to outline a quality management system for organizations concerned with providing products within the supply chain of medical devices.

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 new structure specified in Annex SL of the ISO/IEC Directives, Part 1, while ISO 13485:2016 continues with the structure developed in the previous versions. This new HLS was developed by ISO to implement a common structure and terminology with simplified language, to help organizations that are implementing multiple management systems (such as those for environment, health and safety or business continuity) to integrate those systems. The main reason the exemption was granted by the ISO TMB for ISO 13485:2016 was to allow the working group to keep the standard well aligned with the regulations in most of the member countries. While this difference may cause some difficulties, most organizations that have a connection to the medical device sector will appreciate the continued consistency of the structure of ISO 13485,especially as the difference in structure has little effect on the requirements of the two standards. As mentioned in the background section, users of the standard may refer to Annex B in ISO 13485:2016, which compares the structures of the two standards, to identify the particular 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 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 history, management review, medical device files, complaint handling, regulatory reporting and other regulatory focused documentation.

Focus

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

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 required documentation and risk (in similarities), 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. In ISO 13485:2016, the requirement to specifically identify a management representative is retained.

Assembling medical devices

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 products. This slight change encourages organizations to be more focused on their operations to get products or services to meet the customer needs rather than the documentation of the design and development of the products.

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 automatically integrates preventive action into all processes as the organization is required to 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 HLS outlined in Annex SL of the ISO/IEC Directives, Part 1, and 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 term "documented information". When "documented information" correlates to documents, the word "maintain" is used, i.e. "maintain documented information"; when it correlates to records, the word "retain" is used, i.e. "retain documented information". Note: Detailed guidance on "documented information" is provided by ISO/TC 176/SC 2 on their website: http://isotc.iso.org/livelink/livelink/open/tc176SC2public

Relationships — Traditionally within a quality management system, relationships are identified between the organization and its 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 retains 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 subclause 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.

Top management — The identification of top management within ISO 9001:2015 has led to a change in the name of Clause 5 from "Management" to "Leadership", 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 of the information provided in management review with the improvement outlined in Clause 8 will likely increase management understanding of the improvement actions, it doesn't go as far as ISO 9001:2015 in the engagement of management in those actions.

Definitions — The definitions of the terms "complaint", "product" and "risk" are different in the two standards. ISO 13485:2016 has aligned the definitions with those provided by the Global Harmonization Task Force and the regulatory requirements. These differ slightly from those provided in ISO 9000:2015 (Note: ISO 9001:2015 refers to ISO 9000:2015 for all definitions). This is stated in a note to entry for each of these definitions within ISO 13485:2016.

... and the similarities

While the two standards have some divergence in structure and terminology, they have several similarities that allow them to work together without conflict. This should allow organizations who have or are looking to obtain certification to ISO 9001:2015 to also obtain or maintain certification to ISO 13485:2016.

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 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 products or services. 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.

Methodology

Both revised standards have maintained the use of the 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 and the application of risk management to quality management system processes, however ISO 9001:2015 takes this a step further by integrating risk-based thinking as a key concept within the process approach and eliminating the separate subclause on preventive action.

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 is likely to result in organizations having to determine a way to show that their employees are able to do the job they are assigned.

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

An operating room in hospital

conformity. This is 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 data analysis to drive the actions of the 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 ISO 9001:2015 and ISO 13485:2016 can affect those decisions. Top management of organizations should seek to recognize how each of these two revised standards can work separately or together within their quality management system to achieve the goals and objectives of their organization.

BSI is grateful for the help of the following people in the development of the white paper series.

Author

Mark Swanson, President and Lead Consultant of H&M Consulting Group

The H&M Consulting Group is focused on helping small to mid-sized companies have the same regulatory and quality systems knowledge as the large medical device companies. In addition to this, Mark is also the Director of the Medical Technology Quality graduate programme at St. Cloud State University. Mark has spent the last three years as an active member of ISO Technical Committee 210, Working Group 1 (ISO/TC 210, WG 1) working on the revision of ISO 13485:2003 and has also participated with ISO/TC 176, WG 24 on ISO 9001:2015. 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.

Expert Reviewers

Edward R. (Ed) Kimmelman, Regulatory Affairs/Quality Systems Consultant

Since 1998 Ed has provided consultancy services in the areas of regulatory compliance and quality management systems. During a 35-year career in industry he has served in engineering, product management and senior quality systems management positions. Ed is a former President of the NCCLS (currently CLSI) and has served as Chairman of the HIMA (currently AdvaMed) Standards Section and Science & Technology Section. He is currently the convenor of the ISO/TC 210, WG 1 on quality systems. He has co-authored a reference book, *The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices*, 2nd edition, ASQ:Quality Press, 2008. Ed received a BS degree in Mechanical Engineering from Cornell University and a JD degree from the Seton Hall University School of Law.

Amy L. Peterson, MA, Senior Regulatory Affairs Specialist

Amy has 5 years of regulatory experience in the medical device industry both at an industry-leading corporation and a smaller device company. Her background includes working on a wide variety of US and international medical device regulatory projects with cardiovascular and general surgery products. She is a member of the Regulatory Affairs Professionals Society (RAPS) and has an MA in Organizational Leadership.

Paul Sim, Regulatory Affairs Manager, BSI Healthcare

Paul has worked in the healthcare industry for over 30 years and is currently project managing BSI's implementation of EU Commission Recommendation 2013/473/EU dealing with Unannounced Audits. Previously he held senior RAQA leadership positions at Spacelabs Healthcare, Teleflex Medical, Smiths Medical, and Ohmeda (formerly BOC Group healthcare business). His experience spans a broad range of medical devices including anaesthesia systems, patient monitors, ventilators, single use sterile disposables and devices for re-use, incubators, infusion pumps and surgical instruments. 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 which 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 UK, European and international standards committees. Paul has published articles in medical device industry journals, presents at conferences, and is a Module Advisor at Cranfield University on a Master's programme dealing with regulatory affairs for medical devices.

Advisory Panel

Jane Edwards, Global Product Manager, BSI

Jane holds a BSc in Chemistry and an MBA from Durham University. She has over 10 years' experience in the medical device industry, having previously worked for Coloplast in their ostomy and continence business. Jane's experience includes working within the pharmaceutical, chemical and telecoms industries for Glaxo Wellcome, ICI and Ericsson, allowing her to bring depth of knowledge from across many industries and technologies. Her current role at BSI allows her to work with technical reviewers across all disciplines ensuring that all BSI communications are accurate and relevant. She is a member of the European Medical Writers Association.

Terry Longman, Standards Consultant

Terry has been employed in the medical equipment industry all his working life. Having qualified as a mechanical engineer he then, over the following 40+ years, experienced both sides of the medical industry, the technical side and the commercial side, with various companies that manufactured everything from capital medical equipment to consumable medical devices. Since 1995 he has been a self-employed consultant specializing in all matters related to standards including advising companies on compliance with the European Medical Device Directive and US FDA directives. He represents the members of the British Anaesthetic and Respiratory Manufacturers Association (BAREMA) at BSI meetings. BAREMA comprises manufacturers from all parts of the

anaesthetic and respiratory industry. He also represents several individual companies at ISO and CEN meetings. Terry is on several UK, European and international standards committees, the following as Chairman: CEN/TC 215, CH/121, CH/121/1, CH/121/5, CH/121/9 and CH/210/5.

Pete Philips, Director of the Surgical Materials Testing Laboratory (SMTL)

Pete is the Director of the Surgical Materials Testing Laboratory (SMTL), based in Bridgend in South Wales, which is funded by the Welsh Government to test medical devices for the Welsh NHS and to provide technical advice on medical devices. He has worked in the medical devices field for over 30 years, and sits on a number of BSI, CEN and ISO medical device committees and groups. He chairs the Welsh Non-Luer Connectors Reference Group (WNCRG) for the Welsh Government, which is coordinating the implementation of new ISO compliant non-Luer connectors across the Welsh NHS, and represents the Welsh Government on medical devices on various other groups.

Published white papers

The Proposed EU Regulations for Medical and In Vitro Diagnostic Devices: An Overview of the Likely Outcomes and Consequences for the Market, Gert Bos and Erik Vollebregt

Generating Clinical Evaluation Reports – A Guide to Effectively Analysing Medical Device Safety and Performance, Hassan Achakri, Peter Fennema and Itoro Udofia

Effective Post-market Surveillance – Understanding and Conducting Vigilance and Post-market Clinical Follow-up, Ibim Tariah and Rebecca Pine

What You Need to Know About the FDA's UDI System Final Rule, Jay Crowley and Amy Fowler

Engaging Stakeholders in the Home Medical Device Market: Delivering Personalized and Integrated Care, Kristin Bayer, Laura Mitchell, Sharmila Gardner and Rebecca Pine

Negotiating the Innovation and Regulatory Conundrum, Mike Schmidt and Jon Sherman

The Growing Role of Human Factors and Usability Engineering for Medical Devices: What's Required in the New Regulatory Landscape? Bob North

ISO 13485: The Proposed Changes and What They Mean for You, Bill Enos and Mark Swanson

How to Prepare for and Implement the Upcoming MDR: Dos and Don'ts, Gert Bos and Erik Vollebregt

Forthcoming white papers

The Future of Standards in Europe – Harmonization and other Recognitions of Standards (working title)

How to Prepare for and Implement the Upcoming IVDR: Dos and Don'ts, Gert Bos and Erik Vollebregt

Sterilization Practices in Response to Device Innovation (working title)

Getting your Clinical Data: Away from Clinical Equivalence in Europe (working title)

Cyber Security for Medical Devices (working title)

The Convergence of Pharmaceuticals and Medical Development (working title)

About BSI Group

BSI (British Standards Institution) is the business standards company that equips businesses with the necessary solutions to turn standards of best practice into habits of excellence. Formed in 1901, BSI was the world's first National Standards Body and a founding member of the International Organization for Standardization (ISO). Over a century later it continues to facilitate business improvement across the globe by helping its clients drive performance, manage risk and grow sustainably through the adoption of international management systems standards, many of which BSI originated. Renowned for its marks of excellence including the consumer recognized BSI Kitemark™, BSI's influence spans multiple sectors including aerospace, construction, energy, engineering, finance, healthcare, IT and retail. With over 70,000 clients in 150 countries, BSI is an organization whose standards inspire excellence across the globe.

BSI is keen to hear your views on this paper, or for further information please contact us here:
julia.helmsley@bsigroup.com

Disclaimer – This white paper is issued for information only. It does not constitute an official or agreed position of BSI Standards Ltd. The views expressed are entirely those of the authors. All rights reserved. Except as permitted under the Copyright, Designs and Patents Act 1988, no part of this publication may be reproduced without prior permission in writing from the publisher. Whilst every care has been taken in developing and compiling this publication, BSI accepts no liability for any loss or damage caused, arising directly or indirectly in connection with reliance on its contents except to the extent that such liability may not be excluded in law. Whilst every effort has been made to trace all copyright holders, anyone claiming copyright should get in touch with BSI at any of the addresses below.

This paper was published by BSI Standards Ltd.

For more information please visit:
http://www.bsigroup.com/en-GB/our-services/medical-device-services/BSI-Medical-Devices-Whitepapers/

bsi.

BSI Group Headquarters
389, Chiswick High Road
London W4 4AL
United Kingdom

T: +44 (0) 845 086 9001
E: cservices@bsigroup.com
bsigroup.com

BSI UK
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes MK5 8PP
United Kingdom

T: +44 (0) 845 080 9000
E: MK.customerservices@bsigroup.com
bsigroup.com

BSI Group America Inc
12950 Worldgate Drive
8th Floor Monument II
Herndon
VA 20170
USA

T: +1 800 862 4977 / 703 437 9000
E: inquiry.msamericas@bsigroup.com
bsiamerica.com