Transition of ISO 13485 2003 to 2016

An International Pharmaceutical Supply Chain Consortium

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1. Introduction

a. Purpose

The purpose of this paper is to describe the recent changes between ISO 13485:2003 & ISO 13485:2016. What the changes entail and recommendations for addressing them. This does not compare the new ISO 13485:2016 Industry Standard to Country Regulatory Body Regulations (e.g., US FDA Code of Federal Regulations Title 21 Part 820).

b. Scope

This paper only covers the changes to ISO 13485:2003 to ISO 13485:2016. It does not cover comparisons or changes between any other standards related to medical device regulatory standards or country specific versions of ISO 13485.

2. Background on Changes

ISO 13485 is an internationally recognized quality management standard for organizations involved in the development, manufacture and distribution of medical devices. The standard was first published in 1996. It was updated in 2003 and again recently in 2016.

Manufacturers of medical devices and other organizations that hold an ISO 13485 certificate are required to address the requirements of the new standard. This should be done as soon as it is possible as delays in transitioning over can lead to interruption or even cancellation of their registration. Organizations must allow time so they can assess the extent of the changes that they need to implement in their existing Quality Management System (QMS) to be compliant with the new standard.

The ISO 13485 standard was revised for a number of reasons:

- The Standard had not been updated in more than 10 years.
- To stay current with changes rapidly changing requirements in the medical device industry while addressing the increased risks.
- Globalization-a need to have a harmonized model as the industry becomes more international.

- ISO 13485:2016 is now better in sync with the existing 21CFR820. Also, this version of the standard supports FDA terms, such as establish, documented processes and also clarifies regulatory requirements relative to device safety and performance.
- The 2016 version's release addresses changes due to the release of the new ISO 9001:2015 standard. ISO 13485:2003 was based on the old ISO 9001:2000 standard while the ISO 13485:2016 is structured on the ISO 9001:2008. The governing body, ISO TC 210 decided the former ISO 9001:2008 is structured to better align with the needs of medical device suppliers, regulators, and customers.

3. Why is it important?

- The 2016 version requires a risk-based approach for the entire quality management system, including the processes of:
    - Design and development
    - Verification, validation and revalidation
    - Product planning (i.e., input manufacturing into design considerations)
    - Documentation of risk management in product realization
    - Monitoring, testing and traceability
    - Corrective actions and preventive actions (CAPA)

This risk-based approach must also apply to outsourced processes and suppliers. Furthermore, device manufacturers must ensure that the training third-parties receive is commensurate with the inherent risk of the processes contracted to them to perform.

The impact of the revised standard will be significant on organization leadership:

- Management reviews must specifically address how risk management is incorporated into all of the areas presented in the reviews.
- The responsibilities of top management, emphasizing the effectiveness of the QMS and measurable quality objectives are clarified.
- All personnel will also be impacted. Specifies that the organization will have to determine any user training needed to ensure specified performance and safe use of the medical device. Quality is everyone's responsibility, including organization leadership and not just those functions that have quality in the name.

4. Key Changes

Listed below are the key changes 13485:2003 to 2016:

- ISO 13485 2016 incorporates a risk management approach for product realization as well as post market surveillance. Risk is considered in the context of the safety and performance of the medical device.
- Increased emphasis of regulatory requirements, especially for regulatory documentation.
- Harmonization of the requirements for software validation for different software applications.
- Emphasis on appropriate manufacturing infrastructure, particularly for production of sterile medical devices. This includes validation of processes especially for sterilization.
- Additional requirements for design and development.
- Additional requirements on complaint handling and reporting to regulatory authorities.
- Increased requirements for planning and documenting corrective action and preventive action.

For a detailed explanation of all the changes see section 5a.

It is up to every ISO 13485 system owner to analyze all the changes from 2003 to 2016 for their own organization.

5. Required Steps to make changes

Below is a table of the recommended steps to assess changes:

Step	Action
1	Obtain a licensed copy of both ISO 13485:2003 and ISO 13485:2016.
2	Compare each section of ISO 13485:2003 with the corresponding section of ISO 13485:2016. *NOTE: It is also recommended to compare corresponding sections of 21 CFR 820 to ISO13485:2016, as some of the changes from ISO 13485:2003 to ISO 13485:2016 resulted in greater similarity with 21 CFR Part 820.*
2	Highlight or notate the differences in text that are potentially significant differences.

Step	Action
3	Create a checklist with the following columns *(reference section 5a of this paper)*: • Section Reference (reference to the section of ISO 13485:2016 being assessed) • Use the highlighted text differences and the Appendix A of ISO 13485:2016 to develop a description of differences in text between ISO 13485:2003 and ISO 13485:2016 at a detailed level • Gaps in Internal Processes and/or Quality System – indicate whether gaps exist for your organization (Yes/No) • Remediation Activities for Gaps / Evidence for No Gaps – detail the remediation activities needed with specific reference to individual quality system documents, processes, IT systems and the changes required to address the gaps; if no gaps exist, include the evidence supporting this conclusion • Owner – indicate who is responsible to completing each remediation activity; note that there may be more than one remediation activity; therefore, there may be more than one owner; if no gaps exist, indicate N/A in this column • Risk – assess the risk of the gap using your organization's risk criteria *(reference section 5b of this paper)* NOTE: If no gaps exist, indicate N/A in this column • Estimated Completion Date – use the required work/effort needed to complete each remediation action and the assessed risk to develop an estimated completion date for each remediation action; if no gaps exist, indicate N/A in this column *(reference section 5c of this paper)*
4	Communicate the assessed risk and the action plan(s) to senior management. *NOTE: Ensuring the health of the QMS is a management responsibility detailed in ISO 13485.*
5	Incorporate the remediation actions into the appropriate quality system record(s): e.g., change control record, quality plan, CAPA, etc. to ensure that the remediation actions are monitored and closed on time. *(Reference section 5d of this paper)*

a. Gap Assessment – Check List

Note: Only the first few rows contain a full example for each column; subsequent rows provide a guide on the likelihood the change will result in a gap requiring remediation (No – Unlikely and Yes - Likely) and examples of what to consider when assessing for gaps are contained in the "Evidence for No Gap / Remediation Action(s) for Gaps" column.

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
Forward	No significant changes	N/A	N/A	N/A	N/A	N/A
Introduction 0.1 General, first paragraph	Revised text speaks to the life-cycle stages of a medical device and added the stages of storage and distribution, and final decommissioning and disposal of medical devices	Yes - Likely	*Evidence for No Gap* • Life-cycle approach embedded in QMS as noted in SOP-QM, the organization's Quality Manual • Storage and distribution requirements included in SOP01, section X.X • Final decommissioning requirements detailed in SOP01, section Y.Y *Remediation Action(s) Required* Incorporate "disposal of medical devices" into QMS as follows: 1. SOP-RM – incorporate severity criteria for environmental impact 2. SOP-DI – incorporate that design inputs must address the environmental impact of the disposal of the medical device 3. SOP-DP/SOP-RM -- incorporate, as appropriate, Environmental, Health and Safety experts into design/ risk management planning and processes	Assess per organization's risk management definitions of severity	1. Diego Sanchez 2. Sharon Cantor 3. Deja Williams	1. 31-Dec-2018 2. 31-Dec-2018 3. 19-Mar-2019

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
0.1 General, second paragraph	New paragraph indicating suppliers or other parties can voluntarily choose to conform to the requirements of the standard	No – Unlikely	*Evidence for No Gap* • Text speaks to voluntary use of the standard • No requirements contained in this section of the standard	N/A	N/A	N/A
0.1 General, third paragraph	New paragraph that highlights the obligations of organizations, specifically including requirements regarding the identification of the organization's role with respect to regulations, identification of what requirements are applicable to the organization based upon those identified roles and the requirement for the organization to incorporate these requirements into the quality system	No – Unlikely	*Evidence for No Gap* • Organization's role with respect to specific regulations is identified and documented in the Quality Manual, SOP-QM, section X.X • The requirements within the organization's roles that do NOT apply are documented in SOP-QM, section Y.Y • Organization has a tool, which maps key regulations, standards and guidance documents directly to the contents of QMS documents	N/A	N/A	N/A

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
0.1 General, third paragraph, first bullet	New paragraph noting that the definitions of terms within the standard may vary from the definition of those same terms within regulation and that the organization needs to understand these differences for proper interpretation	No – Unlikely	*Evidence for No Gap* Organization maintains a glossary that has reviewed all applicable regulations and developed definitions for terms based upon the use of a term within the QMS	N/A	N/A	N/A
0.1 General, fourth paragraph	Revised text specifically highlights that the organization's quality management system should reflect customer and regulation requirements applicable to the organization and emphasizes that ISO 13485 is complementary to technical requirements for the product to ensure safety and performance.	Yes – Likely	*Remediation Action(s) Required* Incorporate clear definitions for the terms safety and performance into the organization's glossary to ensure consistent interpretation across the organization	Assess per organization's risk management definitions of severity	Chin Lu	31-Mar-2019

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
0.1 General, fifth paragraph	Revised text adds that both organizational environment and regulatory requirements impact the design and implementation of an organization's quality management system	No – Unlikely	*Evidence for No Gap* • Organization's QMS reflects applicable regulations as evidenced by mapping of QMS to health authority requirements and vice versa • Organization's business processes for QMS updates and continuous improvement incorporates the organizational structure and needs			
0.1 General, sixth paragraph	Revised text clarifies it is not the intent of the standard to imply that the structure of an organization's QMS must conform to the structure of the standard	No – Unlikely	*Evidence for No Gap* • Clarification for interpretation of the standard • No actual change in expectations			
0.1 General, seventh paragraph	No significant changes	N/A	N/A			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
0.2 Clarification of concepts, first paragraph	New clause; this new paragraph provides clarity on the use of the term "as appropriate" in the standard and when the standard would consider a requirement to be appropriate	Yes – Likely	*Remediation Action(s) Required* 1. Review each "as appropriate" requirement in ISO 13485:2016 to confirm that organization's quality manual provides justification for why certain requirements in ISO 13485:2016 are not appropriate and that the organization has not considered a requirement "not appropriate" when it is necessary for meeting product requirements, compliance with regulations, addressing corrective actions or managing risk per the standard 2. Organization's QMS defines the phrases "as appropriate", "as applicable", etc. when used within the organization's QMS			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
0.2 Clarification of concepts, second through seventh paragraphs	Entirely new clause; this paragraph provides clarity on the use of the terms "risk", "documented", "product", "regulatory requirements", "shall", "should", "may" and "can" within the standard and when information in the standard is preceded by the word NOTE.	No – Unlikely	*Evidence of No Gap* New clause provides clarification for interpretation of the standard. HOWEVER, in order for the standard to be appropriately interpreted and incorporated into the organization's QMS it is important for interpreters of ISO 13485 to understand the use of this term within the standard. This is especially important for • The term "documented" as 21 CFR 820.3(k) states "Establish means define, document (in writing or electronically), and implement" whereas, ISO 13485 has the term "establish" and "maintain" as part of the definition of "document" • The term "regulatory requirements" in that the term includes "any law applicable to the user" of ISO 13485, but for the purposes of interpretation of ISO 13485 it is specific to requirements for the QMS and the safety and performance of the device			
0.3 Process approach, all paragraphs	Revised text provides additional detail on the process-based approach to quality management utilized within the standard	No – Unlikely	*Evidence of No Gap* Provides background on the approach utilized within the standard; however, no requirements contained in this clause of the standard			
0.4 Relationship with ISO 9001	No significant changes	N/A	N/A			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
0.5 Compatibility with other management systems	Reference to ISO 9001 was removed	No – Unlikely	*Evidence of No Gap* Organization built its QMS based upon the regulations and this standard; this is shown by mapping of QMS to health authority requirements and vice versa. Applicability or non-applicability of ISO 9001 was not assessed based upon Organization's QMS' adherence to ISO 13485.			
1 Scope, first paragraph	Revised text speaks to the life-cycle stages of a medical device and to the voluntary use of the standard	Yes – Likely	*Remediation Action(s) Required* Reference remediation activities documented for 0.1 General, first paragraph and 0.1 General, second paragraph			
1 Scope, second paragraph	Revised text speaks to the organizations to which the standard applies, specifically that size has no bearing and that the requirements apply to both the product supplied by the organization as well as services supplied.	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
1 Scope, third paragraph	Revised text specifically calls out that the organization that outsources activities retains the responsibility for adherence to the standard	Yes – Likely	*Remediation Action(s) Required* Organization utilized a risk-based approach and transferred risk when activities were outsourced through documented quality agreements and business processes 1. Review QMS documents where risk was specifically transferred to ensure appropriate understanding of the organization's responsibility for adherence to the standard. 2. Review existing quality agreements based upon new understanding and develop plan to address any misalignment of responsibility for adherence to this standard, as appropriate			
1 Scope, fourth paragraph	Revised text clarifies the scope of the term "regulatory requirements"	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
1 Scope, fifth a paragraph	Revised text clarifies how "non-applicability" justification is documented, specifically by reference to sub-clause 4.2.2 of the standard, which requires documentation within the quality manual	No – Unlikely	*Evidence of No Gap* SOP-QM (Quality Manual) is compliant with clause 4.2.2 a) of ISO 13485:2003, which already includes the requirement for the quality manual to contain this information			
2 Normative references	Revised text clarifies that normative references "in whole or in part" are indispensable for the application of ISO 13485	No – Unlikely	*Evidence of No Gap* Clarification only; no requirements contained in this clause of the standard			
3 Terms and definitions, all sub-paragraphs	New and refined definition of terms.	Yes – Likely	*Remediation Action Required* Incorporate new and refined definitions for the terms into the organization's glossary to ensure consistent interpretation across the organization.			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
4.1.1 General Requirements, first paragraph	Revised text emphasizes that an organization's QMS is to be documented and its effectiveness maintained in accordance with BOTH the standard and applicable regulatory requirements	No – Unlikely	*Evidence for No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa			
4.1.1 General Requirements, second paragraph	New paragraph emphasizing the life-cycle management of the QMS itself	No – Unlikely	*Evidence of No Gap* SOP411 utilizes a life-cycle approach to maintain QMS documents and systems			
4.1.1 General Requirements, third paragraph	New paragraph requiring the QMS to document the roles the organization performs	Yes – Likely	*Remediation Action Required* Document in SOP-QM the various roles the organization performs, e.g., manufacturer, authorized representative, importer or distributor. NOTE: Consider the "economic operator" roles detailed in the EU Medical Device Regulation.			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
4.1.2 General Requirements	Revised text emphasizes that the QMS should include requirements based upon the documented roles the organization performs and the use of a risk-based approach for controlling the processes required	No – Unlikely	*Evidence for No Gap* • Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa			
4.1.3 General Requirements	Revised text emphasizes the requirement to monitor the effectiveness of the QMS processes and to maintain records of conformance to the standard	No – Unlikely	*Evidence for No Gap* SOP553 is compliant with ISO 13485:2003 clause 5.5.3, which requires top management to communicate the effectiveness of the QMS. In order to communicate the effectiveness, the effectiveness must be monitored, which is required by SOP51.			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
4.1.4 General Requirements	New paragraph detailing how changes to the QMS processes must be evaluated for impact on the QMS and products and that these process changes must be controlled per the standard	Yes – Likely	*Evidence for No Gap* • SOP542 is compliant with ISO 13485:2003 clause 5.4.2 b) which requires the integrity of the QMS be maintained when changes are implemented • Changes to QMS documents are required to follow the organization's change control SOP (SOP-CC), which requires evaluation of QMS changes on the QMS documents and processes *Remediation Action(s) Required* Revise SOP542 to include how changes to QMS should include assessment of the impact of said changes on products			
4.1.5 General requirements	Revised text specifically calls out that the organization that outsources activities retains the responsibility for adherence to the standard	Yes – Likely	*Remediation Action(s) Required* Reference remediation actions noted for 1 Scope, third paragraph			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
4.1.6 General requirements	Revised text adds the requirement for validation of computer systems used in the execution of the QMS processes, that the approach used be based upon the risk associated with the use of the computer system and requires records of said validation be kept	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			
4.2.1 Document requirements, General	Adds the control of records within the scope of this sub-clause of the standard; clarifies that this applies to records the organization has determined "to be necessary" and emphasizes that other requirements may be relevant per applicable regulatory requirements	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			
4.2.2 Quality manual	No significant changes	N/A	N/A			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
4.2.3 Medical device file	New sub-clause adding a requirement for the creation and maintenance of a "medical device file"	No – Unlikely	*Evidence of No Gap* Organization's QMS is compliant with 21 CFR 820, which requires a device master record, which contains equivalent information to the "medical device file" required in the standard.			
4.2.4 Control of documents, first paragraph	Revised text details that the control of records within the scope of this sub-clause of the standard; clarifies that this applies to records the organization has determined "to be necessary" and emphasizes that other requirements may be relevant per applicable regulatory requirements	No – Unlikely	*Evidence of No Gap* SOP424 details the control of records, which is written in compliance with the requirements of this sub-clause for documentation control HOWEVER, ensure organization has a clear understanding of the terms "document" and "record" both within the QMS and in its interpretation to ensure consistent application within the organization.			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
4.2.4 Control of documents, second paragraph	Revised text details that changes to documents must be identified, that documents from outside the organization that the organization determines important to compliance with the QMS be identified and controlled and that procedures are in place to prevent loss of documentation	No – Unlikely	*Evidence of No Gap* SOP424 details the control of documents, which is written in compliance with the requirements of this sub-clause for documentation control			
4.2.4 Control of documents, third – fifth paragraph	No significant changes	N/A	N/A			
4.2.5 Control of records, first paragraph	Revised text adds requirements for ensuring the integrity of records throughout a record's life-cycle	Yes – Likely	Remediation Action(s) Required Revise SOP425 to include requirements for maintaining the integrity of records			
4.2.5 Control of records, second paragraph	New requirement to protect confidentiality of the information contained in records	Yes – Likely	Remediation Action(s) Required Revise SOP425 to include requirements to protect confidentiality of information within records			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
4.2.5 Control or records, third paragraph	Revised text adds the requirement that record retention may be specified in applicable regulatory requirements	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			
5.1 Management commitment	No significant changes	N/A	N/A			
5.2 Customer focus	Revised text emphasizes that top management must ensure applicable regulatory requirements are determined and met, in addition to customer requirements	Yes – Likely	*Remediation Action(s) Required* Revise SOP-QM to include within top management's responsibilities ensuring applicable regulation requirements are determined and met			
5.3 Quality policy	No significant changes	N/A	N/A			
5.4.1 Quality objectives	Revised text adds the requirement to ensure quality objectives meet applicable regulatory requirements	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa			
5.4.2 Quality management system planning	No significant changes	N/A	N/A			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
5.5.1 Responsibility and authority	No significant changes	N/A	N/A			
5.5.2 Management represented	No significant changes	N/A	N/A			
5.5.3 Internal communication	No changes	N/A	N/A			
5.6 Manage review, 5.6.1 General	Revised text added a new requirement to "document" the procedures for management review	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			
5.6.2 Review input	Revised text added additional sources of information to be utilized in management review, specifically feedback, complaints, health authority reporting, audits, monitoring of both processes and product and CAPA information in general, not just CAPA status	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
5.6.3 Review output	Revised text added a requirement to include changes needed to address new or revised regulatory requirements as part of the output of management review	Yes – Likely	*Remediation Action(s) Required* Revise SOP51 to include as part of the output of management review, changes needed to address evolving regulatory requirements			
6.1 Provision of resources	No significant changes	N/A	N/A			
6.2 Human resources	Revised text added the requirement to document the processes the organization uses to ensure personnel are competent, determining and providing required training, ensuring personnel are aware and that the method used to check the effectiveness of training utilizes a risk-based approach based upon the work being performed	Yes – Likely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include most of the revisions incorporated into the revised standard *Remediation Action(s) Required* Revise SOP62 to include a risk-based approach for confirming the effectiveness of training			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
6.3 Infrastructure	Revised text adds requirement that the organization document requirements for infrastructure that will prevent product mix-up and will ensure proper product handling; adds information systems as a supporting service of the organization's infrastructure	Yes – Likely	*Remediation Action(s) Required* Revise SOP63 to include not just procedures and processes but to include requirements for infrastructure (e.g., plant design information systems), to prevent cross-contamination and to ensure proper handling of product			
6.4.1 Work environment	Revised text adds requirement to document the requirements for the work environment and procedures to monitor and control said work environment, when the work environment can adversely affect product quality	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
6.4.2 Contamination control	New sub-clause which adds requirements for environmental controls (viable and non-viable) for and maintenance of cleanliness during assembly and packaging of sterile medical devices	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			
7.1 Planning of product realization, first paragraph	No changes	N/A	N/A			
7.1 Planning of product realization, second paragraph	New paragraph adding requirement for organization to document one or more processes for risk management utilized in product realization, which is broader than just documenting the requirements for risk management	Yes – Likely	Remediation Action(s) Required Revise SOP-RM to expand scope beyond risk the safety and performance of the product and to the compliance of the organization to the full range of requirements contained within Clause 7 of the standard			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.1 Planning of product realization, second paragraph	Revised text adds requirements to ensure resources are provided for infrastructure and work environment in addition to product specific resource needs, adds requirements for measurement, handling, storage, distribution and traceability activities	Yes – Likely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard with respect to measurement, handling, storage, distribution and traceability *Remediation Action(s) Required* Revise SOP62 to include resource provision for infrastructure and work environment maintenance and update			
7.1 Planning of product realization, third paragraph	No significant changes	N/A	N/A			
7.2.1 Determination of requirements related to product	Revised text adds requirement that the organization determine user training required to ensure safety and performance of the product	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.2.2 Review of requirements related to product	Revised text adds to the review of product related requirements that applicable regulatory requirements are met and user training is available or planned to be available	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			
7.2.3 Communication	Revised text adds the requirement for the organization to communicate with regulatory authorities as required by applicable regulations	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			
7.3 Design and development, 7.3.1 General	New sub-clause that does not add any requirement; re-structuring of text only	N/A	N/A			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.3.2 Design and development planning	Revised text adds requirements to include in design and development planning the review(s) needed at each stage of development, the methods that will be used to ensure traceability of design outputs to inputs and the resources needed, including required competence of personnel	No – Unlikely	*Evidence of No Gap* Organization's QMS is compliant with 21 CFR Part 820 AND the FDA Guidance on Design Controls; the detailed requirements added into the standard are reflective of these two sources for QMS requirements NOTE: It is important to note that the FDA Guidance document contained recommendations that by virtue of the standard revision have been turned into requirements.			
7.3.3 Design and development inputs	Revised text added requirements that design inputs include usability requirements, the inclusion of standards as a source for design inputs and that design inputs be able to be verified or validated	No – Unlikely	*Evidence of No Gap* Organization's QMS is compliant with 21 CFR Part 820 AND the FDA Guidance on Design Controls; the detailed requirements added into the standard are reflective of these two sources for QMS requirements NOTE: It is important to note that the FDA Guidance document contained recommendations that by virtue of the standard revision have been turned into requirements.			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.3.4 Design and development outputs	Revised text added the requirement that design outputs be in a form that can be verified against the design inputs and approved prior to release	No – Unlikely	*Evidence of No Gap* Organization's QMS is compliant with 21 CFR Part 820 AND the FDA Guidance on Design Controls; the detailed requirements added into the standard are reflective of these two sources for QMS requirements NOTE: It is important to note that the FDA Guidance document contained recommendations that by virtue of the standard revision have been turned into requirements.			
7.3.5 Design and development review	Revised text added specific requirements for records of design reviews to include the design under review, participants in the review and the date of the review	No – Unlikely	*Evidence of No Gap* Organization's QMS is compliant with 21 CFR Part 820 AND the FDA Guidance on Design Controls; the detailed requirements added into the standard are reflective of these two sources for QMS requirements NOTE: It is important to note that the FDA Guidance document contained recommendations that by virtue of the standard revision have been turned into requirements.			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.3.6 Design and development verification	Revised text added requirement to document the planned verification activities, that the verification plans specifically include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size, and the requirement to perform verification with the device connected to or interfaced with other medical devices when required by the intended use	Yes – Likely	*Evidence of No Gap* Organization's QMS is compliant with 21 CFR Part 820 AND the FDA Guidance on Design Controls; the detailed requirements added into the standard are reflective of these two sources for QMS requirements NOTE: It is important to note that the FDA Guidance document contained recommendations that by virtue of the standard revision have been turned into requirements. *Remediation Action(s) Required* Incorporate into SOP736 the requirement that verification be performed with the device connected to, or interfaced with, other medical device(s) when intended use requires said connection or interface			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.3.7 Design and development validation	Revised text added requirement to document the planned validation activities, that the validation plans specifically include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size, the requirement to use representative product, the requirement to perform verification with the device connected to or interfaced with other medical devices when required by the intended use, and clarification of the required timing for completion of design validation	Yes – Likely	*Evidence of No Gap* Organization's QMS is compliant with 21 CFR Part 820 AND the FDA Guidance on Design Controls; the detailed requirements added into the standard are reflective of these two sources for QMS requirements NOTE: It is important to note that the FDA Guidance document contained recommendations that by virtue of the standard revision have been turned into requirements. *Remediation Action(s) Required* Incorporate into SOP737 the requirement that validation be performed with the device connected to, or interfaced with, other medical device(s) when intended use requires said connection or interface			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.3.8 Design and development transfer	New sub-clause adding the requirement to have procedures for transfer of design outputs to manufacturing	No – Unlikely	*Evidence of No Gap* Organization's QMS is compliant with 21 CFR Part 820 AND the FDA Guidance on Design Controls; the detailed requirements added into the standard are reflective of these two sources for QMS requirements NOTE: It is important to note that the FDA Guidance document contained recommendations that by virtue of the standard revision have been turned into requirements.			
7.3.9 Control of design and development changes	Revised text added requirement to assess the impact of changes on risk management and the product realization (clause 7 of the standard) processes and added detail on items to consider when assessing change impact, specifically added change impact should consider function, performance, usability, safety and regulatory requirements	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.3.10 Design and development files	New sub-clause adding the requirement to create and maintain a design and development file	No – Unlikely	*Evidence of No Gap* Organization's QMS is compliant with 21 CFR 820, which requires a design history file and EU Medical Device Regulation, which requires technical documentation. These contain equivalent information to the "design and development file" required in the standard.			
7.4.1 Purchasing process, first paragraph	Change in terminology to utilize the term "purchasing information"	No – Unlikely	*Evidence of No Gap* Change in terminology aligns with terminology used in 21 CFR 820.50 with which the organization's QMS is compliant			
7.4.1 Purchasing process, second paragraph	Revised text adds details on the criteria for the evaluation and selection or suppliers rather than just the actual purchased product; specifically, that the evaluation of the supplier include criteria around the performance of the supplier, the effect of the purchased product on the quality of the finished product and that this be proportionate to the risk associated with the finished product	Yes – Likely	*Remediation Action(s) Required* 21 CFR 820.50 implies that supplier evaluation be risk-based; however, the US regulation does not specifically call this out. Therefore, SOP 000005 does not specifically call out that a risk-based approach be used that includes assessment of supplier performance and the effect of the purchased product be used in the evaluation of the supplier			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.4.1 Purchasing process, fourth paragraph	Revised text adds specific details regarding the "type of control" for a supplier, specifically it details that monitoring of supplier performance is required and provides input into the supplier re-evaluation process	No – Unlikely	*Evidence of No Gap* SOP741 already contains the requirement to monitor suppliers and to include this in either "for cause" or "planned" supplier re-evaluation.			
7.4.1 Purchasing process, fifth paragraph	Revised text adds new requirements on utilizing a risk-based approach when a supplier does not meet requirements that is proportionate to both the purchased product and compliance to regulatory requirements	Yes – Unlikely	*Remediation Action(s) Required* SOP741 includes a risk-based approach, but only focuses on product requirements and does not include risks associated with regulatory requirement compliance			
7.4.1 Purchasing process, sixth paragraph	Revised text adds specific details on the content of records	Yes – Likely	*Remediation Action(s) Required* SOP741 includes the requirement to document the results of evaluation, selection, monitoring and re-evaluation suppliers, but does not include the requirement to document necessary actions arising from said activities			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.4.2 Purchasing information	Revised text adds a new requirement for purchasing information to include in a written agreement notification of changes in the purchased product prior to implementation of said changes	No – Unlikely	*Evidence of No Gap* SOP743 is already compliant with 21 CFR 820.50, which includes this requirement			
7.4.3 Verification of purchased product, first paragraph	Revised text adds a new requirement to utilize a risk-based approach when determining the activities required to verify the purchased product meets specifications that includes both the supplier evaluation outcomes and the effect of the purchased product on the finished product	No – Unlikely	*Evidence of No Gap* Organization's QMS already includes the use of a risk-based approach that includes both the results of the supplier evaluation and the effect of the incoming material on the finished product; specifically, reference section X.X of SOP743			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.4.3 Verification of purchased product, second paragraph	Revised text adds the requirement to assess the impact of changes to both the product realization process (the requirements in clause 7 of the standard) and the product itself	Yes – Likely	*Evidence of No Gap* Organization's QMS already includes the requirement to assess the impact of changes on the product. Reference SOPChangeControl. *Remediation Action(s) Required* Incorporate into organization's QMS the requirement to assess the impact of purchased product on the requirements contained within clause 7 of the standard.			
7.4.3 Verification of purchased product, third and fourth paragraphs	No significant changes	N/A	N/A			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.5.1 Control of product and service provision	Revised text adds general requirements related to the scope of controls expected by the standard, specifically, documentation around the methods used for production control and not just the control procedures themselves, inclusion of infrastructure qualification, clarification that monitoring and measurement includes process parameters and product characteristics and the inclusion of product release, delivery and post-delivery activities	No — Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.5.2 Cleanliness of product	Revised text added a new requirement that cleanliness or contamination control of product is required if product is supplier non-sterile, but cleanliness is of significance in use	Yes – Likely	*Evidence of No Gap* SOP752 includes requirements for how cleanliness of product and contamination control of product is achieved when product is cleaned by organization prior to sterilization or its use; product is supplied non-sterile but must be cleaned prior to sterilization or use; product cannot be cleaned prior to sterilization or use and cleanliness is of significance and how process agents are to be removed from product during manufacturing. *Remediation Action Required* Incorporate into SOP752 how organization ensures cleanliness of product and contamination control when product is supplied non-sterile and cleanliness is of significance in use			
7.5.3 Installation activities	No significant changes	N/A	N/A			
7.5.4 Servicing activities	Revised text includes a new requirement to analyze servicing records performed by the organization or its supplier to determine if a complaint should be logged and for input into continuous improvement	Yes – Likely	*Evidence of No Gap* Organization's QMS is compliant with 21 CFR 820.200 Servicing, which includes the requirement to analyze service reports for potential CAPA. Specifically, reference SOP820100, section X.X *Remediation Action(s) Required* Revise SOP820198 to call out that service calls be assessed for possible logging as a complaint.			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.5.5 Particular requirements for sterile medical devices	No significant changes	N/A	N/A			
7.5.6 Validation of processes for production and service provision, first – third paragraphs	Revised text included that validation must ensure planned results are achieved "consistently", added details to the scenarios when a procedure is required, specifically acceptance criteria, statistical techniques with rationale for sample sizes, as appropriate, requirements for revalidation criteria and approval of changes	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.5.6 Validation of processes for production and service provision, fourth paragraph	Revised text added a new requirement to utilize a risk-based approach for the approach and activities required for software validation and revalidation and that these be proportionate to risk associated with the software's use including the software's effect on ability of the finished product to meet specifications	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			
7.5.6 Validation of processes for product and service provision, fifth paragraph	Revised text specifically requires that validation records contain the results, conclusion and necessary actions associated with validation activities	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems	Revised text adds sterile barrier systems into the scope of required documented procedures, the requirement to validate not just prior to initial use but also after product or process changes, as appropriate and adds specific information that must be included in the validation results, specifically, the results, conclusion and necessary actions	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			
7.5.8 Identification	Revised text adds new requirements for procedures for product identification in addition to the existing requirement to identify the product during the various stages of production, distribution, installation and servicing and, if required by regulatory requirements, unique device identification	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.5.9.1 Traceability, General	Revised text emphasizes compliance with applicable regulatory requirements	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			
7.5.9.2 Particular requirements for implantable medical devices	Revised text clarifies that traceability records of components, materials and work environment conditions are required in those instances where these items could impact the finished product's ability to meet specified safety and performance requirements	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			
7.5.10 Customer property	Revised text emphasizes that care of customer property applies only while it is under the organization's control.	No – Unlikely	*Evidence of No Gap* Clarification only.			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.5.11 Preservation of product	Revised text provides detail on how an organization can protect product from alteration, contamination or damage, specifically it details that this can be accomplished through the design and construct of suitable packaging and shipping containers and by documenting requirements for special conditions if preservation cannot be achieved by packaging alone	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
7.6 Control of monitoring and measuring equipment	Revised text adds the requirement to record adjustments/re-adjustments made to monitoring and measuring equipment; the requirement to have documented procedures for calibration and verification of equipment; the use of a risk-based approach for software validation and revalidation activities that is based upon the use of the software, including its ability to effect the finished product's ability to meet specifications; the requirement to document the results, conclusion and necessary actions from validation of monitoring and measurement equipment	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
8.1 Measurement, analysis and improvement, General	No significant changes	N/A	N/A			
8.2.1 Feedback, first, second and third paragraph	Revised text uses the word "effectiveness" of the QMS rather than "performance" and that information be "gathered" from production as well as post-production. Post-production was driven by national/regional regulations in prior version of standard; however, revised text acknowledges regulatory requirements may contain additional specific information to be monitored	Yes – Likely	*Evidence of No Gaps* • SOP821 section X.X requires the inclusion of post-production information as part of the feedback process and describes what type of post-production information is included and is aligned with applicable regulatory requirements *Remediation Action(s) Required:* • Revise SOP821 to include how the KPIs described in SOP821 should be utilized to demonstrate the effectiveness of the QMS			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
8.2.1 Feedback, third paragraph	New requirement to utilize the feedback as an input to risk management into monitoring and maintaining product requirements, as an input to the product realization (clause 7 of the standard) process and the improvement processes.	No – Unlikely	*Evidence of No Gaps* SOP821 includes using the output of the analysis of feedback information to be an input into risk management from both a product and a process perspective.			
8.2.2 Complaint handling	New sub-clause with several new requirements	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. This existing regulations, standards and guidance already address similar requirements for complaint handling *Remediation Action(s) Required* Revise SOP822 to include a requirement to alert any external organization that may contribute to the cause of the complaint			
8.2.3 Reporting to regulatory authorities	New sub-clause to require procedures for reporting to health authorities per applicable regulatory requirements	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
8.2.4 Internal audit	New requirement stating specifically that procedures for internal audits must be documented and that records of said audits must be maintained	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations already require procedures for the planning, conduct, reporting and follow-up on internal audit			
8.2.5 Monitoring and measurement of processes	No significant changes	N/A	N/A			
8.2.6 Monitoring and measurement of product	New requirement to include the test equipment used in product test records	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. It is standard practice to identify the equipment and materials used in executing testing.			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
8.3 Control of nonconforming product; 8.3.1 General, first paragraph	Revised text includes details on the types of controls for nonconforming product to be documented, specifically identification, documentation, segregation, evaluation and disposition	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already address these control considerations for nonconforming product			
8.3.1 General, second paragraph	New requirement to determine if an investigation for nonconforming product is required and to notify external parties, as necessary	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already address investigations and communication related to nonconforming product			
8.3.1 General, third paragraph	No significant changes	N/A	N/A			
8.3.1 General, fourth paragraph	New requirement for records related to nonconforming product	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already address nonconforming product records and their content			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
8.3.2 Actions in response to nonconforming product detected before delivery	New clause; however, most of the requirements were already present in the standard; new requirement related to included justification for use and who authorized the use of product under concession	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already address the use of nonconforming product under concession *Remediation Action(s) Required* Revise SOP832 to include documentation of who authorized the use of nonconforming product under concession.			
8.3.3 Actions in response to nonconforming product detected after delivery	New clause; however, most of the requirements were already present in the standard; new requirement to have procedures regarding advisory notices in accordance with applicable regulatory requirements and to maintain records of said advisory notices	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already address notification regarding nonconforming product			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
8.3.4 Rework	New sub-clause; however, most of the requirements were already present in the standard; clarification on the requirement from ISO 13485:2003 to ensure rework had no negative impact on the product by stating that it must be verified that product meets specifications and regulatory requirements after rework and specifically states rework records must be maintained	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already address rework requirements			
8.4 Analysis of data	Revised text adds additional sources of data to be reviewed, specifically audits and if appropriate, service reports and adds an explicit requirement to use the analysis of data as in input to corrective and preventive actions	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
8.5 Improvement 8.5.1 General	Revised text adds requirement to focus improvement on product safety and the adequacy of the QMS in addition to the effectiveness of the QMS and adds post-market surveillance as one of the tools used to identify areas for improvement	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			
8.5.2 Corrective action	Revised text adds a time factor for execution of corrective actions, a requirement to verify that corrective action does not have a negative effect (compliance or product safety and performance), and a requirement to verify the effectiveness of the corrective action	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			

Clause	Description of Text Differences	Process or QMS Gaps (Yes/No)	Evidence for No Gap / Remediation Action(s) for Gaps	Risk Assessment	Owner	Estimated Completion Date
8.5.3 Preventive action	Revised text adds a requirement to verify that preventive action does not have a negative effect (compliance or product safety and performance)	No – Unlikely	*Evidence of No Gap* Organization's QMS is based on applicable regulations, standards and guidance, including this standard; this is shown by mapping of QMS to said regulations, standards and guidance and vice versa. These regulations, standards and guidance already include the revisions incorporated into the revised standard			

b. Risk Assessment

The definition of risk is as follows: **"**combination of the probability of occurrence of harm and the severity of that harm". The term "risk" is used over 15 times in the new version of the standard which is noticeably more than the previous version. And it is clearly stated in clause 4.2.1; "The organization shall apply a risk-based approach to the control of the appropriate processes needed for the quality management system. Anything that affects the quality system needs to be viewed from that risk perspective".

Harm in this case can be defined with respect to potential longer lead times, need for additional resources, and increased costs related to implementation. The risks related to implementing new regulatory requirements must be evaluated and a mitigation plan created to minimize any unacceptable risk to the business, to regulatory compliance, but most of all to safety.

Part of the task to change over from ISO 13485 2003 to 2016 is to perform a risk assessment on the changes to the standard and how they impact the organization. The organization should analyze the risk to the business regarding the implementation or lack thereof the new standard to the current way business is performed. What will be the impact on your resources, processes, materials, finished products, vendors, customers, and most importantly regulatory compliance?

This can be readily achieved by using any of the numerous existing risk evaluation tools. Once the risk is evaluated and identified the mitigation plan can be initiated. ISO 31000, the standard for general risk management can be useful tool for this task.

Another concept of risk that needs to be considered is how to impart the risk management into the everyday processes. Here you would want to investigate where elements of risk can exist within your quality management system. One good way to do this is to perform a workflow analysis to fully understand the operation and the critical steps to the process that can most have an impact on the final product. These are normally the areas of potential risk and they should be the areas that a risk analysis should be performed.

Additionally, risk should be evaluated any time there is a change to a process. This includes, but is not limited, to product design, change controls, deviations, non-conforming product, CAPA analysis and audit findings.

Work flows can be adjusted to minimize risk and critical processes can be adjusted to require an assessment of risk.

For example, a change to a process under a change control should have a requirement in the procedure on change control and any related forms to require a risk evaluation and its impact on the current process and or product. Prior to implementing the change any unacceptable risk would require mitigation.

ISO 14971 should be used to analyze the operational process risks as required in the new ISO 13485 2016.

The understanding of risk and how it not only effects the business, but also how it can potentially impact safety is an important concept that needs to be ingrained into operations. This way business risk can be minimized.

c. Time Needed to Enact

How long it will take to robustly incorporate the requirements of ISO 13485:2016 into the QMS is dependent on multiple factors:

- The existence and/or current state of the QMS
- The extent and scope of the identified gaps
- The actions needed to include the processes and procedures required to build an ISO 13485:2016 compliant QMS
- The resources available

Enactment of the identified QMS improvements should be based on the risk priority and on the length of time needed to implement the actions. Appropriation of sufficient, qualified resources should be provided by top management to ensure a timely QMS build. Time for effectiveness checks and/or field testing of necessary changes should be part of the time calculation.
Keep in mind that all accredited certifications to ISO 13485:2003 and ISO 13485:2012 have until March 31, 2019 to transition to ISO 13485:2016. This is three years after the publication of the 2016 standard. However, assessment dates against the new standard are largely dictated by the Notified Body or Registrar responsible for the compliance assessment.

In many cases, these entities have earlier dates to which a QMS assessment against the 2016 version must be made if one wishes to maintain or achieve certification. It is crucial that early and clear communication between the organization and the notifying body/registrar take place to ensure proper timing of the 2016 requirements incorporation.

d. Change Control with Action Plan

Once the compliance gaps are identified and the associated risk determined, a documented plan for implementing the changes should be captured and the improvement activities should be addressed within the formalized change control processes. Attached to the change control should be a detailed action plan that includes responsibilities, action items, due dates and verification dates.

There are multiple advantages of taking the time to structure and document the remedial path using these systems:

- The application of established criteria for gap analysis allows for consistent in-depth investigations and a broader assessment of all the impacted systems;
- A systematic approach to integrating all changes and an awareness of their cumulative effect on the QMS, ensures the QMS's integrity is maintained;
- Action items can be prioritized according to their assigned risk and resources can be appropriately allotted;
- Better assessment of the true time needed to fully adopt all needed changes can be made;
- Establishment of the records, the actions needed and taken, the responsible parties and targeted timelines, and the documented decisions made by the appropriate parties (e.g. impacted departments, including Quality and Regulatory) provides evidence that the resulting changes are sufficient and effective over the long-term;
- Internal formal tracking facilitates the required communication to top management so that they sufficiently support the change efforts and fulfill their regulatory obligations.

An action plan should be opened for each identified gap or grouped according to business process and/or CAPA process criteria. As each organization has its own unique QMS structure to best support its business paradigm, how the corrective and preventative actions are integrated should reflect this structure. The degree of action to be taken is dependent on the related risk. Higher risk gaps should be implemented without unnecessary delay. If risk is high or the sufficient resources with the appropriate competencies are missing, such

issues need to be promptly escalated to top management. Organization change control processes should be used were applicable for system, process, and documentation changes.

6. Conclusion

Patient safety, product quality and regulatory compliance are paramount for manufacturers of medical devices. Quality management systems are developed to minimize risks associated with development, manufacturing and distribution because of this.

ISO 13485: 2016 instructs medical device manufacturers, suppliers, and distributors in how to design a quality management system that maintains the effectiveness of their processes. It ensures the consistent design, development, production, installation, and delivery of medical devices that are safe for their intended purpose. ISO 13485 adherence requires discipline, commitment and effort to attain; however, compliance results in additional credibility with regulators and customers and providing a competitive advantage and is worth the energy and resources. Even countries that do not require ISO 13485 certification, view it is as evidence that a device meets the highest quality standards. In addition, in the European Union, it streamlines the conformance assessment process for the European Union Marking process to market devices.

This paper provides the necessary background information, summary of ISO 13485 version differences, and an effective, risk-based approach that the reader can easily reference and apply in the effort to upgrade to the revised ISO 13485:2016 compliant QMS.

8. References

TC 210 ISO 13485:2016, Medical Devices advise from ISO/TR 210

ISO 13485:2016

ISO 14971

21 CFR 820

ISO 9001

Below is a check list that organizations can use to perform a gap assessment when implementing ISO 13485:2016.

Key Changes	Clause	Gap Y/N	Responsible Person	Action Required	Due Date	Verification
Incorporation of risk-based approaches beyond product realization. Risk is considered in the context of the safety and performance of the medical device and in meeting regulatory requirements	4.1 7.1 8.2.1					
Increased linkage with regulatory requirements, particularly for regulatory documentation	4.1.4 7.2.1					
Application to organizations throughout the life cycle and supply chain for medical devices	Introduction and Scope					
Harmonization of the requirements for software validation for different software applications (QMS software, process control software, software for monitoring and measurement) in different clauses of the standard	4.1.6 7.5.6					
Emphasis on appropriate infrastructure, particularly for production of sterile medical devices, and addition of requirements for validation of sterile barrier properties	7.5.5 – This section was not changed 7.5.7					
Additional requirements in design and development on consideration of usability, use of standards, verification and validation planning, design transfer and design records, risk assessment on the changes of design	7.3					

Key Changes	Clause	Gap Y/N	Responsible Person	Action Required	Due Date	Verification
Emphasis on timely complaint handling and reporting to regulatory authorities in accordance with regulatory requirements, and consideration of post-market surveillance	8.2.2					
Planning and documenting corrective action and preventive action. Corrective and Preventive actions required to be verified to demonstrate they do not adversely affect the ability to meet regulatory requirements or the safety or performance of the device. Implementing corrective action without undue delay	8.5.2 8.5.3					