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ISO 13485:2016 Highlights – prepared by Sherman Eagles of SoftwareCPR®

A new version of the Medical Device Quality System Management (QMS) standard, ISO 13485 has just been published. Starting in 2018 new certifications or re-certifications to 13485 will only be done for the new 2016 edition. After March 2019, certifications to the previous edition, 13485:2003, will no longer be valid.

Why revise the standard? There were three primary motivators:

- Perceived inconsistencies in audits due to disagreements between manufacturers and certifiers over interpretation of what was required to conform with the 2003 version;
- Changes in business models and technology since the previous version was developed;
- A desire to harmonize the standard with global regulatory requirements.

Where differences in interpretation of 13485:2003 were noted, or where auditing bodies had identified a difficulty in determining conformity, clarifications have been introduced in the 2016 version. In some cases this resulted in more specific and prescriptive requirements. Some examples include:

- Control of records is included within the document control requirements.
- Lists the documents that would be included in the medical device file.
- Includes requirement for the documentation of a procedure(s) for management review and the requirement for management reviews at “documented planned intervals”.
- Adds requirement that infrastructure prevents product mix-up and ensures orderly handling of product.
- Adds documentation requirements for work environment.
- Adds a requirement related for control of contamination with microorganism or particulate matter for sterile medical devices.
- Adds requirements that the requirements shall be able to be verified or validated.
- Adds details of the contents of records.
- Adds a requirement for documentation of verification plans and interface considerations.
- Adds a requirement for records of verification.
- Adds a requirement for documentation of validation plans.

While being more precise with requirements, the standard recognizes that there are new business arrangements and organizations focused on just a part of the overall product lifecycle. Organizations are provided more flexibility in documenting their roles and determining the processes they need for the QMS. Changes in technology have also resulted in new or modified requirements. Changes include:

- Adds substantially more detail related to the nature of the organization covered by the standard’s requirements and the life-cycle stages covered.

- States that the standard applies to organizations that are involved in one or more stages of the life-cycle of a medical device.
- Indicates that the standard can be used by suppliers or external parties that provide product including QMS-related services to medical device organizations.
- Specifically calls out the responsibilities for monitoring, maintaining, and controlling outsourced processes.
- Adds a requirement to document the role(s) of the organization.
- Requires the determination of processes "taking into account the roles undertaken by the organization."
- Specifies that requirements that are not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, do not need to be included in the quality management system.
- Adds requirements related to validation of the application of computer software used in the QMS.
- Adds a new requirement related to protection of confidential health information.
- Adds information system to the listing of supporting services in infrastructure.
- Adds a requirement for unique device identification.

Regulators played a major role in what needed to be added in this revision. An important addition is the inclusion of risk-based thinking into the standard. Most regulations are risk-based and regulators are expecting to see a more rigorous approach to quality management for higher-risk devices. The phrase "proportionate to the risk" now appears in requirements throughout the standard. Working through the International Medical Device Regulators Forum (IMDRF) a Medical Device Single Audit Program (MDSAP) has been created. The goal of MDSAP is to have just one QMS audit that would be accepted by most regulators. For this to be successful, there needs to be a common set of requirements that satisfies these regulators. 13485:2016 has included new requirements that align with regulatory requirements, especially the US FDA QSR. The US and Canada are expected to begin use of the MDSAP in 2017. Although there may still be some differences between regulatory requirements in different countries, certification to ISO 13485:2016 should provide an acceptable QMS that meets the regulatory requirements. Changes to the standard to support regulation include:

- Alerts organizations about their obligations related to regulatory requirements focused on quality management systems (QMS).
- Alerts organizations about differences in local regulation definitions and their obligation to understand how these definitions will affect their QMS.
- Specifies that if applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system.
- Adds two additional criteria associated with the description of appropriate requirements:
    - compliance with regulatory requirements;
    - the requirement is necessary for the organization to manage risks.
- Requires the application of a risk based approach to the control of the appropriate processes needed for the quality management system
- Limits application of risk to the safety or performance requirements of the medical device or for meeting applicable regulatory requirements.
- Clarifies that the term "regulatory requirements" includes statutes, regulations, ordinances or directives; and limits the scope of the "applicable regulatory requirements" to those requirements for the quality management system and the safety or performance of the medical device.

- Includes control of records within the document control requirements.
- Requires the establishment and maintenance of a medical device file.
- Lists the documents that would be included in the medical device file.
- Adds new sub-clauses for design and development transfer and for design and development files.
- Requires that the retention period of documentation be defined taking into account applicable regulatory requirements.
- Specifies that customer focus includes applicable regulatory requirements.
- Adds new sub-clauses on complaint handling and reporting to regulatory authorities.

What should you be doing to prepare for this new version of 13485? Like any new or revised standard that is important to your business, you should obtain a copy of the standard and do a gap analysis between the requirements of the standard and your current practices. For organizations that currently conform to both the 2003 edition of 13485 and the FDA QSR there may not be too many changes needed. Once the differences are understood, the timing for achieving needed conformity should be explored and a plan to bring your practices into conformity should be created. Remember that most certification bodies require your processes to be implemented for a period of time before they will certify your conformity to the standard. Be sure to discuss your plans with your certification body well in advance of when you will be seeking certification.

If you intend to hold dual certification to ISO 13485 and ISO 9001, you will need to do some extra effort. 13485:2016 did not adopt the revised structure that was introduced in ISO 9001:2015. As in the past, conformity to 13485 should not hinder conformity to 9001, but there will be a need to show where requirements in the new structure of 9001 are implemented in a QMS structured to align with 13485. There are also some requirements in 9001 that have been removed in 13485, so an additional gap analysis between 9001 and the processes implemented to conform to 13485 will be needed. 13485:2016 provides some help with this by including a table comparing the contents of 13485:2016 with that of 9001:2015.

A future update of 13485 may occur much faster than in the past. A review of 13485:2016 has been set for 2019. If the standard is not meeting the goals of more consistent audits and global regulatory use there may be a need for another revision. Also the question of whether to move to a structure based on ISO 9001:2015 will be considered. As this review approaches, attention should be paid to ISO Technical Committee 210 which is responsible for maintaining ISO 13485.

As part of our RegulatoryCPR services we can assist you in your gap analysis and interpretation of this new revision. Although many know SoftwareCPR® as experts in software related regulation, compliance, and safety, we also have a long track record providing expert consultation, training, and negotiation with regulatory authorities (including FDA enforcement actions) related to Quality System requirements, including international standards, and premarket submissions. Our focus is on efficient compliance and product safety and effectiveness and we can assist you in planning for implementation of this new version of 13485, including applying risk management to its interpretation.. For more information contact Alan Kusinitz at 781-721-2921 alan@softwarecpr.com or Brian Pate 813-766-0563 brian@softwarecpr.com .