The Transition to ISO 13485:2016

On March 1, 2016, the International Organization for Standardization, ISO, issued a new QMS standard for medical device manufacturers. ISO 13485:2016[1] is the third edition of the standard.

Many companies involved in medical devices obtain a certificate to demonstrate compliance with the standard. This certificate provides evidence to both customers and regulators that an independent third party reviewed the QMS implementation and found it satisfactory. This certification is a key element in legally marketing a medical device in some jurisdictions. However, there are potential complications that are important to device makers.

The ISO Recommendation

ISO uses Technical Committees with defined responsibilities; ISO/TC 210 *Quality Management and Corresponding General Aspects for Medical Devices* has responsibility for this QMS standard.

While ISO doesn't certify companies to the standard, ISO/TC 210/WG1 published a white paper on Nov. 18, 2015 with recommendations for the transition to ISO 13485:2016

- The publication date is March 1, 2016
- Two years after publication (March 1, 2018), all new certifications or re-certifications should be to ISO 13485:2016.
- Three years after publication (March 1, 2019), ISO 13485:2003 certificates will not be valid.

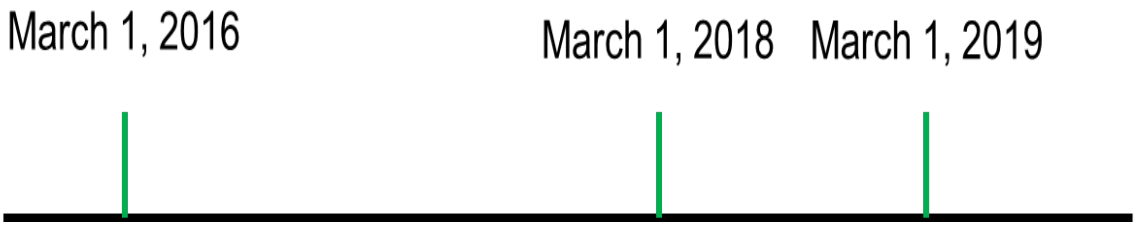

Figure 1 ISO/TC 210 Recommended Timeline

MDSAP

The International Medical Device Regulators Forum, IMDRF, has developed a plan for a Medical Device Single Audit Program, MDSAP. Under this program, regulators from Australia, Brazil, Canada, Japan, and the US agree to use MDSAP audits as regular surveillance audits.

This requires the companies that perform the audits to qualify as an Auditing Organization, AO, under MDSAP.

The pilot program, due to end on Dec. 31, 2016, uses ISO 13485:2003 as the basis for the QMS portion of the audit. The operational program expects to transition to ISO 13485:2016.

[1] Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

MDSAP grades nonconformities using a point system that eliminates subjective terms such as minor, major, or critical. GHTF SG3 N19:2012 *Quality Management System – Medical Devices – Nonconformity Grading System for Regulatory Purposes and Information Exchange* describes the system. The document is available for download at www.imdrf.org.

Health Canada

A medical device manufacturer must have a license from Health Canada, HC, to sell a medical device in Canada. Part of the licensing requirements is a QMS that conforms to ISO 13485:2003 and audited under the Canadian Medical Device Conformity Assessment System, CMDCAS. HC approves the auditing companies to conduct CMDCAS audits.

HC will end CMDCAS and replace it with MDSAP. From January 1, 2017 to January 1, 2019, they will accept either a CMDCAS certificate or an MDSAP certificate. After January 1, 2019, they will accept only MDSAP certificates. If a medical device manufacturer doesn't have an MDSAP certificate on January 1, 2019, HC will revoke the license.

In addition, any company that conducts an MDSAP audit must qualify as an Auditing Organization, AO.

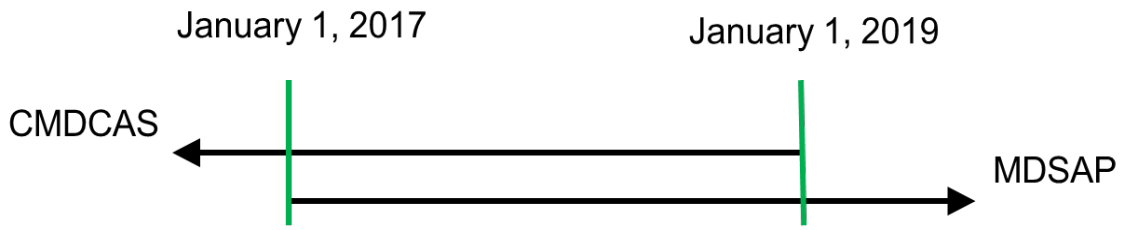

Figure 2 Health Canada Transition to MDSAP

Food and Drug Administration

On Dec. 17, 2015, FDA announced it would participate in the operational phase of MDSAP. This allows an MDSAP auditing organization (AO) to submit audit reports that FDA will utilize for routine inspections.

FDA will review each MDSAP report to determine if it meets the conditions for Official Action Indicated, OAI.

- If not, then FDA expects the Auditing Organization to follow-up on the nonconformities – there would not be a 483.
- If the report is OAI, then FDA prefers a regulatory meeting rather than a Warning Letter.

FDA plans to continue for cause inspections, PMA inspections, *etc.*

European Union

The European Union is not a participant in MDSAP. Instead, it will continue its own audit program using the current Notified Body system. This includes the current unannounced audits.

The EU published its own version of the QMS standard, EN ISO 13485:2016. The annexes point out the differences between the international version and the current directives.

Medical device manufacturers will need a new QMS certificate to the EU version.

The EU intends to replace the three current directives with two regulations. The transition period will start at the end of 2016 or early in 2017. During this period, the Notified Bodies must qualify under the new requirements in the regulations; prior designation will expire. Medical device manufacturers will need a new QMS certificate since EN ISO 13485:2016 will become obsolete. In addition, the manufacturers will need to revise the product documentation to demonstrate conformance with the new regulations.

Summary
A manufacturer with an ISO 13485:2003 based QMS must upgrade to ISO 13485:2016. This also requires an audit to qualify for a new certificate.

In most cases, the form and content of the audit will change to the MDSAP system. The companies performing these audits must qualify as an AO.

The FDA will use MDSAP audit reports in lieu of routine inspections.

In the EU, manufacturers will transition from EN ISO 13485:2012 to EN ISO 13485:2016 under the current system of directives and Notified Bodies. However, the EU will also introduce the new regulations requiring the Notified Bodies to requalify.

Device manufacturers with a CE Mark will implement a new EU version of the QMS standard and bring the device to conformity with the new regulations.