ISO 13485:2016 – The Final Countdown

12 June 2018

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This document is intended to facilitate an oral briefing.
It is not intended for use as a stand-alone report.

Learning Objectives

- Understand major differences between ISO 13485:2003 and ISO 13485:2016
- Identify transition timelines
  - ISO 13485:2016
  - CMDCAS to MDSAP
- Recognize ISO 13485:2016 impact on MDSAP

0.2 Clarification of Concepts

- Describes phrase “as appropriate” and provides two additional considerations for determination of appropriateness:
  - Compliance with regulatory requirements
  - Necessary to manage risks
- Limits “risk” to safety and performance of the medical device or meeting regulatory requirements and excludes “business risk”
- Explains when term “**documented**” is utilized that it includes concepts of ***establish, implement and maintain***

4.1 Quality management system

4.1.1 General requirements

The organization shall ~~*establish,*~~ document~~*, implement and maintain*~~ a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements.

~~The organization shall identify~~ The organization shall establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this International Standard or applicable regulatory requirements.

The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements.

NOTE: Roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor.

4.1 Quality management system

4.1.2 The organization shall:

a) determine the processes needed for the quality management system and ~~their~~ the application of these processes throughout the organization ~~(see 1.2),~~ taking into account the roles undertaken by the organization;

b) apply a risk based approach to the control of the appropriate processes needed for the quality management system;

c) determine the sequence and interaction of these processes~~,~~.

4.1 Quality management system

4.1.4 The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be:

a) evaluated for their impact on the quality management system;

b) evaluated for their impact on the medical devices produced under this quality management system;

c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.

4.1 Quality management system

4.1.5 When the organization chooses to outsource any process that affects product conformity ~~with~~ to requirements, ~~the organization~~ it shall monitor and ensure control over such processes. ~~Control of such~~ The organization shall retain responsibility of conformity to this International Standard and to customer and applicable regulatory requirements for outsourced processes ~~shall be identified within the quality management system *(see 8.5.1).*~~

~~NOTE Processes needed for the quality management system referred to above should~~ . The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4. The controls shall include ~~processes for management activities, provision of resources, product realization and measurement~~ written quality agreements.

4.1 Quality management system

4.1.6 The organization shall document procedures for the **validation of the application of computer software** used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.

The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software.

Records of such activities shall be maintained (see 4.2.5).

4.2 Documentation requirements

4.2.3 Medical device file

For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements.
The content of the file(s) shall include, but is not limited to:

a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use;
b) specifications for product;
c) specifications or procedures for manufacturing, packaging, storage, handling and distribution;
d) procedures for measuring and monitoring;
e) as appropriate, requirements for installation;
f) as appropriate, procedures for servicing.

5.2 Customer Focus

Top management shall ensure that customer requirements and applicable regulatory requirements are determined and ~~are~~ met ~~(see 7.2.1 and 8.2.1)~~.

6.2 Human resources

~~6.2.1 Competence, awareness and training~~

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

~~6.2.2 Competence, awareness and training~~

The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.

The organization shall:

a) determine the necessary competence for personnel performing work affecting product quality~~,~~;

b) provide training or take other actions to ~~satisfy these needs,~~ achieve or maintain the necessary competence;

6.2 Human resources

c) evaluate the effectiveness of the actions taken~~,~~;

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives~~, and~~;

e) maintain appropriate records of education, training, skills and experience (see 4.2.~~4~~5).

NOTE ~~*National or regional regulations might require*~~ The methodology used to check effectiveness is proportionate to the ~~*organization to establish documented procedures*~~ **risk associated with the work** for ~~*identifying*~~ which the training ~~*needs*~~ or other action is being provided.

6.4 Work environment and contamination control

6.4.2 Contamination control

As appropriate, ~~special~~ the organization shall plan and document arrangements ~~shall be established and documented~~ for the control of contaminated or potentially contaminated product in order to prevent contamination of ~~other product,~~ the work environment ~~or~~, personnel ~~(see 7.5.3.1).~~, or product.

For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system ~~(see 4.1).~~.

The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes~~,~~ and documents~~,~~ (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment;

c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product ~~and~~ together with the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.~~4~~5).

7.2 Customer-related processes

7.2.1 Determination of requirements related to ~~the~~ product

The organization shall determine:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities~~,~~;

b) requirements not stated by the customer but necessary for specified or intended use, ~~where~~ as known~~,~~;

~~statutory and~~

c) applicable regulatory requirements related to the product~~, and~~;

d) any **user training needed** to ensure specified performance and safe use of the medical device;

e) any additional requirements determined by the organization.

7.3 Design and Development

7.3.1 General

The organization shall document procedures for design and development.

7.3 Design and Development

7.3.3 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.~~4~~5). These inputs shall include:

a) functional, performance, usability and safety requirements, according to the intended use~~,~~;

b) applicable ~~statutory and~~ regulatory requirements~~,~~ and standards;

~~where~~

c) applicable output(s) of risk management;

d) as appropriate, information derived from previous similar designs~~,~~;

e) other requirements essential for design and development~~,~~ of the product and processes.

~~*e) output(s) of risk management (see 7.1).*~~

These inputs shall be reviewed for adequacy and approved.

Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other.

NOTE Further information can be found in IEC 62366–1.

7.3 Design and Development

7.3.6 Design and development verification

~~Verification~~ Design and development verification shall be performed in accordance with planned and documented arrangements ~~(see 7.3.1)~~ to ensure that the design and development outputs have met the design and development input requirements. ~~Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).~~

The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced.

Records of the results and conclusions of the verification and necessary actions shall be maintained (see 4.2.4 and 4.2.5).

7.3 Design and Development

7.3.7 Design and development validation

Design and development validation shall be performed in accordance with planned and documented arrangements ~~*(see 7.3.1)*~~ to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. ~~*Validation shall be completed prior to the delivery or implementation of the product (see Note 1).*~~

~~Records of the results of~~ The organization shall document validation plans that include methods, acceptance criteria, and ~~any necessary actions~~, as appropriate, statistical techniques with rationale for sample size.

Design validation shall be ~~maintained~~ conducted on representative product. Representative product includes initial production units, batches or their equivalents. The rationale for the choice of product used for validation shall be recorded (see 4.2.~~4~~5).

7.3 Design and Development

7.3.7 Design and development validation

As part of design and development validation, the organization shall perform clinical evaluations ~~and/~~or ~~evaluation of~~ performance evaluations of the medical device~~, as required by national or regional regulations (see Note 2).~~

~~NOTE 1 If a~~ in accordance with applicable regulatory requirements. A medical device ~~can only be validated following assembly and installation at point of use, delivery~~ used for clinical evaluation or performance evaluation is not considered to be ~~complete until the product has been formally transferred~~ released for use to the customer.

~~NOTE 2 Provision of the medical device for purposes of clinical evaluations and/or evaluation of performance is not considered to be delivery.~~

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.

7.3 Design and Development

7.3.8 Design and development transfer

The organization shall document procedures for transfer of design and development outputs to manufacturing. These procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements.

Results and conclusions of the transfer shall be recorded (see 4.2.5).

7.3 Design and Development

7.3.9 Control of design and development changes

The organization shall document procedures to control design and development changes. The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use.

Design and development changes shall be identified ~~and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before~~ . Before implementation~~.~~ , the changes shall be:

a) reviewed;

b) verified;

c) validated, as appropriate;

d) approved.

7.3 Design and Development

7.3.9 Control of design and development changes

The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes.

Records of ~~the results of the~~ changes, their review ~~of changes~~ and any necessary actions shall be maintained (see 4.2.4~~4~~5).

7.3 Design and Development

7.3.10 Design and development files

The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.

7.4 Purchasing

7.4.1 Purchasing process

The organization shall ~~*establish documented*~~ document procedures (see 4.2.4) to ensure that purchased product conforms to specified ~~*purchase requirements*~~ purchasing information.

~~The type and extent of control applied to~~ The organization shall establish criteria for the ~~supplier and~~ evaluation and selection of suppliers. The criteria shall be:

a) based on the ~~purchased~~ supplier's ability to provide product ~~shall be dependent upon~~ that meets the organization's requirements;

b) based on the performance of the supplier;

c) based on the effect of the purchased product on ~~subsequent product realization or the final product.~~ the quality of the medical device;

7.4 Purchasing

7.4.1 Purchasing process

~~The organization shall evaluate and select suppliers based on their ability to supply product in accordance~~

d) proportionate to the risk associated with the ~~organization's requirements. Criteria for selection, evaluation and~~ medical device.

The organization shall plan the monitoring and re-evaluation ~~shall be established.~~ of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process.

Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.

Records of the results of ~~evaluations~~ evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from ~~the evaluation~~ these activities shall be maintained (see 4.2.~~4~~5).

7.4 Purchasing

7.4.2 Purchasing information

Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.

To the extent required for traceability given in 7.5.~~3.2~~9, the organization shall maintain relevant purchasing information~~, *i.e.*~~ in the form of documents (see 4.2.~~3~~4) and records (see 4.2.~~4~~5).

7.4 Purchasing

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified ~~purchase requirements~~ purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

~~Where~~ When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device.

When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification ~~arrangements~~ activities and method of product release in the purchasing information.

Records of the verification shall be maintained (see 4.2.~~4~~5).

7.5 Production and service provision

7.5.4 Servicing activities

If servicing of the medical device is a specified requirement, the organization shall ~~establish documented~~ document servicing procedures, ~~work instructions and~~ reference materials, and reference ~~measurement procedures~~ measurements, as necessary, for performing servicing activities and verifying that ~~they meet the specified~~ product requirements are met.

The organization shall analyse records of servicing activities carried out by the organization or its supplier:

a) to determine if the information is to be handled as a complaint;

b) as appropriate, for input to the improvement process.

Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.~~4~~5).

~~NOTE Servicing can include, for example, repair and maintenance.~~

7.5 Production and service provision

7.5.11 Preservation of product

The organization shall ~~*establish documented*~~ document procedures ~~*or documented work instructions*~~ for preserving the conformity of product to requirements during ~~*internal*~~ processing ~~*and delivery to the intended destination.*~~

~~*This preservation shall include identification*~~, storage, handling, ~~*packaging, storage*~~ and ~~*protection*~~ distribution. Preservation shall ~~*also*~~ apply to the constituent parts of a ~~*product*~~ medical device.

The organization shall ~~*establish documented procedures or documented work instructions for the control of product with a limited shelf-life or requiring special storage*~~ protect product from alteration, contamination or damage when exposed to expected conditions~~*. Such*~~ and hazards during processing, storage, handling, and distribution by:

a) designing and constructing suitable **packaging and shipping containers**;
b) documenting requirements for special ~~*storage*~~ conditions needed if packaging alone cannot provide preservation.

If special conditions are required, they shall be controlled and recorded (see 4.2.~~4~~5).

8.2 Monitoring and Measurement

8.2.1 Feedback

As one of the measurements of the ~~*performance*~~ effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements.

The methods for obtaining and using this information shall be ~~determined~~ documented.

The organization shall ~~*establish a documented procedure*~~ document procedures for ~~*a*~~ the feedback ~~*system [see 7.2.3 c)]*~~process. This feedback process shall include provisions to ~~*provide early warning of quality problems and for*~~ gather data from production as well as post-production activities.

8.2 Monitoring and Measurement

8.2.1 Feedback

The information gathered in the feedback process shall serve as potential input into ~~the corrective~~ risk management for monitoring and ~~preventive action~~ maintaining the product requirements as well as the product realization or improvement processes ~~(see 8.5.2 and 8.5.3).~~.

If ~~national or regional regulations~~ applicable regulatory requirements require the organization to gain specific experience from ~~the~~ post-production ~~phase~~ activities, the review of this experience shall form part of the feedback ~~system (see 8.5.1).~~ process.

8.2 Monitoring and Measurement

8.2.2 Complaint handling

The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements.
These procedures shall include at a minimum requirements and responsibilities for:

a) receiving and recording information;
b) evaluating information to determine if the feedback constitutes a complaint;
c) investigating complaints;
d) determining the need to report the information to the appropriate regulatory authorities;
e) handling of complaint-related product;
f) determining the need to initiate corrections or corrective actions.

8.2 Monitoring and Measurement

8.2.2 Complaint handling

If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented.

If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved.

Complaint handling records shall be maintained (see 4.2.5).

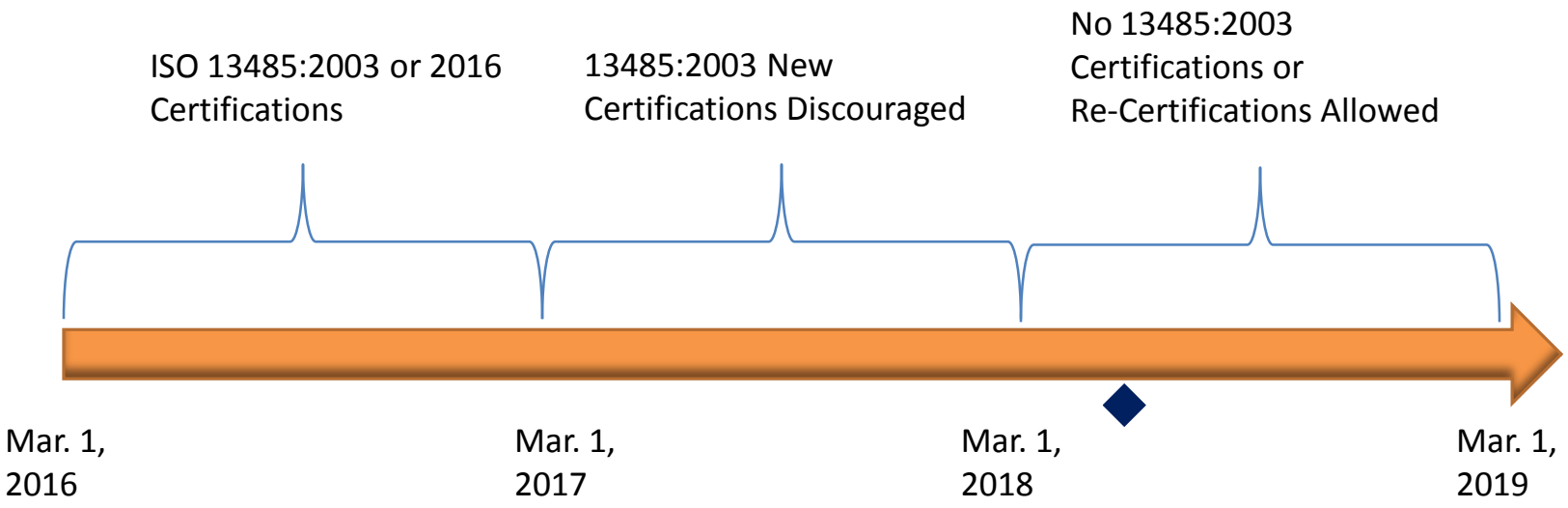
8.2 Monitoring and Measurement

8.2.3 Reporting to regulatory authorities

If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities.

Records of reporting to regulatory authorities shall be maintained (see 4.2.5).

ISO 13485:2016 Timeline



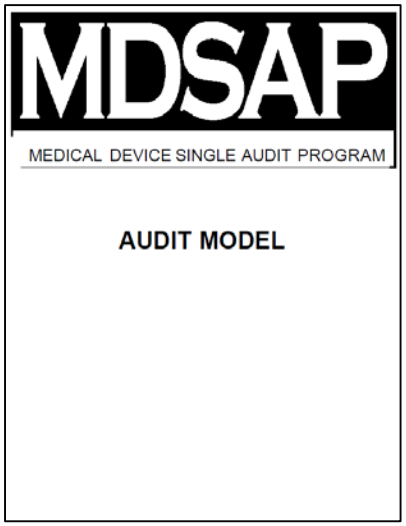
MDSAP and ISO 13485:2016

ISO 13485:2016 is the “backbone” of the MDSAP Audit Model

“Country-specific” regulatory requirements are audited at appropriate points during the audit of corresponding MDSAP processes and tasks

https://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM390382.pdf

https://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM390383.pdf



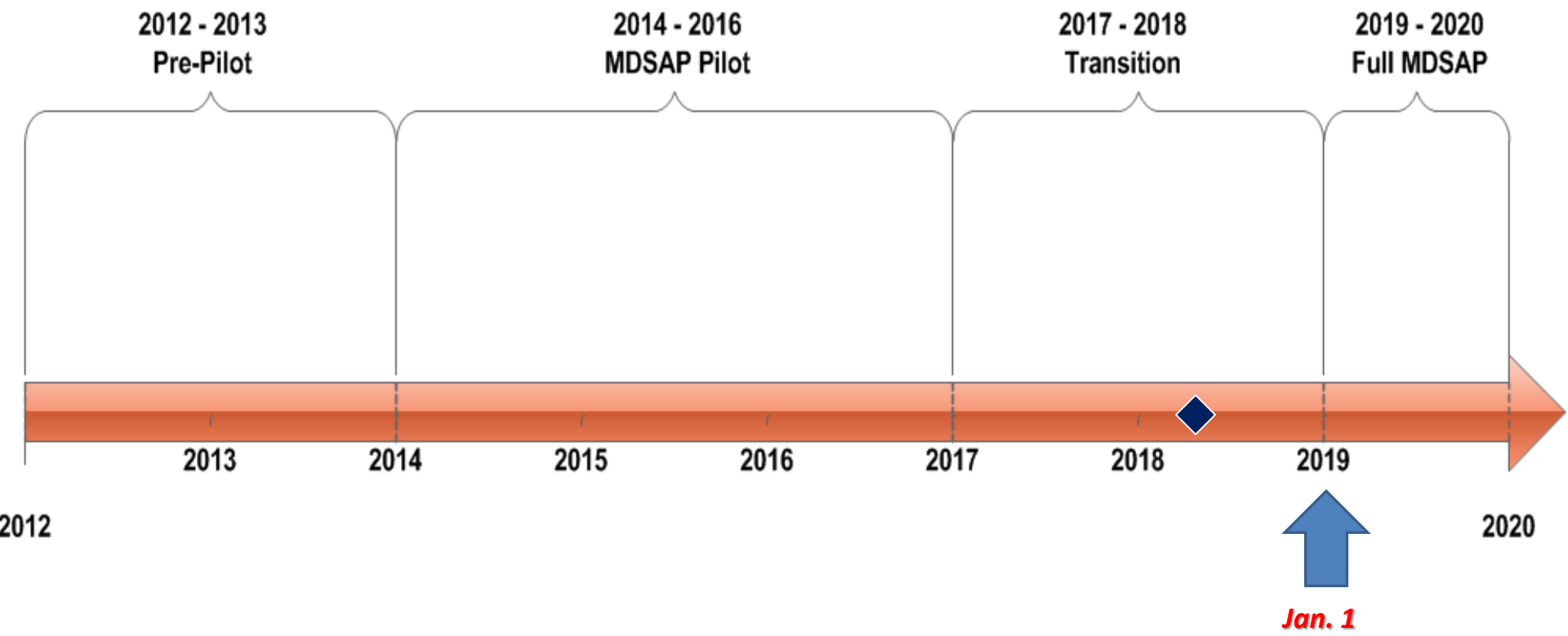
MDSAP and Health Canada

Notice: Transition Plan for the Medical Device Single Audit Program (MDSAP) 04 December 2015

"MDSAP will replace the current Canadian Medical Devices Conformity Assessment System (CMDCAS) program, even in situations when a manufacturer intends to sell only in Canada. This implementation will begin at the conclusion of the Pilot on January 1, 2017, and will span a period of two years. During this two year period, Health Canada will accept certificates issued under both CMDCAS and MDSAP. As of January 1, 2019, only MDSAP certificates will be accepted."

www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/international/notice-transition-plan-medical-device-single-audit-program.html

Health Canada MDSAP Timeline



ISO 13485:2016, MDSAP Timeline