Drugs and Health Products

Notice: Transition to the Revised Version of ISO 13485 and its impact on the Compliance to the Quality Management System Requirements of the Canadian Medical Devices Regulations

August 4, 2016
Our reference number: 16-108859-627

To: All Canadian and Foreign Manufacturers
Attention to persons responsible for regulatory affairs and quality management systems

Application

The transition to ISO 13485:2016 applies to:

- all **Canadian** and **Foreign** manufacturers holding class II, III, and IV medical device licences
- all **Canadian** and **Foreign** manufacturers applying for class II, III and IV medical device licences

Note

A **Manufacturer** is defined in the *Medical Devices Regulations* as a person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

Revised Version of ISO 13485

On March 1st, 2016, the International Organization for Standardization (ISO) published the revised version of ISO 13485 titled "ISO 13485 - Medical Devices - Quality management systems - Requirements for regulatory purposes". This revised version will supersede ISO 13485:2003. This revised standard is referred to as ISO 13485:2016.

Transition Period

ISO will withdraw ISO 13485:2003 on March 1st, 2019, three years after the publication of ISO 13485:2016.

Health Canada has set March 1st 2019, as the transition date to ISO 13485:2016. **All manufacturers of class II, III, and IV medical devices holding licences or applying for new or amended licences must complete the transition to ISO 13485:2016 by March 1st, 2019.**

Obligation to Submit Certificate

In accordance with section 43.1 of the *MedicalDevicesRegulations*a manufacturer is required to submit to Health Canada a copy of any new or modified certificate within thirty days of the certificate being issued.

Failure of a manufacturer to transition to ISO 13485:2016 by the appropriate date or to comply with section 43.1 of the *Medical Devices Regulations* may lead to Health Canada taking compliance action against the medical device licences held by the manufacturer.

CMDCAS Recognized Registrars

Health Canada will only accept ISO 13485:2016 certificates issued by CMDCAS recognized registrars.

Health Canada Guidance Documents

Health Canada will revise its existing guidance documents to address the revision of the standard.

MDSAP Transition Reminder

In accordance with Health Canada's announced MDSAP transition plan, CMDCAS certificates will no longer be accepted after December 31st 2018. Manufacturers will be required to submit valid MDSAP certificates by no later than January 1st, 2019 in order to maintain their medical device licences. To facilitate a smooth transition, Health Canada is encouraging manufacturers to begin the transition process in a timely matter to ensure compliance with the regulatory requirements at the end of the transition period. More information on the MDSAP transition plan and the regulatory requirements can be found in a Health Canada notice.

Questions or concerns regarding this notice should be directed to:

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