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

December 4, 2015
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Background

The Medical Device Single Audit Program (MDSAP) was initiated at the International Medical Devices Regulators Forum's (IMDRF) inaugural meeting in Singapore in 2012. The program was designed and developed so that a single audit, performed by an authorized Auditing Organization (AO), meets the quality management system (QMS) requirements of multiple regulatory agencies, derived from the International Organization for Standardization (ISO) 13485:2003. Employing a single audit program allows regulatory agencies to efficiently leverage resources, reduce regulatory burden on industry without compromising public health, and promote more aligned and consistent technical requirements, among other benefits. In addition to Health Canada, the participating agencies are the Australian Therapeutic Goods Administration (TGA), the Brazilian Agência Nacional de Vigilância Sanitária (ANVISA), the Japanese Ministry of Health, Labour and Welfare (MHLW), the Pharmaceuticals and Medical Devices Agency (PMDA), and the United States Food and Drug Administration (FDA).

The MDSAP pilot (the Pilot) was launched on January 1, 2014, for a projected three year term and the Mid-Pilot Status Report was recently published on the FDA's website.

Transition Plan

The Pilot is scheduled to conclude December 31, 2016, and as stated in Health Canada Notices dated January 2014 and January 16, 2015, Health Canada intends to implement MDSAP as the sole mechanism for manufacturers to demonstrate compliance with the quality management system requirements of the *Medical Devices Regulations* (the Regulations). 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. Further details will be released as the transition plan is finalized. Health Canada's transition to MDSAP is an attempt to align with the transition period for the revised version of ISO 13485, which is anticipated to be published in early 2016.

All CMDCAS-recognized registrars have been given the opportunity to apply to be authorized MDSAP AOs during the Pilot and have stated their intentions to do so. Manufacturers who have a contract with registrars not yet authorized under MDSAP should contact their registrar and inquire about their expected timeline for approval.

Alternatively, manufacturers can consult the status list of AOs. To facilitate transition, MDSAP audits may take the place of CMDCAS surveillance audits but certification documents will only be issued once all certification requirements have been met.

Manufacturers who plan to market their devices only in Canada are required to comply with the regulatory requirements set out in the Regulations; compliance with foreign regulatory requirements will not be enforced. However, the CDMCAS QMS certificate will need to be replaced with an MDSAP certificate, which may require the services of another registrar or AO.

Health Canada is committed to working with the Standards Council of Canada, recognized third party AOs, and medical device manufacturers to ensure the smooth transition to MDSAP.

Documents and information about MDSAP can be found on the IMDRF website and questions on it and the transition plan can be directed to:

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