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## **StarFish Analysis: Health Canada plans to phase out the CMDCAS program and transition to MDSAP**

**By Virginia Anastassova, 15 December 2015**

Health Canada is planning to replace the current Canadian Medical Devices Conformity Assessment System (CMDCAS) program with the Medical Device Single Audit Program (MDSAP). Implementation will begin 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.

What does that mean for manufacturers? Instead of requiring the CMDCAS certification, Health Canada will recognize quality system audits performed by the US FDA, Brazilian ANVISA, Australian Therapeutic Goods Administration and the Japanese Pharmaceuticals and Medical Devices Agency. Quality system audits performed by one of these participating jurisdictions will be sufficient to meet one another's quality system requirements.

This is not new as the MDSAP pilot (the Pilot) was launched on January 1, 2014, for a projected three year term and is scheduled to conclude December 31, 2016.

All CMDCAS-recognized registrars have been given the opportunity to apply to be authorized MDSAP auditing organizations 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.

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 CMDCAS QMS certificate will need to be replaced with an MDSAP certificate, which may require the services of another registrar or auditing organizations.

More information is available on [Health Canada's website](#) and [IMDRF website](#).