

MDSAP Transition Update

*MDSAP Forum Stakeholder Day
December 5, 2018*

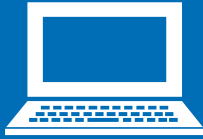
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Overview

- 1 Progress of Transition
- 2 Mitigation Measures
- 3 Documentation to Submit
- 4 Contact Information

Progress of Transition



Data analysis

Health Canada analyses data from multiple sources to gauge the progress of the transition and to proactively detect risks to the Canadian healthcare system.



~75% of manufacturers have transitioned

- This figure is consistent with 2017 manufacturer survey.
- Manufacturers still submitting transition information.



Continue to monitor and support

- Health Canada continues to monitor the transition
- Technical support is available for manufacturers who need help to navigate the transition.

Mitigation Measures

- In April and May of 2018, Health Canada and the MDSAP Consortium put in place mitigation measures to address stakeholder concerns and challenges.
 - Adjustments to Transition Plan
 - Audit Duration Reductions
- Health Canada has developed mitigation measures to support the healthcare system and patients during, and after, the MDSAP transition.
 - The objective of these is to support the on-going delivery of healthcare services while facilities adjust to changing device availability.

Documentation to Submit

- In August, Health Canada broadcast instructions and clarification on the documentation to submit as evidence of transition to MDSAP
- The [MDSAP FAQ](#) was subsequently updated on October 3rd to include this information

Documentation to Submit

2018

Manufacturers completing
the transition to MDSAP in
2018

Documentation to Submit

Submit a copy of your MDSAP certificate to MDB before
2018/12/31.

Documentation to Submit

2019

Manufacturers completing
the transition to MDSAP in
2019

Documentation to Submit

Submit, before 2018/12/31:

1. Your CMDCAS certificate valid until 2018/12/31
2. An ISO 13485 certificate (non-CMDCAS) issued by an MDSAP Auditing Organisation valid after 2019/01/01
3. Documented evidence that you have made firm arrangements to undergo an initial or recertification MDSAP audit in 2019

Documentation to Submit

Surveillance audit

Manufacturers
transitioning to MDSAP
during a surveillance audit
in 2018 or 2019

Documentation to Submit

Submit, before 2018/12/31:

1. Your CMDCAS certificate valid until 2018/12/31
2. An ISO 13485 certificate (non-CMDCAS) issued by an MDSAP Auditing Organisation valid after 2019/01/01
3. An MDSAP Surveillance Audit Confirmation Notification completed by your AO (MDSAP AU G00026.1)

OR

Documented evidence that you have made firm arrangements to undergo an MDSAP surveillance audit in 2019

Documentation to Submit

When submitting your transition documentation to the Medical Devices Bureau, the documents must be submitted as a single PDF file, in the order listed above, along with a completed form F202, to the following email address: hc.qs.mdb.sc@canada.ca Please use the following subject line: “MDSAP Transition Plan”

Contact Information



Quality Systems Section
Medical Devices Bureau
HC.QS.MDB.SC@canada.ca



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<https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/international/transition-medical-device-single-audit-program.html>