



IMDRF

International Medical
Device Regulators Forum

Regulatory and Policy Updates
Therapeutic Products Directorate
Health Canada

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Overview

- Medical Device Single Audit Program (MDSAP)
- Regulatory Review of Drugs and Devices
- Scientific Advisory Committee on Digital Health Technology (SAC-DHT)
- Notices
- Guidances



Transition to Medical Device Single Audit Program (MDSAP)

December 2015 - Health Canada announced that the CMDCAS program would be replaced by MDSAP as of January 1st, 2019.

Health Canada worked in collaboration with international regulatory MDSAP partners to develop mitigation measures to address stakeholders' feedback (audit cycle & audit duration/costs)



MDSAP
January 1, 2019

MDSAP – mandatory

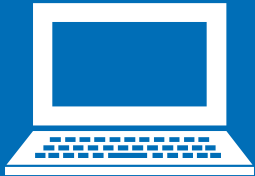
Health Canada will continue to monitor the transition closely to ensure an effective and successful transition to MDSAP

Mitigation measures

1. Reduction of audit duration for SMEs (meeting the criteria)
2. Allowing manufacturers to transition to MDSAP while carrying-on with their existing certification cycle under CMDCAS



Status of Transition to Medical Device Single Audit Program (MDSAP)



MDSAP Survey



December 2017 - about half of companies planning to transition expected to do so in the second half of 2018

2500* facilities registered with MDSAP



Approximately 280* MDSAP certificates received by Health Canada to date

- long wait times between audits and certificate issuance
- certificates received by manufacturers but not submitted to HC?

* as of August 20, 2018



Continue to monitor

MDSAP will bring:

- greater alignment of rules with regulators in other jurisdictions
- important benefits to manufacturers operating in multiple markets



Regulatory Review of Drugs and Devices

Device advice

To improve communication of regulatory requirements and expectations to stakeholders:

- Interactive e-Learning course
- Development of a formal meeting framework

Digital Health

March 28, 2018 – establishment of the Digital Health Division

- Review of software, diagnostic, therapeutic, and cosmetic radiation devices
- Will undertake newer digital health related initiatives: cybersecurity, artificial intelligence, 3D printing, mobile apps, software as a medical device, etc.

Outcomes

New e-learning courses

Formal device advice framework

Targeted pre-market review of digital health technologies

Improved access to innovative digital health devices



SAC-DHT

- Online call for candidates occurred in June/July resulted in 100+ nominations.
- Committee selected by end of August.
- Proposed inaugural meeting is planned for Nov on the topic of cybersecurity.
- Recommendations and advice from the Committee may be used to develop a draft guidance document.



New Notices and Upcoming Guidance Documents

- Cybersecurity notice – HC outlines our plans and how we will be assessing the manufacturer's cybersecurity risk control measures as part of the pre-market evaluation process.
- Guidance document is focusing on the premarket controls aspect and is expected to be finalized for public comment later this year.



New Notices and Upcoming Guidance Documents

- 3D Printing notice – HC outlines plans to develop a draft guidance document to assist medical device manufacturers seeking to licence 3D-printed devices.
- Guidance document will focus on the evidence to support premarket Class III and IV licence applications for implantable medical devices manufactured by 3D printing processes under ISO 13485.



New Notices

- Infusion pumps – HC recently published a notice outlining expectations with regards to the delivery accuracy testing requirements to support new Class II and Class III medical device licence applications.



New Notices

- Adoption of GMDN – HC published a notice to announce that they will be transitioning from their current medical device categorization to GMDN
- As of July 19th, about almost half of the manufacturers have provided GMDN codes for currently licensed medical devices.
- HC is currently running a pilot to assign GMDN codes for incoming applications.



Upcoming Guidance Documents

- Final Guidance Document: Applications for Medical Device Investigational Testing Authorizations expected to be published in September.
 - Clarified application requirements and processes, and addressed longstanding concerns from stakeholders such as timing of research ethics board (REB) approval and filing requests for revisions to an ITA.



Upcoming Guidance Documents

- Software as a Medical Device (SaMD) Draft Guidance Document is expected to be published soon for public comments.



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Questions/comments

Thank you!