Health Canada Santé Canada

Canada

COVID-19 Medical Devices and MDSAP

from *Interim Orders* to the *Medical Devices Regulations*

February 14th, 2023

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YOUR HEALTH AND SAFETY... OUR PRIORITY.

Notice of Intent and Consultation

- A Notice of Intent was published on May 2nd, 2022 regarding proposed changes to the *Medical Devices Regulations*
  - to allow ongoing sale of COVID-19 devices after expiry of Interim Orders
  - to create permanent pathway for authorising COVID-19 medical devices
  - to establish framework for ongoing regulation of authorised COVID-19 medical devices

- A consultation on this proposal ran from the 2nd to the 22nd of May, 2022.

What was proposed?

- Holders of class II, III, and IV COVID-19 medical devices authorised under the IOs that no longer have Urgent Public Health Need (UPHN) would need to comply with new requirements:
  - Initiate the certification process under MDSAP
  - Submit a copy of a signed contract for MDSAP certification within 120 days
  - Submit a copy of a valid MDSAP certificate within 2 years.

What is MDSAP?

An International Consortium of countries

Therapeutic Goods Administration (TGA)

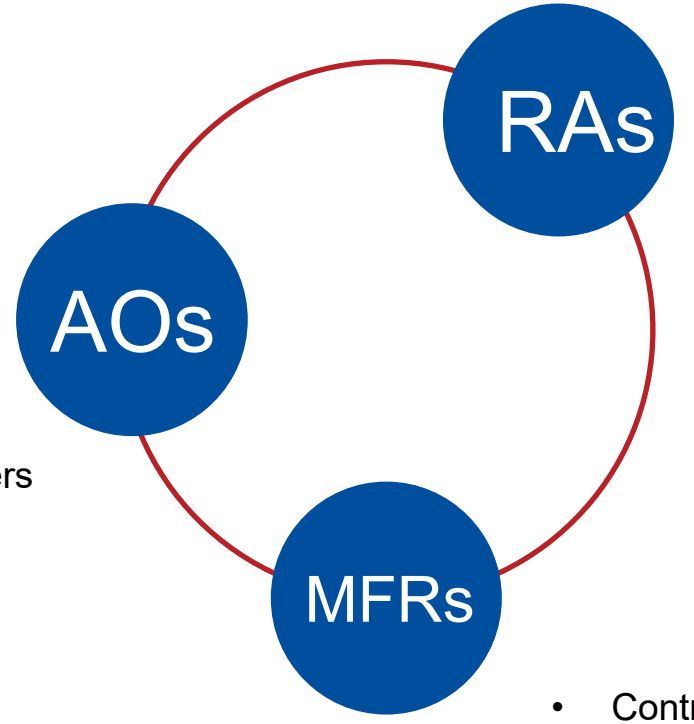
Agência Nacional de Vigilância Sanitária (ANVISA)

Health Canada (HC)

Pharmaceuticals and Medical Devices Agency (PMDA)

U.S. Food and Drug Administration (FDA)

What is MDSAP?



- Assess and recognise AOs
- Take regulatory decisions about manufacturers

- Audit and certify manufacturers
- Share audit reports and certificates with Regulators

- Contract with AOs for MDSAP audits and certification
- Submit MDSAP documents (as appropriate)

What is MDSAP?

Criteria	• ISO 13485:2016 • Part 1, *Medical Devices Regulations*
Scope	• Design (class III & IV) and manufacturing • Covers device(s) subject to licensing
AO	• Recognition by Minister • Competence requirements • Reporting obligations

MDSAP

QMS Certificate issued under MDSAP

Used by manufacturers to demonstrate that QMS obligations are fulfilled.

Provides confidence to Health Canada that manufacturers are compliant.

What is MDSAP?

Preparing for an MDSAP Audit

Know your scope

- Countries
- Products
- Locations
- Roles

Know the program

- Audit Model
- NC grading
- Q&A
- Online training

Update your QMS

- Are all reg. requirements addressed?
- Is everything up to date?

Train your employees

- Regulatory requirements
- Recent changes

Prepare Records

- Marketing authorizations
- Complaints
- Incidents
- Recalls
- Suppliers
- DHF
- DMR

Resources

- Official MDSAP Consortium Website (hosted by FDA):
  - Regulatory Requirements
  - Audit Model and Companion Document
  - Grading of NCs
  - Marketing Identifiers and Post-Market Data
  - Procedures / Forms
  - Contact Info for AOs and RAs
  - Training material

Resources

- Medical Devices, General Enquiries

  devicelicensing-homologationinstruments@hc-sc.gc.ca

  613-957-7285
  613-954-4587

- Quality Management Systems (ISO 13485, MDSAP)

  qs.mdb@hc-sc.gc.ca

  613-948-7194

- Medical Device Establishment Licensing

  mdel.questions.leim@hc-sc.gc.ca

  613-954-6790

Questions?