MDSAP: A Successful Work in Progress

Brian Ludovico
Executive Director, MDSAP Regulatory Certification
Health Sciences Medical Devices
NSF International
Outline

1. Where it all began
2. How we’ve grown
3. Potential and Pitfalls
4. So many questions
5. What’s the latest?
6. What lies ahead
MDSAP: Where it all began

International consortium of countries dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices on an international scale in an Audit and Assessment Pilot Program

→ Not an “FDA” product
This global approach included the development of an international coalition of countries dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices on an international scale in a Pilot Program starting in January 2014 for three years before becoming operational.
The mission of the MDSAP International Consortium is to jointly leverage regulatory resources (including third party and Regulatory Authority inspectorates) to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers allowing for greater coverage in auditing manufacturers around the globe.
The MDSAP Program was designed to be completely transparent, giving manufacturers full access to the documentation used by both the Regulatory Authorities and the Auditing Organizations, including requirements for:
- the audit process
- competency and training
- policies, procedures, templates and forms

https://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377578.htm
The international consortium of countries for MDSAP as of October 2018:

- Therapeutic Goods Administration (TGA)
- Agência Nacional de Vigilância Sanitária (ANVISA)
- Health Canada (HC)
- Ministry of Health, Labor and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA)
- U.S. Food and Drug Administration (FDA)
MDSAP International Consortium

Official Observers to MDSAP as of October 2018:

World Health Organization (WHO)

European Union (EU)
## MDSAP Scope of Regulations

<table>
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<tr>
<th>Requirements</th>
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<tr>
<td>Therapeutic Goods Act 1989</td>
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<td>Therapeutic Goods (Medical Devices) Regulations 2002</td>
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<td>ANVISA Pre-Market Approval RDC 185/2001</td>
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<td>ANVISA Good Manufacturing Practices RDC 16/2013</td>
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<td>R 807 subparts A to D, Device Tracking 21 CFR 821</td>
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<td>MHLW Ministerial Ordinance No. 169</td>
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Third Parties and Regulatory Inspectorates

Under MDSAP, use of third party auditors, in addition to Regulatory Authority Inspectorates, allows greater coverage in auditing manufacturers around the globe.

Government resources can then be focused on high risk or problematic medical devices, manufacturers that are not in compliance with the regulations, and oversight of the third party auditing organizations.
The MDSAP audit process was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the quality management system requirements:

- Brazilian Good Manufacturing Practices (ANVISA RDC 16)
- Japanese requirements (MHLW MO 169)
- FDA’s Quality System Regulation (21 CFR Part 820)
AND other specific requirements of medical device regulatory authorities participating in the MDSAP program such as:
- registration
- licensing
- adverse event reporting and more
The MDSAP governing body is the Regulatory Authority Council (RAC), which is comprised of two senior managers from each participating jurisdiction, as well as representation from observing jurisdictions.
Regulatory Authority Council

Responsibilities:

– Perform executive planning, strategic priorities, sets policy and makes decisions on behalf of the MDSAP Consortium.

– Reviews and approves MDSAP documents, procedures, work instructions, etc.

– Makes Auditing Organization authorization and recognition decisions.
Regulatory Authority Council

RAC Constitution:

– Chair, Health Canada (rotates)
– Vice Chair, ‘In Transition’ (rotates)
– Executive Secretariat (rotates with Chair)
– Permanent Secretariat (US FDA)
– Permanent Information Technology (IT) Director (PAHO)
Oversight of the Auditing Organizations

In accordance with these best practices, the Consortium has developed a transparent and robust plan/schedule of assessing the competence and compliance of MDSAP Auditing Organizations as part of a four year recognition process.
Assessment Process

Assessment Program

Assessment Activities

Assessments

Initial Assessment
- Application Review
  - Stage 1 Assessment including Documentation Review
    - Stage 2 On-Site Assessment (Head Office)
      - 3 Witnessed Audits
        - On-Site Assessment of all Critical Locations (as necessary)

Surveillance Assessment
- Surveillance On-Site Assessment (Head Office)
  - 1 Witnessed Audit
    - 1 Witnessed Audit per Critical Location and per Assessment Cycle (as necessary)

Re-Recognition Assessment
- Re-Recognition On-Site Assessment (Head Office)
  - 1 Witnessed Audit
    - 1 Witnessed Audit per Critical Location and per Assessment Cycle (as necessary)
MDSAP Exponential Growth

MDSAP Participating Manufacturer Sites - Calendar Year

Number of Sites Added | Cumulative Total

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<tr>
<th>Quarter</th>
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Currently, 14 Auditing Organizations (AOs) under MDSAP
- All but 2 are also Notified Bodies
- Combined/integrated audits are likely
- All following ISO 17021-1:2011
- IAF requirements → Mandatory Documents (MDs)
- Competency requirements very specific
Who Benefits From MDSAP?

- Organizations selling in Canada and internationally
- Manufacturing sites of finished medical devices
- Relatively large organizations (~ 70 people and more)
- Manufacturers of combination products selling in Australia
- Organizations intending to sell in Brazil
- Manufacturers of high risk medical devices
- Organizations participating in WHO *Prequalification of In Vitro Diagnostics (IVDs) Programme*

- In the future: Organizations intending to sell in countries requiring premarket QMS audit and accepting MDSAP certificates as evidence of compliance
Manufacturers’ Concerns

- Audit duration/cost
- Health Canada’s MDSAP transition
- Potential heightened scrutiny by AOs during witness audits
- Complexity of multi-site schemes
- Learning curve regarding the preparedness for audits
- Processing and security of audit reports
- Auditing Organization’s readiness, capacity, differences
Manufacturers’ Feedback

Comments concerning audits:
- Coverage of requirements was as anticipated
- Competency of AO auditors was impressive
- Audit documentation completion was timely
- Familiarity with audit style was a beneficial
- AO auditors were found to be fair and impartial
- Transition into MDSAP was explained
- Marketing benefits
FAQs

What about Security?

– Regulatory Exchange Platform Secure (REPs)
– The “portal” that will be used for all internal MDSAP communication (Audit Reports, etc.)
  - PAHO administered
  - Phase 1: NOW LIVE
    – Management of the list of participating manufacturers
    – Submission of audit reports
FAQs

Why is the audit longer?

– The increased duration is a result of the MDSAP covering 5 jurisdictional areas at one time → saves resources (time and money), NCR responses are coordinated, and maintains scheduling

– Tasks are predetermined within each process

– Additional resources may be necessary (e.g., technical experts)
FAQs

Why in some cases are surveillance audits the same duration as certification/recertification audits?

– AOs are auditing against a prescribed set of tasks and regulations

– General interpretation differences

– Discussions between RAs and AOs to ensure the necessary coverage of requirements is maintained
FAQs

What is the cost of an MDSAP audit?
- As with duration, the cost is analogous to the overall time spent on audit planning, conduct, and completion
- AOs are allowed to determine prices
- Prices are expected to fluctuate with the jurisdictional coverage
FAQs

Will there be heightened scrutiny by AOs during witness audits?

– It should not be the case but…

– Witness audits may be thought to be much more intense due to RAs looking over the AOs’ shoulders, but the intensive training and impartiality of the auditors is designed to mitigate this
FAQs

What is the risk/benefit if only Canada is mandating MDSAP?
– While MDSAP may not be attractive to all manufacturer’s since they may not have experienced consistent audits/inspections by their applicable jurisdictions, those manufacturers participating can potentially take a decided advantage in market share
Canada’s Initial Action

Health Canada sunsets the CMDCAS Program for MDSAP

→ Effective January 1, 2019, the Health Canada CMDCAS Program will cease to operate


- Health Canada will cease to accept certificates issued under CMDCAS as of December 31st, 2018
Canada’s Action

- Regulation changes will ensure that device licenses will be sustained/supported by the MDSAP, but if manufacturers have not transitioned, their licenses may be suspended.

- A revised version of the MDSAP audit model that incorporates ISO 13485:2016 has been published.

- Clear message: CMDCAS and MDSAP will run concurrently until the end of the CMDCAS Program → all program requirements and sector qualifications must continue to be met.
Canada’s Action

- All manufacturers with CMDCAS certificates must have transitioned to the MDSAP
- Wait, what?
Canada’s Transition To MDSAP

Manufacturers have options for MDSAP

– If a manufacturer has had an MDSAP certification audit in 2018, an MDSAP certificate needs to be provided to Health Canada.

– If a manufacturer has had an MDSAP certification audit and has had trouble getting their certificate, Health Canada should be notified.

– If a manufacturer has not had an MDSAP certification audit, there is a likelihood that regulatory action could be taken against their device licenses.
What’s the Latest?

We’ve heard you….

Changes continue to be made to the Program based on feedback from manufactures, Regulatory Authorities and Auditing Organizations

– Revised Health Canada Transition
– Audit duration (several) modifications
– Task coverage during audits
– Auditing Organization harmonization
– Modification of documentation (audit report, etc.)
Manufacturers wishing to enter the MDSAP Program can now do so during a surveillance audit, but…

…Read the fine print:

– Specific criteria must be satisfied
– Must have verifiable proof of an AO contract
– Must have confirmed audit date prior to Dec. 31, 2019, provided to Health Canada before Dec. 31, 2018
– Be aware of the affect on other jurisdictional requirements

EU Perspective on MDSAP:

Overall the Program makes sense but needs to be weighed against the resources required by regulatory authorities, competent authorities and other organizations

- Audit Report is comprehensive and can be used for EU audits
- Contractual/legal requirements
- EU Technical Documentation Review (TDR)
- Nonconformity grading
Regulatory Timeline: The Perfect Storm

- **ISO 13485:2003 or 2016 Certifications**
  - Mar. 1, 2016

- **13485:2003 New Certifications Discouraged**
  - Mar. 1, 2017

- **No 13485:2003 Certifications or Re-Certifications Allowed**
  - Mar. 1, 2018

- **ISO 13485:2016**
  - Mar. 1, 2019

- **MDSAP**
  - Mar. 1, 2019

- **EU MDR and EU IVDR**
  - Jan. 1, 2019

- **ASEAN Medical Device Directive (AMDD)**
  - Jan. 1, 2020

MDSAP Certificate to ISO 13485:2016 Mandatory in HC
Thank you

bludovico@nsf.org