3M Health Care Business Group

Medical Device Single Audit Program (MDSAP) Overview

The role of MDSAP as a Harmonized Post Market Control

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What is the MDSAP program?

MDSAP is an 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 which started January 2014.

Statement of Cooperation - The heads of the regulatory agencies of Australia, Brazil, Canada and the United States signed a Statement of Cooperation on the MDSAP International Consortium program at the Head of Agency Summit in Manaus, Brazil in November 2012

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Pilot International Consortium

- The international consortium of countries for the MDSAP Pilot are:
  - Therapeutics Goods Administration (TGA) of Australia,
  - Brazil's Agência Nacional de Vigilância Sanitária (ANVISA),
  - Health Canada, and
  - U.S. Food and Drug Administration
  - Official Observers since June 2013:
    - Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA)
  - Newest additions since Spring 2014:
    - World Health Organization (WHO) Diagnostic Prequalification Program
    - European Union as Observers

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Pilot International Consortium

The MDSAP program intends to jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers in the post market framework. The MDSAP governing body is the Regulatory Authority Council (RAC)

Regulatory Authority Council

Two Sr. Managers from each jurisdiction including observers

- Chair, US FDA (rotates)
- Vice Chair, ANVISA (rotates)
- Executive Secretariat (rotates with Chair)
- Permanent Secretariat (US FDA)
- Permanent Information Technology (IT) Director (Currently being established)

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MDSAP Pilot Audit Process

The MDSAP audit process was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the requirements of medical devices – quality management systems:

- ISO 13485:2003
- Brazilian Good Manufacturing Practices (RDC ANVISA)
- Quality System Regulation (21 CFR Part 820)

AND other specific requirements of medical device regulatory authorities participating in the Pilot MDSAP program such as:

- registration,
- licensing,
- adverse event reporting and more.

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IMDRF Documents

The MDSAP Pilot documents just described are based on the foundation established by the International Medical Device Regulatory Forum (IMDRF) MDSAP documents.

- IMDRF/MDSAP WG/N3FINAL:2013 – "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition"
- IMDRF/MDSAP WG/N4FINAL:2013 – "Competence and Training Requirements for Auditing Organizations"
- IMDRF/MDSAP WG/N11FINAL:2014 – "MDSAP Assessment Outcomes and Recognition/Re-recognition Decision by Regulatory Authorities"
- IMDRF/MDSAP WG/N24 (In progress) – "MDSAP Audit Report Guidance"
- New Work Item Extension approved in September with a due date of end of 2015.

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IMDRF MDSAP Documents for Specific to Regulatory Authorities

Documents for the Regulatory Authority assessments of AOs throughout the application, recognition, monitoring, and re-recognition cycle are based on:

- IMDRF/MDSAP WG /N5 FINAL:2013 – "Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations"
- IMDRF/MDSAP WG /N6 FINAL:2013 – "Regulatory Authority Assessor Competence and Training Requirements"
- IMDRF/MDSAP WG/N8 (In progress) – "Regulatory Authority Assessment Method Guidance" Due date end of 2015

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IMDRF Final Documents

http://www.imdrf.org/documents/documents.asp

IMDRF Proposed Documents

http://www.imdrf.org/consultations/consultations.asp

Regulatory Authorities 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.

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What Auditing Organizations can apply to the MDSAP Pilot?

During the Pilot, the only Auditing Organizations that will be allowed to apply to the MDSAP program for recognition will be the accredited organizations/registrars currently utilized in the Health Canada CMDCAS Program. The list of Registrars Recognized by Health Canada can be found on the Health Canada website.

The CMDCAS registrars were allowed to start submitting their application for MDSAP recognition starting this past January. Almost half of the CMDCAS Auditing organizations have already submitted their application for MDSAP recognition within the first five months of the program.

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How can medical device manufacturers participate?

The MDSAP project plan targets the review of 3-5 applications every six months with the associated required assessments for the duration of the pilot through 2016.

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How can medical device manufacturers participate?

Some Auditing Organizations have already successfully passed their initial assessments and are ready to start auditing medical device manufacturers.

The MDSAP Auditing Organizations will be authorized to perform MDSAP audits and issue MDSAP Certificates for medical device manufacturers that will be utilized by the Regulatory Authorities as described in the MDSAP 2013 Announcement.

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MDSAP Pilot

Volunteer to participate!

Be apart of the process during the pilot to help shape the policies and procedures for the operational program scheduled to begin in 2017.

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Volunteer with a MDSAP Auditing Organization Today

- At the conclusion of each MDSAP audit during the Pilot, the manufacturer with be requested to fill out a survey in order to improve and optimize the MDSAP processes.
- Only manufacturers that volunteer and have a MDSAP Audit performed between now and next May – will be invited to a workshop in June 2015 to further refine the MDSAP processes.
- This workshop will be a collaboration between those manufacturers, the Regulatory Authorities in the Consortium and the Auditing Organizations involved in the Pilot.

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Volunteer with a MDSAP Auditing Organization Today

Be a part of the Pilot now - help to form and shape an effective and efficient program for all parties prior to the operational phase, when Health Canada and potentially other Regulatory Authorities switch to MDSAP making it compulsory!

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Medical Devices International Programs

http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM372066.pdf

MDSAP CDRH Learn Module

http://www.fda.gov/Training/CDRHLearn/ucm372921.htm