# Medical Device Single Audit Program (MDSAP) Pilot Update

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# Update

This presentation assumes that the audience has basic knowledge of the Medical Device Single Audit Program (MDSAP) Pilot which started this past January. If not please, see the MDSAP CDRH Learn Module at:

# MDSAP CDRH Learn Module

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

# 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.

# MDSAP
# 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

# 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

# Pilot International Consortium

- Official Observers since June 2013:

  Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA)

  - Intent for full membership during the Pilot after some legislative work

# Pilot International Consortium

- Newest additions since Spring 2014:
  - World Health Organization (WHO) Diagnostic Prequalification Program
  - European Union as Observers

# Pilot International Consortium

The mission of the MDSAP International Consortium is to jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers.

# Regulatory Authority Council

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

RAC Constitution:

- 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)

# Regulatory Authority Council

- RAC performs executive planning, strategic priorities, sets policy and makes decisions on behalf of the MDSAP Consortium.
- RAC reviews and approves MDSAP documents, procedures, work instructions, etc.

# International Subject Matter Expert (SME) Working Groups

- MDSAP IT Portal SME Working Group
  - Developed IT requirements for the MDSAP Portal to include business requirements, IT specifications, security needs, and other procurement specifications
  - WG will work with the MDSAP IT Director and oversee the Cooperative Agreements with the IT Director and the IT Host Organization

# International Subject Matter Expert (SME) Working Groups

- MDSAP Audit and Assessment SME Working Group (WG)
  - Develops procedures, work flows, work instructions, templates, training, etc. for the auditing of medical devices manufacturers by recognized Auditing Organizations (AOs) to include:

# Audit and Assessment SME WG

- Audit Model
- Audit Model Companion Guidance
- Web based Audit Model Training
- Audit Report Fillable Form
- Audit Time Calculations
- MDSAP Certificate Procedures

# Medical Devices International Programs

http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377580.htm

# Audit and Assessment SME WG

- Develops procedures, work flows, work instructions, templates, training, etc. for the assessment of Auditing Organizations (AOs) by Regulatory Authority Assessors to include:

# Audit and Assessment SME WG

- Application review process
- Head Office Assessments
- Critical Location Assessments
- Witnessed Audits of Manufactures
- Special Assessments

# Medical Devices International Programs

http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377581.htm

# Audit and Assessment SME WG

- Develops procedures, work flows, work instructions, templates, training, etc. for the MDSAP Quality Management System to include:

# Audit and Assessment SME WG

- Quality Manual
- Complaint process
- Improvement Process
- Appeals Process

# Medical Devices International Programs

http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377583.htm

# 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)

# MDSAP Pilot Audit Process

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

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

# 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 Documents

Recognition, monitoring and re-recognition of Auditing Organizations documents:

– IMDRF/MDSAP WG/N3FINAL:2013 – "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition"

# IMDRF MDSAP Documents

– 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 Documents

- 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.

# IMDRF MDSAP Documents

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 Documents

– 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

# 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.

# *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 MDSAP website.

# *How can medical device manufacturers participate?*

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.

# *How can medical device manufacturers participate?*

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.

# Medical Devices International Programs

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

# 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.

# 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 .

# Volunteer with a MDSAP Auditing Organization Today

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.

# Volunteer with a MDSAP Auditing Organization Today

This workshop will be a collaboration between those manufacturers, the Regulatory Authorities in the Consortium and the Auditing Organizations involved in the Pilot.

# 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!

# Breaking News

- Another Announcement this January on the MDSAP Pilot

- NEW Announcement on FDA's utilization of MDSAP Audits