Medical Device Single Audit Program (MDSAP) Pilot Update

Marc-Henri Winter

Staff Fellow

Division of International Compliance Operations

Office of Compliance

Center for Devices and Radiological Health

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 and ends December 2016.

MDSAP
Statement of Cooperation

Heads of Agency Commitment to MDSAP

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,
  - Japanese PMDA and
  - U.S. Food and Drug Administration
- Observers
  - World Health Organization (WHO) Diagnostic Prequalification Program
  - European Union

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)
- RAC Responsibilities:
  - 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
- 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

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

Audit and Assessment SME WG

- Develops procedures, work flows, work instructions, templates, training, etc. for the MDSAP Quality Management System to include:
  - Quality Manual
  - Complaint process
  - Improvement Process
  - Appeals Process

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)
- Japanese JPAL requirements
- FDA's 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.

www.imdrf.org

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 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 – "MDSAP Audit Report Guidance"; *approved September 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 WG /N6 FINAL:2013 – "Regulatory Authority Assessor Competence and Training Requirements"
- IMDRF/MDSAP WG/N8 FINAL:2015 – "Regulatory Authority Assessment Method Guidance" Approved in September 2015

MDSAP Nonconformity Grading System

GHTF/SG3/N19:2012 – "Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange"

http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n19-2012-nonconformity-grading-121102.pdf

Audit Report and NC Exchange Form

- MDSAP AU P0019.002: Quality Management System Audit Reports Policy (PDF - 649KB)
- MDSAP AU F0019.1.005 Medical Device Regulatory Audit Report (PDF - 1MB)
  MDSAP AU F0019.2.005: NC Grading and Exchange Form (XLS - 791KB)
- MDSAP AU G0019.3.003 Medical Device Regulatory Audit Report Form Guidelines (PDF - 344KB)
- MDSAP AU G0019.4.002 NC Grading Exchange Form Guidelines (PDF - 348KB)

MDSAP Audit Model			ISO 13485:2003			Related Regulatory Requirement		
Process	Task#	Task	Task-related clauses	Clause	Requirement	Task-related clauses	Clause	Requirement
Management	1	Verify that a quality manual, management review, and quality management system procedures and instructions have been defined and documented. United States (FDA): Confirm the organization has established	4.1, 4.2.1, 4.2.2, 5.4.2		/	TG(MD)R Sch3 P1 1.4(4)		/

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.

- Some Auditing Organizations have already successfully passed their assessments and are ready to audit medical device manufacturers. See the website for current listing:

http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM429978.pdf

How can medical device manufacturers participate?

- Certain MDSAP Auditing Organizations are already 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 2015 Announcement.

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.
- Only manufacturers that volunteered and had a MDSAP Audit performed during the pilot – will be invited to a workshop in June 2016 to further refine the MDSAP processes, a collaboration between pilot participants, RACs and Auditing Organizations.
- ***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

- New Announcement on the MDSAP Pilot, January 2015

http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM429958.pdf

- Announcement on Japans Full Membership, June 2015

http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm452243.htm

- MDSAP Mid-Pilot Status Report, August 2015

http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM461661.pdf

- Updated Q&A Document, October 2015

http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM430563.pdf

Resources

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

Medical Device International Programs:
http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377580.htm
http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377581.htm
http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377583.htm

IMDRF Final Documents:
http://www.imdrf.org/documents/documents.asp

IMDRF Proposed Documents:
http://www.imdrf.org/consultations/consultations.asp