International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP) Pilot

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IMDRF

The International Medical Device Regulators Forum (IMDRF) recognizes the value in developing a global approach to auditing and monitoring the manufacturing of medical devices to ensure safe medical devices.

IMDRF

The IMDRF, at its inaugural meeting in Singapore in 2012, identified a Work Group to develop specific documents for advancing the concept of the Medical Device Single Audit Program (MDSAP).

IMDRF

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.

IMDRF

For many reasons not all IMDRF member countries are able to move at this very rapid pace, including changes of medical device legislation, the necessity of country to country confidentiality agreements, etc.

IMDRF

This does not diminish the support of all IMDRF member countries in the concept and base documents being developed by the IMDRF MDSAP Working Group.

Pilot International Coalition

- The international coalition of countries for the MDSAP Pilot Program are:
  - Therapeutics Goods Administration (TGA) of Australia,
  - Brazil's Agência Nacional de Vigilância Sanitária (ANVISA),
  - Health Canada, and
  - U.S. Food and Drug Administration

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 Coalition program at the Head of Agency Summit in Manaus, Brazil in November 2012

Pilot International Coalition

In addition, Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) recently became official observers and active participants in the Pilot Program's Regulatory Authority Council and subject matter expert groups.

Pilot International Coalition

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

Objectives

- To operate a single audit program that provides confidence in program outcomes.

- To enable the appropriate regulatory oversight of medical device manufacturers' quality management systems while minimizing regulatory burden on industry.

Objectives

- To promote more efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among regulators while respecting the sovereignty of each authority.

- To leverage, where appropriate, existing conformity assessment structures.

Objectives

- To promote, in the longer term, greater alignment of regulatory approaches and technical requirements globally based on international standards and best practices.

- To promote consistency, predictability and transparency of regulatory programs

Third Parties and Regulatory Inspectorates

The development of MDSAP includes the use of third party auditors, much like some current regulatory audit programs, as well as regulatory inspectorates. Use of third party auditors, in addition to Regulatory Authority Inspectorates, allows greater coverage in auditing manufacturers around the globe.

Third Parties and Regulatory Inspectorates

The government resources can then be focused on high risk or problematic medical devices, manufactures that are not in compliance with the regulations, and oversight of the third party auditing organizations.

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.

How will Regulatory Authorities utilize the Single Audit Program and the resulting audit report/certificate?

Australia: TGA will use an MDSAP audit report as part of the evidence that is assessed for compliance with medical device market authorization requirements unless the medical device is otherwise excluded or exempt from these requirements or if current policies restrict the use of MDSAP audit reports.

How will Regulatory Authorities utilize the Single Audit Program and the resulting audit report/certificate?

Brazil: ANVISA will utilize the outcomes of the program, including the reports, to constitute an important input on ANVISA's pre-market and post-market assessment procedures, providing, when applicable, key information that are expected to support regulatory technical evaluation on these issues.

How will Regulatory Authorities utilize the Single Audit Program and the resulting audit report/certificate?

Canada: HC will use a MDSAP audit as part of their Canadian Medical Device Conformity Assessment System (CMDCAS) certification program. Upon the successful conclusion of the pilot, Health Canada's intent is to implement the Medical Device Single Audit Program, as the mechanism to achieve regulatory compliance for quality management system requirements in Canada.

How will Regulatory Authorities utilize the Single Audit Program and the resulting audit report/certificate?

United States: FDA will accept the MDSAP audit reports as a substitute for FDA routine inspections. Inspections conducted "For Cause" or "Compliance Follow-up" by FDA will not be affected by this program. Moreover, this MDSAP program would not apply to any necessary pre-approval or post approval inspections for Premarket Approval (PMA) applications.

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.

What Auditing Organizations can apply to the MDSAP Pilot?

As part of the MDSAP application process, the Auditing Organizations will have to comply with the following IMDRF MDSAP document in addition to other documents approved by the Pilot Coalition Regulatory Authority Council:

- **IMDRF MDSAP WG N3 –** "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition"
- **IMDRF MDSAP WG N4 –** "Competency and Training Requirements for Auditing Organizations"

What oversight will Regulatory Authorities have over the Auditing Organizations?

In accordance with best practices, the Regulatory Authorities involved in the Pilot Coalition have developed a robust plan and schedule of assessing the competence and compliance of MDSAP Auditing Organizations to include headquarter office assessments, witness audits, and critical site location assessments on an annual basis as part of a four year recognition process.

What oversight will Regulatory Authorities have over the Auditing Organizations?

The Regulatory Authorities involved in the Pilot Coalition will utilize as the basis of the recognition and assessment process the following IMDRF MDSAP documents in addition to other documents drafted and approved by the Pilot Coalition Regulatory Authority Council:

What oversight will Regulatory Authorities have over the Auditing Organizations?

- IMDRF MDSAP WG N5 – "Regulatory Authority Assessment Strategy for the Recognition and Monitoring of Medical Device Auditing Organizations"
- IMDRF MDSAP WG N6 - "Regulatory Authority Assessor Competency and Training Requirements"

What oversight will Regulatory Authorities have over the Auditing Organizations?

In addition, IMDRF MDSAP WG N11 is a document being produced to “grade” nonconformities resulting from a Regulatory Authority assessment of an Auditing Organization and to document the decision process for recognizing an Auditing Organization or revoking recognition. When finalized, this document will also be utilized under the Regulatory Authority assessment program.

How can medical device manufacturers participate?

The CMDCAS registrars will be allowed to start submitting their application for MDSAP recognition starting January 2014. The MDSAP project plan targets the review of applications every six months for the duration of the pilot.

How can medical device manufacturers participate?

After a successful assessment, the MDSAP Auditing Organization applicants will be allowed to perform MDSAP audits for medical device manufacturers that will be utilized by the Regulatory Authorities as described above.

How do I find out more specifics on the documents, policies, and procedures that will be utilizing in the MDSAP Pilot?

The MDSAP Pilot will be utilizing the IMDRF MDSAP documents that can be found at: http://www.imdrf.org/

How do I find out more specifics on the documents, policies, and procedures that will be utilizing in the MDSAP Pilot?

Also, there are many other MDSAP Regulatory Authority Council reviewed and approved documents for implementing the pilot to include the audit strategy for auditing medical device manufacturers such as:

How do I find out more specifics on the documents, policies, and procedures that will be utilizing in the MDSAP Pilot?

- requirements for the audit reports,
- audit time calculations,
- MDSAP Quality Management System procedures, etc.

These documents can be found at the FDA webpage.

IMDRF MDSAP Pilot

- Begins January 2014 with the application by Auditing Organizations

- June 2014 is the target date for manufacturers to start utilizing the program.

IMDRF 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.