



International Medical Device Regulators Forum

Medical Device Single Audit Program

International Coalition Pilot Program

January 2014

I. Background

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. 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). See <http://www.imdrf.org/>

This global approach opens possibilities and pathways to support the development of an international initiative 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 many reasons not all IMDRF member countries are able to participate in the pilot at this stage, including changes of medical device legislation, the necessity to have in place country to country confidentiality agreements, etc. This does not diminish the support of all IMDRF member countries in the concept and, most importantly, in the development of the base documents being developed by the IMDRF MDSAP Working Group.

The international partners for the MDSAP Pilot Program starting January 2014 are the Therapeutic Goods Administration (TGA) of Australia, Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada, and the U.S. Food and Drug Administration; Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) are official observers and active participants in the Pilot Program's Regulatory Authority Council and subject matter expert groups.

The mission of the IMDRF participants in 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. The objectives for the MDSAP are:

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

2. To enable the appropriate regulatory oversight of medical device manufacturers' quality management systems while minimizing regulatory burden on industry without compromising public health.
3. 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.
4. To promote, in the longer term, greater alignment of regulatory approaches and technical requirements globally based on international standards and best practices.
5. To promote consistency, predictability and transparency of regulatory programs by standardizing:
 - a. oversight practices and procedures of participating regulators over third party auditing organizations, and
 - b. practices and procedures of participating third party auditing organizations.
6. To leverage, where appropriate, existing conformity assessment structures.

The development of the MDSAP includes the use of third party auditors, much like some current regulatory audit programs, as well as regulatory inspectorates. Recognizing the increasingly global nature and number of medical device manufacturers, the use of third party auditors in addition to Regulatory Authority Inspectorates, allows greater coverage in auditing manufacturers as opposed to relying solely on the government resources of individual countries. The 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 requirements of medical devices – quality management systems – Requirements for regulatory purposes (ISO 13485:2003), Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013), the Quality System Regulation (21 CFR Part 820), and other specific requirements of medical device regulatory authorities participating in the Pilot MDSAP program including registration, licensing, technical documentation review and adverse event reporting.

The pilot MDSAP is intended to allow MDSAP recognized Auditing Organizations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the medical device regulatory authorities participating in the pilot program.

II. Pilot Program Specifics

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

All of the Regulatory Authorities involved in the MDSAP International Coalition are committed to the MDSAP Program as a multilateral initiative. It will be a significant and reliable tool to leverage the conformity assessment structures of all the participants, improving the safety and oversight of medical devices.

Australia: The Therapeutics Goods Administration - 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.

Brazil: The Brazilian National Health Surveillance Agency – 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.

Canada: Health 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.

United States: U.S. Food and Drug Administration’s Center for Devices and Radiological Health – 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 or to decisions under section 513(f)(5) of the Act (21 U.S.C. 360c(f)(5)) concerning the classification of a device.

Which 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. Australia’s TGA Inspectorate has a Memorandum of Understanding with Health Canada on the reciprocal recognition of quality management system (QMS) certificates for medical device manufacturers utilizing the CMDCAS Program. The U.S. FDA has worked closely with Health Canada over the last 10 years on the use of third party auditing organizations in a regulatory program, including within the CMDCAS Program. In addition, those third parties that were recognized under FDA’s Third Party Inspection program and also accredited under the CMDCAS program, had for several years performed pilot Multi-Purpose Audits (pMAP) under a separate initiative. ANVISA, TGA, and U.S. FDA have also observed several assessments of CMDCAS Auditing Organizations as well as observed witnessed audits of CMDCAS accredited Auditing Organizations. Therefore, the Regulatory Authorities involved in this pilot have several years of confidence building with the CMDCAS Auditing Organizations. Many of CMDCAS registrars are also designated as Notified Bodies under the European regulatory scheme. The list of Registrars Recognized by Health Canada can be found at: http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/list_liste_regist-eng.php

When the Pilot has concluded, estimated for the end of 2016, additional Auditing Organizations may be eligible for the application in the MDSAP.

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 Regulatory Authority Council that oversees the program:

- IMDRF MDSAP WG N3 – “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”
- IMDRF MDSAP WG N4 – “Competence and Training Requirements for Auditing Organizations”

What oversight will Regulatory Authorities have over the Auditing Organizations?

The audits of medical device manufacturers will be performed by MDSAP Auditing Organizations that will be assessed and monitored by Regulatory Authorities. In accordance with best practices, the MDSAP pilot incorporates a transparent assessment program by which Regulatory Authorities will oversee the compliance of the Auditing Organizations with MDSAP standards and requirements. This program includes a robust plan and schedule for assessing the competence and compliance of MDSAP Auditing Organizations to include assessments of their head office and critical sites, as well as performing assessments during witnessed audits, as part of a four year recognition process.

The Regulatory Authorities involved in the pilot will base their recognition and assessment process on the following IMDRF MDSAP documents in addition to other documents drafted and approved by the Regulatory Authority Council:

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

These two IMDRF MDSAP documents N5 and N6 are focused on how Regulatory Authorities will evaluate or “assess” medical device Auditing Organizations’ compliance to the requirements in the IMDRF MDSAP N3 and N4 documents listed above.

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. 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. June 2014 is the target date by which a number of Auditing Organizations are expected to be ready to start performing MDSAP audits for medical device manufacturers.

The MDSAP Regulatory Authority Council feels confident in using the MDSAP audit reports during the pilot and before official “recognition” since these CMDCAS registrars are currently recognized under Health Canada’s regulatory scheme, and over the years there has been much confidence building between the Regulatory Authority partners in the Coalition and the CMDCAS registrars through a variety of programs. At the successful conclusion of the pilot, it will be announced which MDSAP auditing organization applicants will be formally recognized under the MDSAP program to begin the operational phase of the program.

Medical device manufacturers may contact the CMDCAS registrars directly to enquire at what stage of the MDSAP recognition process a given CMDCAS registrar is with regards to its ability to perform regulatory audits under the MDSAP pilot. There is no application process to the Regulatory Authorities for interested medical device manufacturers.

How will the Pilot be evaluated?

The Regulatory Authority Council that oversees the program will consider factors such as the satisfaction of the participating regulators that public health outcomes are not diminished and that resource efficiencies have been achieved, as well as the level of uptake by industry and other factors.

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 utilize the IMDRF MDSAP documents that can be found at:

<http://www.imdrf.org/>

Also, there are many other MDSAP Regulatory Authority Council reviewed and approved documents for implementing the pilot including the audit strategy for auditing medical device manufacturers, the requirements for the audit reports, audit time calculations, the MDSAP Quality Management System procedures, etc. For further information on the Pilot and associated documents, please contact the participating Regulatory Authorities.