



Medical Device Manufacturers Participation in the Medical Device Single Audit Program (MDSAP) Pilot

The MDSAP Regulatory Authority Council (RAC) is pleased to announce that medical device manufacturers are now invited to participate in the MDSAP Pilot. The participants in the process during the pilot will help shape the policies and procedures for the operational program scheduled to begin in 2017.

The MDSAP Pilot, which started on January 1, 2014, is an implementation of the MDSAP initiative based on the foundational work of the International Medical Device Regulators Forum ([IMDRF](#)).

The international partners for the MDSAP Pilot are:

- the Australian Therapeutic Goods Administration (TGA),
- the Brazilian National Health Surveillance Agency (ANVISA),
- Health Canada, and
- the U.S. Food and Drug Administration (FDA);

Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) are observers and active participants in the Pilot Program's Regulatory Authority Council and subject matter expert groups. The World Health Organization is also an observer in the Pilot program and discussions are on-going with the European Commission on their Observer status.

The MDSAP Pilot enables medical device manufacturers to have an authorized Auditing Organization under the MDSAP Pilot conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of those medical device regulatory authorities participating in the pilot program. MDSAP Pilot audit reports may be used by regulatory authorities participating in the MDSAP Pilot in lieu of their own inspection reports.

The MDSAP Pilot audit process was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the requirements for a quality management system for medical devices derived from; ISO 13485:2003 – Medical devices - Quality management systems – Requirements for regulatory purposes, the 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 MDSAP Pilot program including registration, licensing, advisory notices or recalls, adverse event reporting, etc.

The initial MDSAP Pilot [announcement](#) provides additional background information on the program.

Does the MDSAP Pilot add requirements for the manufacturer?

No. The MDSAP Pilot audit model was developed to cover existing requirements from the Regulatory Authorities participating in the MDSAP Pilot. The program does not add any new requirements to existing requirements from ISO 13485:2003 or from the medical device regulations of the participating Regulatory Authorities.

What are the potential benefits for the manufacturer?

The MDSAP Pilot offers many benefits to medical device manufacturers including the following:

- A single audit is used in lieu of multiple separate audits or inspections by participating regulatory authorities or their representatives. Therefore, for many medical device manufacturers, the MDSAP Pilot reduces the overall number of audits or inspections and optimizes the time and resources expended on audit activities.
- Additionally, as a longer term goal, it is expected that the program will enhance confidence in the reliability of third party audits, that more Regulatory Authorities will join the program, and that other Regulatory Authorities will use information made available through the program to limit the need for additional audits.
- Some participating regulatory authorities will use MDSAP Pilot audit outcomes as an alternative to their own inspections to process applications for medical device marketing authorization.
- Like in any third party auditing program, the medical device manufacturer is free to choose among all authorized auditing organizations to perform the audits. Routine audits are announced and planned with the manufacturer.
- The MDSAP Pilot is expected to improve the predictability of audit outcomes through:
 - enhanced auditing organization recognition criteria,
 - monitoring of auditing organizations by the participating Regulatory Authorities,
 - the use of a standard [MDSAP audit model](#),
 - the grading of any nonconformity using objective criteria to characterize the significance of the finding,
 - the reporting of the audit outcomes using a standard report template.
- Enrolling in the MDSAP Pilot may be seen as evidence of a medical device manufacturer's commitment to product quality and regulatory compliance. It may be promoted as a tool for marketing differentiation.

What are the potential benefits to the manufacturer, specific to each jurisdiction?

Australia: The Therapeutic Goods Administration – TGA

Where regulations do not require a manufacturer or product to hold a TGA Conformity Assessment Certificate;

- The TGA will take into account MDSAP Pilot audit reports when considering whether a manufacturer has demonstrated compliance with an Australian Conformity Assessment procedure; or

Where regulations require a manufacturer or product to hold a TGA Conformity Assessment Certificate;

- The TGA will take into account MDSAP Pilot audit reports when considering whether to issue or maintain a TGA Conformity Assessment Certificate in relation to manufacturers of kinds of products prescribed in regulation¹. Under some circumstances a manufacturer may avoid routine TGA inspections.

Following a successful evaluation of the MDSAP Pilot, the following may apply:

Where regulations do not require a manufacturer or product to hold a TGA Conformity Assessment Certificate;

- The TGA will accept MDSAP certificates as evidence of compliance with ISO13485:2003 where the Standard has been used to demonstrate partial compliance with the requirements of an Australian Conformity Assessment Procedure. It is expected that Australian Sponsors may be required to submit to the TGA, additional technical documentation to demonstrate compliance with the requirements of the Essential Principles of Safety and Performance and the manufacturer's chosen Conformity Assessment Procedure.

Where regulations require a manufacturer or product to hold a TGA Conformity Assessment Certificate;

- The TGA will take into account MDSAP audit reports when deciding whether to issue or maintain a TGA Conformity Assessment Certificate. Under some circumstances a manufacturer may avoid routine TGA inspections.

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.

Due to recent regulatory changes (RDC 15:2014), ANVISA may use MDSAP Pilot audits in lieu of a premarket inspection by ANVISA to grant ANVISA's GMP Certificate to manufacturers intending to put medical devices of class III or IV on the Brazilian market. Undergoing an MDSAP Pilot audit may accelerate ANVISA's GMP certification process, which is a pre-requisite to the marketing authorization. ANVISA can also use MDSAP Pilot audits to renew ANVISA's GMP Certificate bi-annually, as an alternative to an ANVISA comprehensive inspection.

¹ Currently these are; manufacturers of medical devices that incorporate a medicinal substance, or a material of animal origin that has been rendered non-viable, or that contains tissues, cells or substances of microbial or recombinant origin, or that incorporate stable derivatives of human blood or human plasma.

Canada: Health Canada will operate the current Canadian Medical Devices Conformity Assessment System (CMDCAS) and MDSAP in parallel during the three year pilot.

Health Canada will accept either an MDSAP certificate or a CMDCAS certificate for the purpose of obtaining a new (or maintaining an existing) Class II, III, or IV medical device license, pursuant to section 32 of the Canadian Medical Devices Regulations.

Upon the successful conclusion of the pilot, Health Canada intends to implement MDSAP 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 Pilot audit reports as a substitute for FDA routine inspections (biennial by policy). Additional benefits include:

- MDSAP Pilot routine audits are announced, scheduled by the Auditing Organization with the manufacturer, with a pre-established duration;
- The FDA will review MDSAP Pilot audit reports with a level of scrutiny commensurate to the significance of audit findings, taking into account the review and follow-up performed by the Auditing Organization;
- Firms have one month to provide their full response to critical nonconformities (grade 4 and 5) to the Auditing Organization (as opposed to 15 working days following a FDA inspection);
- Certification documents issued by the Auditing Organization state compliance with applicable US regulations, which may provide a marketing advantage.
- FDA will utilize other forms of Advisory Notice, where necessary instead of FDA Warning Letters for MDSAP Audits during the Pilot. Warning Letters will only be considered when the MDSAP audit conclusion reveals an imminent/unreasonable risk to public health.

Note: 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.

Japan: Japan’s Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) are evaluating the following possibilities:

- For manufacturers intending to put medical devices of class II, III or IV on the Japanese market, an MDSAP Pilot audit report might be utilized for a desk review instead of a premarket inspection performed by PMDA or registered certification bodies in Japan. An MDSAP Pilot audit report might also be utilized in this manner for periodical post market inspections. Undergoing an MDSAP Pilot audit may accelerate the Marketing Authorization with fewer burdens as well as reduce some burden for a post market phase. MHLW/PMDA are encouraged to accelerate tasks for the official participation of this project once the revised Pharmaceutical Affairs Law (Pharmaceuticals and Medical Devices Act) is implemented at approximately the end of November 2014.

World Health Organization (WHO): In the framework of the *Prequalification Program* for diagnostic devices, the WHO may recognize successful MDSAP Pilot audits as acceptable evidence of QMS compliance with international regulations. This may result in either abbreviated or waived WHO inspection depending on the scope of audit. In addition, WHO has adopted the MDSAP audit model, nonconformity grading scheme, and many other MDSAP procedures as part of their Diagnostic Prequalification audit procedures.

How will audits be conducted under the MDSAP Pilot?

The Auditing Organization will perform an MDSAP Pilot audit taking into account the applicable documents developed by the participating Regulatory Authorities for the implementation of the program pilot. Some relevant policies and procedures introduced by the program include the following:

- The auditors must follow the sequence of tasks specified in the audit model (see [MDSAP AU P0002](#)), ensuring consistency across auditor teams and auditing organizations.
- The Auditing Organization determines the audit duration based on planned audit tasks (see [MDSAP AU P0008](#)), ensuring consistency across auditing organizations. For many medical device manufacturers, in addition to the ISO 13485 audit under current certification programs, the audit duration will not exceed the accumulated time of the multiple audits and inspections they would undergo if the participating Regulatory Authorities performed their inspections according to their governing policies.
- The Auditing Organization writes an audit report for each audited site, using a standard fillable [template](#) specifically designed for medical device regulatory audits.
- Nonconformities identified during an audit are graded on a scale from 1 (least critical) to 5 (most critical), according to explicit criteria (see [GHTE/SG3/N19](#)). This ensures consistency across audit teams and auditing organizations.
- In some cases, high grade nonconformities may trigger the performance of an unannounced audit;
- The manufacturer provides – and the Auditing Organization reviews – remediation plans and evidence of implementation of these plans according to a specified timeline (see [MDSAP AU P0027](#)).
- Auditing Organizations will share the audit outcomes with the participating Regulatory Authorities to support their pre-market or post-market programs;
- Upon successful certification or recertification audits, Auditing Organizations issue MDSAP-specific certification documents stating compliance to MDSAP audit criteria (See [MDSAP AU P0026](#)).

Can the manufacturer exclude a jurisdiction from the scope of an MDSAP pilot audit?

A manufacturer may exclude the requirements of a jurisdiction where the organization does not intend to supply medical devices. In other words, audit criteria under the MDSAP Pilot include at a minimum ISO

13485:2003 and the medical device regulations that are applicable in any of the participating regulatory authority's jurisdiction where the organization supplies medical devices.

How and when can medical device manufacturers participate?

Medical device manufacturers should contact a participating Auditing Organization directly and enquire whether the participating Regulatory Authorities have authorized them to perform regulatory audits under the MDSAP pilot. A manufacturer who wishes to be audited under the MDSAP pilot does not need any prior notification to, or authorization from the participating regulatory authorities.

Note that communication between the Auditing Organization and the Regulatory Authority will enable the Regulatory Authority to adjust their inspection work plan taking into consideration a manufacturer's participation in the MDSAP Pilot.

During the pilot phase of the MDSAP, in order to minimally impact pre-existing ISO 13485 certifications issued to manufacturers for regulatory purpose (e.g. under the Canadian Medical Device Conformity Assessment System – CMDCAS), the MDSAP certification cycle can be synchronized with the pre-existing certification cycle. As a consequence, the first MDSAP Pilot audit(s) performed at a facility may be a surveillance audit (a non-comprehensive audit). In such case, the Auditing Organization would not issue a [certification document](#) until a subsequent comprehensive audit is performed. Instead, the Auditing Organization may issue a [“Surveillance Audit Confirmation Notification”](#).

How Regulatory Authorities will oversee the Auditing Organizations?

As part of the MDSAP Pilot application process, the participating Regulatory Authorities will assess the compliance of the candidate Auditing Organizations with requirements that take into account the following documents:

- [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”
- [MDSAP Audit Procedures](#) approved by the Regulatory Authority Council

The Regulatory Authorities involved in the pilot will base their assessment and recognition processes on the following documents:

- [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”
- [IMDRF MDSAP WG N11](#)- “MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization”
- [MDSAP Assessment Procedures](#) approved by the Regulatory Authority Council

The 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 and the competence of the assessors that undertake the assessments.

In addition, IMDRF MDSAP WG N11 defines the process and lifecycle for recognizing, maintaining or ceasing recognition of an Auditing Organization and the process of managing, grading, and closure of assessment nonconformities issued to an Auditing Organization.

Which Auditing Organizations are authorized to audit under the MDSAP pilot?

During the MDSAP Pilot, all Auditing Organizations currently recognized under the Canadian Medical Device Conformity Assessment System (CMDCAS) program are invited to apply for recognition under MDSAP. The participating Regulatory Authorities will decide whether to officially recognize all or some candidate Auditing Organizations upon completion of the MDSAP Pilot.

Meanwhile, Auditing Organizations that undergo an application review, stage 1 assessment, stage 2 on-site assessment, and, if applicable, on-site assessment at their critical locations, and successfully resolve any identified deficiency, are authorized to perform MDSAP Pilot audits. Medical device manufacturers interested in the program should contact the Auditing Organization of their choice to determine if they are – or when they expect to be – authorized to perform MDSAP Pilot audits.

An MDSAP Pilot audit may be “witnessed” by regulatory authority assessors. These regulatory authority assessors will evaluate the Auditing Organization’s ability to fulfill MDSAP requirements. These regulatory authority assessors will not conduct a concurrent audit of the manufacturer.

Where can I find additional information on the MDSAP?

Documents specific to the MDSAP Pilot are currently hosted on the [FDA website](#).

The [IMDRF website](#) includes the governing documents N3, N4, N5, N6 and N11 specifying the requirements for the Regulatory Authorities and the Auditing Organizations and are the basis for the MDSAP Pilot.

Version
Approval

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