Medical Device **Single Audit** Program

The Medical Device Single Audit Program (MDSAP) is a foundational international initiative led by Regulatory Authorities of the International Medical Device Regulatory Forum (IMDRF) to implement a certification program where recognized third party Auditing Organizations (AO) can conduct a single audit of a medical device manufacturer that will be accepted by multiple regulators to address various QMS/GMP requirements.

Five of the Regulatory Authorities (Australian TGA, Brazilian ANVISA, Health Canada, US FDA, and Japan MHLW and PMDA) have decided to proceed with a three year MDSAP pilot. The World Health Organization (WHO) are officially participating as observers. BSI is fully supporting the MDSAP pilot and participating in the process as an AO.

Regulatory Authorities

There has been significant progress with the Medical Device Single Audit Program pilot. The five RA's in the MDSAP pilot have made the following statements on how they intend to utilize MDSAP reports:

- **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 is expected to support regulatory technical evaluation on these issues. ANVISA may use MDSAP Pilot audits in lieu of a premarket inspection by ANVISA to grant ANVISA's GMP Certificate to manufacturers intent 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.
- **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 has indicated that it is intending to implement MDSAP as the mandatory replacement for CMDCAS, 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 CDRH) 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, the MDSAP program would not apply to any necessary pre-approval or post- approval inspections for Pre-market 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.

  Recently FDA CDRH has also stated the intention to allow MDSAP AO's to follow-up on non-conformities raised during the pilot, not raising 483's or warning letters unless escalation to direct FDA action is needed.
- **Japan:** The Ministry of Health, Labour and Welfare (MHLW) and Pharmaceutical and Medical Devices Agency (PMDA) will utilize these audit reports in both premarket and periodical post market audit under regulations in Japan.

  Japan officially joined the pilot in June 2015, and is in the midst of implementing the transition of AOs to include the Japanese requirements.

BENEFITS

Single Audit by Auditing Organizations would:

- minimize medical device manufacturer disruptions due to multiple regulatory audits
- provide predictable audit schedules (agendas with opening and completion dates)
- benefit patient health and patient access (addressing barriers of factory inspections)
- leverage regulatory resources
- incorporate ISO 13485 and CE Marking conformity assessment
- consistent auditing from a single source for multiple regulatory requirements.

To qualify under MDSAP, Auditing Organizations (AO) need to be capable of conducting audits/certifications that are acceptable to the RA's as an alternative to their own GMP/QSR/ISO 13485 routine audits. Full details of the MDSAP pilot, including a comprehensive FAQ document, are available on FDA website at: http://www.fda.gov/MedicalDevices/.

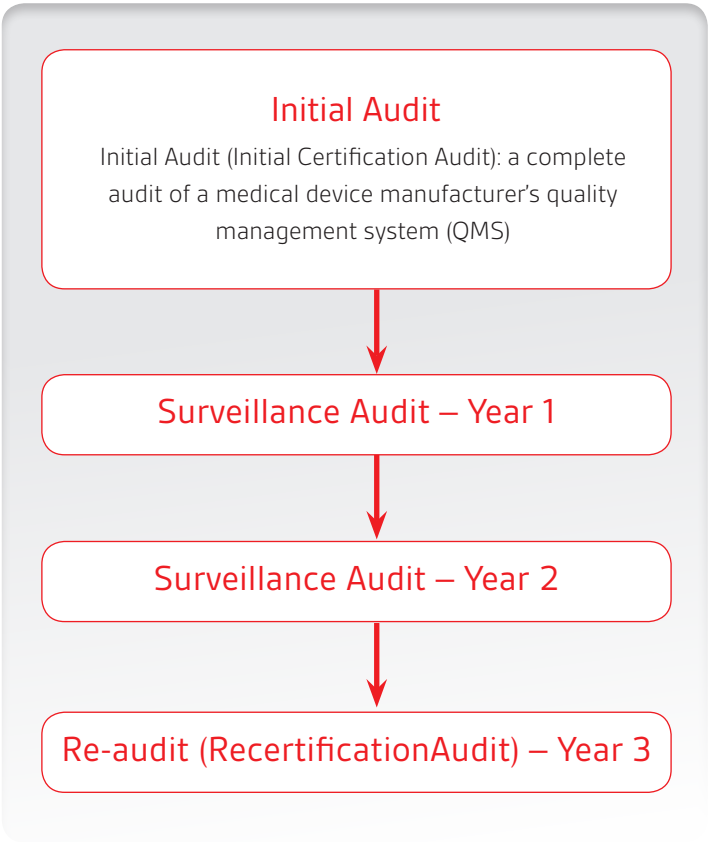
MDSAP is a voluntary pilot program today, but, it should be noted by manufacturers that Health Canada has indicated that, if the pilot program is successful, it is intended to mandate MDSAP certification for Canadian market clearance in the future. All RA's are strongly recommending manufacturers consider joining the pilot to help refine and improve the program while it is still voluntary.

NOTE: For current clients, we can start the audit in the current visit cycle, ie, surveillance or recertification. BSI can discuss with you the available options depending on your business needs.

Special audits, audits conducted by Regulatory Authorities, and unannounced audits are extraordinary audits that may occur at any time within the audit cycle. These will be based on what we consider today to be major nonconformities.

Medical Device Single Audit Program:

The MDSAP is based on a three year audit cycle.



For clients holding ISO 13485 and/or CMDCAS, BSI can roll in the MDSAP audit right into the existing certification cycle.

Your provider in worldwide compliance auditing and certification.

Call BSI today at 1300 730 134 or visit www.bsigroup.com/en-au

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