Medical Device Single Audit Program (MDSAP) Pilot

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The International Medical Device Regulators Forum (IMDRF) recognizes that a global approach to auditing and monitoring the manufacturing of medical devices could improve their safety and oversight on an international scale. At its inaugural meeting in Singapore in 2012, the IMDRF identified a work group to develop specific documents for advancing a Medical Device Single Audit Program (MDSAP).

Beginning in January 2014, FDA will be participating in a MDSAP Pilot alongside other international partners. FDA will accept the MDSAP audit reports as a substitute for routine Agency inspections.

The MDSAP Pilot 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.

International partners that are participating in the MDSAP Pilot include:

- Therapeutic Goods Administration of Australia
- Brazil's Agência Nacional de Vigilância Sanitária
- Health Canada
- Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency
- The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme and the European Union (EU) are Official Observers

See what the industry has to say about MDSAP audits:

"With a Mission to improve the quality of life for patients, prevent progression of chronic diseases, and reduce overall healthcare system costs, ResMed is committed to driving innovation and efficiencies across all aspects of our business. The MDSAP program has allowed us to consolidate the global regulatory assessment process across multiple international locations, reducing internal costs while increasing the overall predictability of these efforts across our global footprint. By minimizing disruption to our business, we can focus on delivering the safest, most effective and technologically advanced products possible. ResMed is proud to participate in a program that is designed to increase efficiencies within our industry while having a positive impact on the cost of global healthcare."

"Auditors followed published MDSAP audit guidance very closely. We are now preparing to obtain MDSAP certificates for all ISO 13485/CMDCAS locations when MDSAP becomes fully operational in 2017."

"MDSAP allows a reduction in the number of audits conducted resulting in less business disruption. The MDSAP audit was well planned and the well-organized audit expectations allowed us to plan resources ahead of time. Additionally, qualified and competent auditing organizations conduct audits in a consistent manner. The transition from our previous audit cycle to the MDSAP audit program was easy due to the documents available on the MDSAP website. Definitely, more sites will be added to the MDSAP program in 2017 and 2018."

"MDSAP auditors are experienced and well-trained and apply a task-based audit approach. There is a reduction in the number of audits which brings less business disruption. GREAT web-based materials and guidelines are available to industry."

MDSAP Participant Survey

Medical Device Firms and Auditing Organizations participating in the Medical Device Single Audit Program are invited to provide feedback through targeted surveys:

- Following each AUDIT, for the Medical Device Firm
- Following each AUDIT, for the Lead Auditor
- Following each ASSESSMENT, for the Auditing Organization

Past Notices and Announcements

- Federal Register Notice: International Medical Device Regulators Forum, Medical Device Single Audit Program International Coalition Pilot Program, November 15, 2013

- MDSAP Pilot Announcement, January 2014, (PDF - 79KB) (PDF - 79KB)

Spotlight

- Medical Device ISO 13485:2003 Voluntary Audit Report Pilot Program;Termination of Pilot Program; Announcement of the Medical Device Single Audit Program Operational Phase
- MDSAP Mid-Pilot Report, August 2015 (PDF - 244KB)
- Japan joins the Medical Device Single Audit Program (MDSAP) June 23rd, 2015
- MDSAP Announcement to Medical Device Manufacturers, January 2015 (PDF - 158KB)

ANVISA Resolution

- ANVISA Resolutions

Related Programs

- Unique Device Identification (UDI)

Resources for You

- CDRH Learn Course: IMDRF Medical Device Single Audit Program (MDSAP) Pilot
- International Medical Device Regulators Forum
- MDSAP Pilot Eligible AOs 2016-07-25 (PDF - 256KB)
- Questions and Answers on the Medical Device Single Audit Program 2016-06-13 (PDF - 188KB)
- MDSAP Regulatory Authority Contact Information 11 July 2016 (PDF - 198KB)

More in Medical Device Single Audit Program (MDSAP) Pilot

MDSAP Documents

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