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FDA Announces Commitment to MDSAP

The US Department of Health and Human Services, Food and Drug Administration (FDA) announced on December 17, 2015, that it would participate in the operational phase of the Medical Device Single Audit Program (MDSAP), starting January 1, 2017. The FDA currently participates in the ongoing MDSAP pilot program, scheduled to run until the end of 2016.

Background: What is MDSAP?

The MDSAP program was created by the International Medical Device Regulators Forum, a consortium of nine medical device regulators from around the world, in an attempt to streamline their inspection operations. Five regulators currently participate in the MDSAP pilot program: the US FDA, Health Canada, Japan's PMDA, Brazil's ANVISA, and Australia's TGA. The MDSAP program also helps the regulators focus their resources where needed most and prioritize true public health issues. The MDSAP program is designed to harmonize the quality management system regulations and requirements for these five regulatory jurisdictions into one comprehensive audit, depending on the jurisdictions in which the audited establishment needs to be certified.

How the MDSAP Program Works

Used at full strength, the program allows an establishment to undergo one scheduled audit that covers the quality management system requirements for all five jurisdictions at once instead of many inspections from the different regulators. The audit process is a top-down, task-based audit, taking a similar form to the FDA inspections. The audit scope would cover all the member jurisdictions from whom the manufacture has marketing approval for their devices, or ones to which the manufacturer plans to apply for marketing approval in the coming year. If the establishment does not send products to all five countries, then the MDSAP audit can be customized to only include the jurisdictions to which it does sell products.

MDSAP audits in the pilot program are carried out by an Auditing Organizations (AO). Currently, the only eligible AOs are those that are currently recognized under the CMDCAS (Canadian Medical Devices Conformity Assessment System) program. A medical device manufacturer would contract with an AO to perform the MDSAP audit, and work with the AO to schedule the audit and conduct post-audit activities such as responding to nonconformities. The AO then passes the audit report along to the regulators, who consider the report when determining any actions with respect to the manufacturer.

Notably, each jurisdiction has different plans for using the reports from the pilot program:

- **US FDA:** Audit reports from the pilot program "will be used as a substitute for FDA routine inspections," but not inspections for cause or initial inspections for a PMA applicant.[1]
- **Australia TGA:** Audit reports from the pilot program would be taken into account when TGA determines if a manufacturer demonstrated compliance to an Australian Conformity Assessment procedure.[2]
- **Brazil ANVISA:** Audit reports from the pilot program may be used "in lieu of" the required premarket inspection to grant a GMP certificate for Class III or IV devices, and ANVISA can use the MDSAP pilot audits to renew an ANVISA GMP certificate.[3]
- **Health Canada:** Health Canada will operate the CMDCAS program and the MDSAP program at the same time as the MDSAP pilot program, and will accept either a CMDCAS or MDSAP certificate for the purpose of showing quality management system conformity to Section 32 of the CMDR.[4]
- **Japan PMDA:** The PMDA may use an MDSAP pilot audit report in a premarket inspection by PMDA or a registered certification body, it could accelerate the marketing authorization, and it may be used in the periodical post-market inspections that PMDA or the registered certification bodies perform.[5]

What This Could Mean for Medical Device Manufacturers

The MDSAP program presents both pros and cons to the medical device industry, and an establishment should carefully weigh its options before submitting to an MDSAP audit. First, combining audits is a clear money- and resource-saver for medical device manufacturers, especially larger ones and ones that sell products around the world and that may be subject to lengthy inspections as a result of their size and operations. Second, the MDSAP audits are scheduled months in advance, allowing manufacturers to set aside the time and resources necessary to successfully go through the audit.

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1 Int'l Medical Device Regulators Forum, Medical Device Single Audit Program: Frequently Asked Questions, at 15, 2015-10-16 v 003 (16 Oct., 2015).

2 Id. at 14.

3 Id. at 14-15.

4 Id. at 15.

5 Id.

However, the MDSAP program's requirement to include all jurisdictions in the audit in which the establishment's products are sold brings questions of what exactly the different regulators will look at in the reports, especially if an establishment has different products for different countries. For example, all the regulators in the MDSAP program will have access to all the audit reports, even for those manufacturers who do not currently have marketing approval in their particular country. If a manufacturer later applies for market access to a new jurisdiction, it is unclear how, or whether, the regulator would view the manufacturer's previous audit reports. In addition, the inability to exclude a jurisdiction for which the manufacturer currently holds marketing approval could be worrisome for some manufacturers. For example, if a problem comes to light in an MDSAP audit, the manufacturer would need to fix the problem with all their products' regulators closely watching and potentially following up.

One point that should make the decision easier for some establishments is Health Canada's announcement that it will wind down its CMDCAS program over the next couple years, and will only accept MDSAP certificates starting on January 1, 2019. In its notice, Health Canada stated that its "[t]ransition to MDSAP is an attempt to align with the transition period for the revised version of ISO 13485," which may be published in early 2016. As a result, product submissions and establishment registrations for Canada would have to be accompanied by an MDSAP certificate instead of a CMDCAS certificate.

Participating in an MDSAP audit, similar to making a global regulatory strategy, is a complex question. Manufacturers should seek out respected global partners to help them analyze their needs and set a global regulatory strategy, including participating in the MDSAP program.

Our lawyers have significant experience advising clients on FDA issues related to medical devices and continue to monitor international regulatory changes in this area. For more information these and other health care and life sciences regulatory matters, please contact your principal Squire Patton Boggs lawyer or any of those listed below.

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