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Client Alert

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FDA's Invitation to the Medical Device Industry: Show Us Yours, and We May Leave You Alone

Beginning June 5, 2012, the Food and Drug Administration (FDA) will allow medical device companies to participate in a pilot program that will allow firms to seek a one-year reprieve from FDA inspections by voluntarily submitting recent International Organization for Standardization (ISO) 13485 audit reports and additional data to the agency. The basic concept is that if the FDA is comfortable that the manufacturing site meets ISO quality standards, it can "leverage" (FDA's term) off of those audits and allow the agency to focus its inspectional resources elsewhere. The pilot program is for two years. On March 19, 2012, the FDA issued a guidance document to describe its expectations entitled "Guidance for Industry, Third Parties and Food and Drug Administration Staff – Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program."[1]

The pilot program is intended as an incentive for companies to share quality audit information to the FDA in exchange for a one-year inspectional reprieve. Some companies may choose to participate in the pilot program, but there are also concerns that may curb industry enthusiasm for the initiative.

Background

The Food and Drug Administration Amendments Act of 2007 amended the Federal Food, Drug, and Cosmetic Act to encourage voluntary submissions "of reports of audits assessing conformance with appropriate quality system standards set" by ISO.[2] ISO 13485 is an international quality-related standard, formally known as "Medical Devices Quality-Management Systems Requirements for Regulatory Purposes."

If the establishment owner agrees to submit the audit reports, it must also provide audit reports of the establishment during the preceding two years. The audit must be performed by an auditor under one of the Global Harmonization Task Force (GHTF) founding members' regulatory systems (Canada, the EU, Australia, and Japan).

Manufacturers facing for-cause inspections, compliance follow-up inspections, and Premarket Approval Application pre-approval inspections are not eligible for the pilot program.

1 See www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm212795.htm.
2 See 21 U.S.C. § 374(g)(7).

In addition to the aforementioned audit report submissions to the FDA, a company electing to participate in the pilot program will provide the following information to the agency:

- Company responses and communications between the auditor and the manufacturer regarding corrective actions (optional);
- A copy of the ISO certificate provided by a third-party auditor to reflect that the company's quality system is registered and certified to ISO 13485 (mandatory);
- Work with the third-party auditor prior to the audit to ensure that the audit and report will be eligible for the pilot program (i.e., comply with the guidance from the GHTF and the U.S.) (good idea and recommendation);
- Attest during the FDA electronic submission process (i.e., the FDA e-Submitter system) that a determination and arrangements for eligibility have been made and provide the requested information through e-Submitter (mandatory); and
- Ensure that ISO reports are consistent with Health Canada's guidance document GD211—"Guidance on the Content of Quality Management System Audit Reports" (mandatory).

The FDA will reject audit reports that fail to follow the aforementioned conditions and guidance documents. The agency will take 30 days to review the audit report; during that period, the agency will not inspect the firm.

Is the Pilot Program Really Worth It?

Under the pilot program, the FDA intends to use the ISO 13485 reports as a risk-based process for planning and using FDA resources and setting inspection priorities more wisely and effectively. While some companies might choose to participate in the pilot program to eliminate some disruption in their facility by having one less regulatory inspection for the year, there are some in the industry that have expressed reservations and concerns. The following are some potential limitations to consider:

- Only one report is allowed for one FDA Establishment Identifier number associated with the audit, so the program might not be useful if a company has multiple sites.

- By submitting audit reports, a company might remind the FDA that it has not been inspected for some time.

- Participation might raise FDA scrutiny if an auditor describes a particular concern.

- Some, particularly large firms, expect to be routinely inspected by the FDA, so the incentive of no inspection in such cases might not materialize.

- If the company is not on the FDA's yearly inspectional list, it might send the audit report to the FDA with little benefit (i.e., the FDA wasn't planning to inspect anyway).

- An ISO audit report might provide the FDA with access to certain information it would not typically review (e.g., internal audits).

- The one-year reprieve may actually be only eight months (submission within 90 days of audit close and 30 days of FDA review of the audit report, which is four months).

- It may generate fear of the unknown and skepticism of the FDA.

In conclusion, the pilot program is an effort by the FDA to conserve resources and offer a one-year reprieve to medical device companies that demonstrate compliance with quality standards. However, device firms should give careful thought before participating in the voluntary program given the concerns noted above. The key to whether a large number of device firms will participate will turn on whether the benefits of the new program are perceived to outweigh the risks and efforts associated with providing the audit reports and other information to the FDA. Similar to most areas when evaluating new FDA initiatives, only time will tell whether the program is a success and whether participation yields benefits, both to the agency and to industry.