

## Progress Report October 2010

*LNE/G-MED: Sharing a Passion for Progress*

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### Will FDA recognize ISO 13485 registration? Draft Guidance Document May Open the Door

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Most countries rely on third party inspections of medical device manufacturers to ensure regulatory conformity, relying on specific directives (i.e. CE Marking) or by use of the widely recognized ISO 13485 standard for Quality Management Systems (QMS) dedicated to medical devices. The FDA remains unique in performing the bulk of its assessments through direct inspections by its own staff.

However, the FDA recently opened the door to recognizing, or at least taking into account, ISO 13485 registration in a draft guidance document the agency issued for comments. While you shouldn't rule out visits from FDA inspectors any time soon, the proposed program of voluntary audit report submissions could lower your inspection frequency.

This month's newsletter examines details of the proposed policy, including how manufacturers could benefit from reduced time spent in inspections or audits over a given year and current programs that already provide this benefit to eligible manufacturers.

#### FDA Would Use ISO 13485 Audit Reports to Set Priority

Published in May 2010, "Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program," proposes that the FDA uses the output of voluntarily submitted ISO 13485 "audit results as part of its risk assessment to determine whether that establishment can be removed from FDA's routine work plan for 1 year." The purpose is to leverage the audits performed by identified, accredited third parties to help the agency set risk-based inspection priorities. (See document at: <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM212798.pdf>)

Per FDA policy, medical device manufacturers can expect an inspection every two years. Yet, the FDA didn't reach this target according to a 2009 study by the General Accounting Office (GAO). In addition, the number of FDA inspections of medical device companies has steadily decreased between 2004 and 2008. (See box below for highlights of GAO Report or go to: <http://www.gao.gov/new.items/d09581.pdf>)

#### Not to be Considered an Adoption of ISO 13485

The FDA acknowledges that ISO 13485 contains consistent requirements with the U.S. QSR so audits

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performed by competent auditors or inspectors should lead to the identification of similar deficiencies. However, such audits will not reveal deficiencies related to other U.S. specific regulatory requirements within the FDA 21 CFR Part 820. (For additional details on this topic, see the GHTF's Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers, available at: [http://www.ghrf.org/documents/sg4/sg4final\\_n30.pdf](http://www.ghrf.org/documents/sg4/sg4final_n30.pdf).)

However, the consideration of ISO 13485 audit reports demonstrates an increased willingness by the FDA in its planning to take into account the information available on the assessment of manufacturers QMS according to foreign regulations. Based on the voluntary submission by the manufacturer of their third-party audit report, the FDA would determine through a risk-based approach whether the manufacturer should be included or postponed from its annual work plan.

## Key Program Requirements

For the FDA to consider submitted audit reports, they would need to meet several requirements:

- **Auditing Body:** Only assessments by organizations acting in the framework of the regulation of the founding members of the GHTF (Global Harmonization Task Force), Europe, Canada, Japan and Australia, would be eligible.
- **Submission Timeframe:** Audit reports would be due 60 days after the last day of the on-site audit. **Note:** LNE/G-MED submitted comments to the FDA that suggests extending this timeline to 90 days in order to allow the auditing organization time to complete its certification process.
- **Report Contents:** Along with the audit report, a manufacturers submission to the FDA would need to include:
  - Any related communications between the manufacturer and the auditor
  - All audit reports performed within 2 years prior to recent audit's last day
  - A copy of the most recent certificate stating compliance with ISO 13485:2003
- **Audit Report Criteria** must match those as specified in the GHTF auditing guidelines (<http://www.ghrf.org/sg4/sg4-final.html>)

## Other FDA Programs Involving Third-Party Audits

In the past, the FDA has considered and implemented several approaches to work with third party Auditing Organizations (AO).

LNE/G-MED was involved in each of these programs and remains active for the programs still being offered:

- The Mutual Recognition Agreement between the U.S. and the European Union (EU) was the first attempt to recognize the competency of Notified Bodies to assess medical device manufacturer quality management systems (QMS) with reference to the U.S. Quality System Regulations (QSR as developed in the FDA 21 CFR Part 820). This program remained experimental and was never ratified nor fully implemented.
- The Accredited Person Program set up in 2004 per the MDUFMA (Medical Device User Fee Modernization Act) allows the FDA to train and qualify auditing organizations and their auditors to perform inspections according to the QSR. This program though does not refer to ISO 13485 by any means.
- The Pilot Multipurpose Audit Program (PMAP), set up between the FDA and Health Canada, seeks to further evaluate the feasibility of an audit using both the QSR and ISO 13485 as reference.

## LNE/G-MED is Ready to Support Program

LNE/G-MED's experience as part of the Pilot Multipurpose Audit Program (PMAP) gives us a clear understanding of how an ISO 13485 audit can help satisfy FDA expectations. We're ready to actively

support this program and have already sent comments to the FDA in order to suggest some clarifications to the document.

Should the Voluntary Audit Submission Report Program be adopted, manufacturers could enhance the outcome of a successful third-party audit under the ISO 13485 standard. While manufacturer will still be subject to FDA inspection, either by the FDA or a third party recognized under the Accredited Persons Inspection Program, medical device manufacturers could proactively provide the FDA with clear information on their quality management system's level of compliance, demonstrating their willingness to work transparently with the FDA.

Such a program would help the FDA determine where to focus their resources and give manufacturers the ability to lower their time spent in inspection/audit over a given year.

## Frequency and Number of Inspections According to GAO

The General Accountability Office (GAO) found that during the period between 2004 and 2008 the FDA did not conduct inspections of medical device manufacturers every two years as required. In addition, the number of compliance inspections conducted decreased during this timeframe.

### FDA's Estimated Frequency of Inspections of Device Manufacturers

Establishment Type	Frequency of Inspections	
Domestic Device Manufacturing	Class III (high-risk) devices:	3 years
	Class II (medium-risk) devices:	5 years
Foreign Device Manufacturing	Class III (high-risk) devices:	6 years
	Class II (medium-risk) devices:	27 years

### Number of Domestic and Foreign Compliance Inspections for Devices Programs, FY 2004 through 2008

Devices Program	2004	2005	2006	2007	2008
Compliance (Domestic/Foreign)	1,645 / 293	1,486 / 225	1,530 / 209	1,318 / 268	1303 / 208

Source: "FDA Faces Challenges Meeting Its Growing Medical Product Responsibilities and Should Develop Complete Estimates of Its Resource Needs;" GAO, June 2009. Above information is extracted from pages 32 and 58 of <http://www.gao.gov/new.items/d09581.pdf>

**Editor's Note:** To learn more about the FDA Third Party Audit Program, ISO 13485 or other LNE/G-MED America certification services, please contact us at (301) 495-0477 or [www.LNE-America.com/medical](http://www.LNE-America.com/medical).

**Technical Questions?** Ask our experts here: <http://www.lne-america.com/quality-news-faqs/ask-our-experts.html> to get clear answers or directed to the proper resources.