



## Progress Report November 2009

LNE/G-MED: Sharing a Passion for Progress

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LNE/G-MED North America provides you with periodic updates on the status of various regulatory and quality related issues. As a service to help you best determine your current and future certification needs, we provide you with the following updates:

### FDA Third Party Inspection Program

#### Purpose and history of the program

The FDA third Party Inspection program authorizes medical device manufacturers to mission the FDA accredited inspection body of their choice to perform an inspection in lieu of the FDA, but according to the FDA practices.

In the late nineties, the FDA trained and qualified auditors from European Notified Bodies to inspect manufacturing facilities located on their territories. This initial qualification program was part of the USA-EU Mutual Recognition Agreement (MRA) and LNE/G-MED succeeded to fully qualify several auditors under this program.

The Medical Device User Fee and Modernization Act (MDUFMA), in 2002, gave a new push on third party inspection by establishing a direct accreditation program directly managed by the FDA. The full qualification of auditors, according to the FDA inspector training process involves the attendance to training courses as well as the participation to three (3) inspections with increasing responsibility.

In 2006, as part of a broad cooperation program between the USA and Canada, Health Canada and the FDA set up a joint program called the Pilot Multipurpose Audit Program (PMAP). It aims at increasing the regulatory cooperation between Countries and building the confidence in the effectiveness of joint audits/inspections.

#### LNE/G-MED a leading Accredited Person

As of 2009, LNE/G-MED appears as one of the most dynamic organizations involved in the FDA third party inspection program. LNE/G-MED performed approximately 30% of all inspections by Accredited Persons since the start of the program. LNE/G-MED just completed the qualification of a new inspector based in North America. With qualified FDA inspectors based in both the USA and Europe, LNE/G-MED increases its ability to address manufacturers requests internationally. American based customers may therefore take full advantage of the benefits of this program:

- Pre-announced inspection for better-planned activities
- Pre-established inspection duration with full quality system assessment
- Concomitant inspection with ISO and/or CE audit to optimize Company's resources
- Affordable and competitive service



## Inspection Process

The process for an inspection follows the phases below:

### Ø Pre-inspection

- A company may contact LNE/G-MED proactively in order to combine the FDA inspection with their renewal CE/ISO audit. Because the renewal CE/ISO audits cover the entire quality management system, the gap between the audit and the FDA inspection is not as significant as compared with shorter surveillance audits.
- A company may also contact LNE/G-MED upon notification by the FDA of their intention to inspect.

In both cases, the feasibility of the inspection will then be evaluated carefully with the company.

The elements to cover during this phase include:

- Contacts between the manufacturer and the Accredited Person (LNE/G-MED)
- Verification of firm's eligibility to the program according to the guidance document issued by FDA
- Application issued by the firm to participate in the program sent to FDA
- If performed under PMAP, both FDA and CMDCAS programs policies apply
- Application issued by the firm to participate in the program sent to both FDA and Health Canada
- Scheduling and contracts establishment
- Designation of the audit team to cover all the manufacturers needs and specificities
- If performed under PMAP, Establishment of the inspection-audit plan

### Ø Inspection

This on site inspection is a Quality System Inspection Technique (QSIT) comprehensive Level II inspection intended to assess a Medical Device Manufacturer's compliance with the QSR and related regulations. It may be combined with other international regulations (CE, CMDCAS, etc...)

#### • FDA inspection:

The above-mentioned QSIT reference guidance is intended to be used in conjunction with:

- Compliance Program Guidance Manual for Inspection of Medical Device Manufacturers (CP 7382.845).
- Investigations Operations Manual (IOM).
- Code of Federal Regulations, Title 21 (21 CFR) Part 820 Quality System Regulation; Part 803 Medical Device Reporting; Part 806 Medical Device Corrections and Removals; Part 821 Medical Device Tracking.
- Compliance Policy Guides (CPG) for devices (Sub Chapter 300).
- Guideline on General Principles of Process Validation.

#### • ISO/CE:

When the inspection is performed jointly with the ISO 13485 – possibly under CMDCAS – and/or CE audit, the specific requirements of these references are also taken into account during the inspection.

At the end of the inspection, the auditor issues an FDA 483 form and ISO/CE non-conformity forms if any.



## Ø Post-inspection

- Form FDA 483, if any, is sent to FDA.
- Establishment Inspection Report (EIR) sent to the FDA and FDA will take over the process
- If performed under PMAP, the ISO/CE audit report is sent to Health-Canada
- Follow-up of the CE/ISO audit between LNE/G-MED and the manufacturer according to the regular auditing process

## Eligibility criteria

The eligibility criteria are documented in the guidance document available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085187.htm>

We will be pleased to assist your firm in determining its eligibility.

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## Last Minute Notice:

The New European Commission Web Portal on Medical Devices has just been released; it is more user friendly, initiative and attractive. It still includes all the relevant information relative to the implementation of the medical device regulations:

- Text of directives
- Guidance documents (MEDDEV, interpretive docs, consensus statements)
- Link to the TEAM – NB web site for notified bodies recommendations
- List of harmonized standards
- Etc.

You can visit this website on: [http://ec.europa.eu/enterprise/sectors/medical-devices/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/medical-devices/index_en.htm)

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