



## Progress Report March 2009

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

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LNE and G-MED North America (LNE/G-MED) would like to provide our valued Medical Device customers with periodic updates on the status of various regulatory and quality related issues. As a complimentary service to help you best determine your current and future certification needs, we provide you with the following updates:

#### **Evolution of the ISO 9001 Standard: Changes and Impacts**

On November 15<sup>th</sup>, 2008, a new version of the standard ISO 9001 was published. You will find in the letter the information about the impact and transition period for your certification.

The new ISO 9001:2008 does not incorporate any new requirement. It enhances the understanding of existing requirements, in particular the notion of conformity of product and control of processes outsourced. It also introduces the concept of risk management and improves the consistency with ISO 14001 (Environmental management systems)

The transition from your ISO 9001: 2000 certification to 2008 version, defined by the International Standardization Organization (ISO) and the International Accreditation Forum (IAF), requires:

Conducting an audit according to ISO 9001: 2008 before issuing the corresponding certificate;  
Compliance with the timetable for the transition depending on the type of audit to be performed (see attached diagram)

Certificates according to ISO 9001:2000 shall not be renewed after 15 November 2009. Therefore, all renewal audits made by G-MED North America **after 16 August 2009** will be carried out under the 2008 version.

Certificates to ISO 9001:2000 can be maintained until 15 November 2010. Therefore, all surveillance audits performed by G-MED North America **after 16 August 2010** will be carried out under the 2008 version.

As a certified ISO 9001: 2000 company, you can examine this new version of the standard and verify the impact on your quality system at the following address : <http://www.iaf.nu/>

We wish to inform you that the new ISO 9001 version does not affect the duration of the audit provided by G-MED North America.

Also, this revision of ISO 9001 will not impact ISO 13485. Hence your ISO 13485 certification is not affected by this revision.



## **Clinical Evaluation of Medical Devices: Meeting the European Essential Requirements for the CE Marking**

With Directive 2007/47/EC revising the Medical Devices Directives (MDD and AIMD), clinical evaluation of medical devices is no longer an option. The requirements have been clarified and manufacturers must evaluate this impact on their activities. The deadline for full implementation is March 21, 2010. It is time to take action and assure the compliance to the essential requirements applicable to your medical device. LNE/G-MED offers a new intensive 1-day training on the Clinical Evaluation process (limited to 20 trainees). To register by telephone call (301) 495 0477 or E-Mail your registration request to [GMEDNA@LNE-GMED.com](mailto:GMEDNA@LNE-GMED.com).

### **Dates and Locations:**

**June 2, 2009** (8:00 am – 5:00 pm EST) – Washington, DC area  
**September 29, 2009** (8:00 am – 5:00 pm PST) – San Francisco, CA  
**October 27, 2009** (8:00 am – 5:00 pm EST) – Boston, MA  
**Cost: US \$890**

## **Medical Design & Manufacturing (MD&M East) Exposition & Conference, June 8 -11 2009, Jacob Javits Convention Center, New York City: Visit LNE/G-MED and register to win a free bottle of fine Bordeaux wine (booth #2737)**

**MD&M East** is the premier East Coast annual conference for medical manufacturing professionals involved in R&D, design, engineering manufacturing, quality and regulatory affairs. LNE/G-MED is once again exhibiting and would like to learn more about your products and services as well as introduce you to our team of engineers. To thank you for your time and effort, you will be registered to win a bottle of fine Bordeaux wine. In addition, if a Request for Proposal (quote) is desired, you may fill out our *Application for Certification of Medical Devices* form provided at our booth (#2737) and receive a complimentary bottle of wine. For appointments or if LNE/G-MED can be of assistance regarding any of your testing, training, regulatory or quality management needs, please feel free to contact us or visit booth #2737.

### **For more information**

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