



Progress Report June 2009

LNE/G-MED: Sharing a Passion for Progress

LNE-GMED North America (LNE/G-MED) would like to provide 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:

Impact of Directive 2007/47/EC on future CE Marking audits for Manufacturers of Medical Devices (excluding IVD)

The revision of the Medical Directives MDD 93/42/EEC and AIMD 90/385/EEC includes amendments related to the audit performed by your Notified Body; for example:

- Sampling regime for selection of the technical documentations of class IIa and IIb medical devices
- Audit of the control of outsourced activities
- Audit of activities related to the clinical evaluation and post-marketing surveillance (including post marketing clinical follow-up)
- Document retention period defined in the procedures, i.e. 15 years for implantable Medical Device

The harmonized European standard on quality management systems (EN ISO 13485) is not affected by the publication of the Directive 2007/47/EC hence audit modalities will remain mostly unaffected. During the next audit we will review your action plan demonstrating that relevant regulatory changes have been taken into account, in particular:

- Is the new definition of Medical Devices applicable to your products?
- Are your products affected by the changes in the classification rules?
- Are the essential requirements compliance rationales updated in your product's technical documentation and those related to clinical evaluation?
- If the classification of the products changes, will it have any impact on your choice of assessment routes (annex of the Directive)?

Dates and Details of Implementation

Implementation becomes mandatory on March 21, 2010 and **note that Directive 2007/47/EC does not define any transitional period.** Any new or pre-existing medical device placed on the market or put into service after March 21, 2010 must comply with the updated requirements. After March 21, 2010 the CE mark will demonstrate proof of your commitment to comply with the amended rules. The European Commission recently published an interpretative document on this matter; the document may be viewed at the following link:

http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/transitionalperiod_2007-47-EC_guidance_final.pdf

Concerned manufacturers should voluntarily take into account these new requirements before March 21, 2010 to ensure a smooth transition towards their full application of the new rules. LNE/G-MED North America is committed to helping you meet this important target. **From June 30, 2009**, our auditors will take into account the revised Directives as references for your audits. Where discrepancies are identified between your Quality System and the amended requirements, they will be documented as non-conformities to be addressed before March 21, 2010.



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 (3 01) 495 0477 or E-Mail your registration request to GMEDNA@LNE-GMED.com.

Dates and Locations:

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

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