

November 10, 2009

Company

First name

Department

Address

Tel.

E-mail

Int. VAT no.

Surname

Position

Postcode

City

Fax

 PAYMENT

Invoice to be sent to

Company stamp

Person to contact

Date

Tel.

Signature

I enclose a cheque for € 410

Corresponding to the registration fee.
Cheque to be made out to "l'Agent Comptable du LNE"

TO BE RETURN TO
Laboratoire national de métrologie et d'essais
Centre de Formation
1, rue Gaston Boissier
75724 PARIS CEDEX 15

OR BY FAX
+33 1 40 43 37 37

 Seminar reference

Medical devices: chinese/japanese markets – JT 917 – November 10, 2009

 Location

Maison de la Mécanique - Paris La Défense
39-41, rue Louis Blanc – 92400 Courbevoie – France

 Registration fee

Full day: € 410

This fee covers all presentations, seminar materials, lunch and refreshments.

 Registration

As the number of places is limited, we would advise you to **register immediatly**. You can do this **by fax** (+33 1 40 43 37 37) or **on our website** (www.lne.fr, section *Formation*). You will be registered for the symposium as soon as we receive your completed registration form and payment. The form and payment should be sent to:

Laboratoire national de métrologie et d'essais
Centre de Formation
1, rue Gaston Boissier – 75724 PARIS CEDEX 15

Please make out your cheque to "l'Agent Compable du LNE". Alternatively, a bank transfer may be made to LNE's account:

FR76 1820 6002 8058 3819 5600 104

International Bank Account Number (IBAN)

AGRIFRPP882

Bank Identifier Code (BIC)

On receipt of your registration and payment, we will send you notification and an access map.

If a registered participant is unable to attend, he or she may be replaced by a colleague up to the day before the seminar. Please inform us by fax (+33 1 40 43 37 37).

Contact

E-mail: jt@lne.fr

Tel.: +33 1 40 43 37 35 / Fax: +33 1 40 43 37 37



PARIS

November 10
2009

MEDICAL DEVICES ENTERING THE CHINESE AND JAPANESE MARKETS

:: Regulations - Experience

EMERGO  FRANCE



9:30 am

Participants are welcomed

9:45 am

Opening and presentation of the programme

- Corinne Delorme, Regulatory Affairs Manager, LNE

:: ENTERING THE CHINESE MEDICAL DEVICE MARKET

10:00 am

The registration and approval process for medical devices in China

- Ian P. Gordon, Senior Vice President, EMERGO Group Inc

10:45 am

Questions and answers

11:00 am

Break - Networking

11:20 am

Placing medical devices on the chinese market

- Ian P. Gordon, Senior Vice President, EMERGO Group Inc

11:50 am

Questions and answers

12:00

Advantages of the services provided by LNE in Asia

- Luc Busiau, Head of Healthcare Market, LNE

12:30 pm

Lunch

:: ENTERING THE JAPANESE MEDICAL DEVICE MARKET

2:00 pm

The registration and approval process for medical devices in Japan

- Ian P. Gordon, Senior Vice President, EMERGO Group Inc

3:00 pm

Questions and answers

3:15 pm

Break - Networking

3:30 pm

Quality Management System

- Differences and similarities between the ISO 13485 standard and Ministerial Ordinance no. 169 (2004)
- Advantages of the agreements between LNE and JQA (Japan Quality Assurance Organization)
- Thierry Thomas, G-MED Certification Division Manager, LNE

4:00 pm

Questions and answers with all contributors

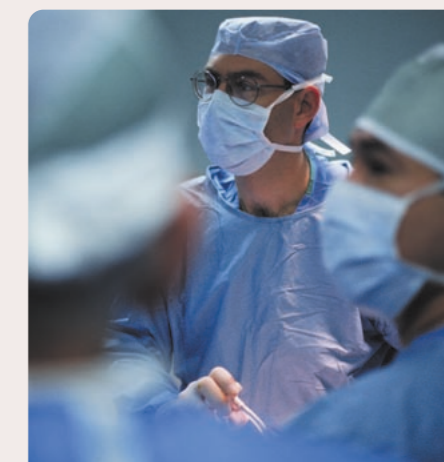
4:15 pm

Closing remarks

- Corinne Delorme, Regulatory Affairs Manager, LNE

4:30 pm

Close of forum



A one-day forum for:

- **Manufacturers of medical devices**
 - Company directors
 - Regulatory affairs managers
 - Quality managers
 - Asian markets managers



Asian markets, particularly China and Japan, appear highly attractive for the medical device industry. They represent a considerable challenge, however, as manufacturers have to understand fast-changing local regulations and comply with the statutory procedures covering tests, etc.

The purpose of this bilingual international forum is to provide European manufacturers with a comprehensive overview of the regulatory context in each of the two countries.

Participants will be able to share their experience of these markets, exchange views with a panel of experts, and learn about the steps to be taken and the pitfalls to avoid.

Topics covered:

- Which administrative procedures and regulations must be complied with before placing medical devices on the Chinese and Japanese markets?
- What experience of the Chinese and Japanese markets can manufacturers share?
- Which strengths can European manufacturers bring into play?

Simultaneous English-French translation is provided.

