Medical Devices Workshop
Regulatory insights: China, Europe and U.S.A.
23rd of April 2015 – Michelangelo Hotel, Milan, Italy

International panel of speakers:

Albrecht Poth
Scientific Director Medical Device Testing - Eurofins

Edwin Wen
Strategic Operating Division & Medical Device Legislation Compliance
Dept. Manager - CIRS (Chemical Inspection & Regulation Service - China)

Michael Petersen
Business Developer of Medical Device Legislation Compliance Department
CIRS (Chemical Inspection & Regulation Service - China)

Enrico Perfler
CEO - Atricath

Paolo Dentis
Certification Manager - Eurofins

Elena Aleotti
Regulatory Affairs Specialist - Sorin Group
Introduction

Medical devices market environment is undergoing rapid change with a raft of new regulatory measures. The risk of non-compliance has become an increasingly major concern in recent years, particularly for manufacturers with operations in multiple countries and jurisdictions. Regulatory compliance has become a major milestone in product development and marketing for most manufacturers of medical devices.

While European and U.S. market are prospected to have a positive growth trend, China is currently one of the world's most promising markets for medical devices, which on the back of its vast market size, offers huge potential to medical device companies. The rapid growth of import supply and export of medical devices makes China the fourth largest market in the world.

All medical devices marketed or sold for use in China must be registered with China's Food and Drug Administration (CFDA). While there are many similarities with registration requirements in the U.S.A. and the European Union, the classification of medical devices in China follows the peculiar requirements of CFDA, and includes some important deviations from classification schemes in other countries.

This workshop will focus on its first part on the international testing approach of medical devices and challenging regulatory environment in China. The second part will give highlight on two different perspectives comparing the EU Medical Devices Directive and FDA requirements and expectations for biocompatibility testing: Notified Body and expert consultants from the industry.

This workshop represents a unique opportunity for participants to benefit from the significant experience of the most relevant experts of the industry regarding the compliance environment affecting medical devices companies with main focus on the Chinese, European and U.S. market.

Benefits in attending

Understand the ISO approach applied to medical devices
Become more familiar with medical devices management in China and latest regulatory updates
Be aware of medical devices’s market and approval process in China
Gain practical advice on successful biocompatibility submissions in Europe
Understand FDA requirements and expectations for biocompatibility testing and evaluation compared to European requirements
Opportunity to bring your specific questions along to the workshop for discussion with industry-leading experts and highly skilled consultants.
Programme

• 9.30 - 9.50 Welcome and introduction
• 9.50 - 10.30 The ISO approach to internationalization
  (Albrecht Poth - Eurofins)
• 10.30 - 11.15 Medical devices management in China and latest regulatory updates
  (Edwin Wen - CIRS)
• 11.15 - 11.45 Coffee break
• 11.45 - 12.40 Practical know-how on medical devices’s market entry and approval process
  (Michael Petersen - CIRS)
• 12.40 - 13.10 Question & Answer session
• 13.10 - 14.00 Networking lunch
• 14.00 - 14.40 The EU Medical Devices Directive: state of art and expectations
  (Enrico Perfler - Atricath)
• 14.40 - 15.20 Notified Body perspective
  (Paolo Dentis - Eurofins)
• 15.20 - 16.10 FDA requirements and expectations for biocompatibility testing and evaluation compared to Europe
  (Elena Aleotti - Sorin Group)
• 16.10 - 16.40 Open forum, questions, concerns, clarifications
  (All speakers)
• 16.40 - 16.45 Conclusions

Workshop moderator:
Paolo Pescio, Medical Devices & GLP Division Manager in Eurofins. Chairman of the UNI U4201 Committee for non-active medical devices for transfusion and biological evaluation.

Who should attend
This workshop will be relevant to those in the medical device industry operating in the following departments: Regulatory Affairs, Regulatory Officer, R&D, Quality Assurance, Notified Bodies and all experts interested to enhance the learning experience of pertinent laws, regulations, and industry guidance that pertain to the medical devices industry.

Workshop language
The official workshop language will be English.

Speakers

Albrecht Poth
Scientific Director Medical Device Testing in Eurofins. He has gained estimable skills and expertise as Technical Director, Senior Manager in Regulatory Affairs, Study Director in leading companies of the industry. Before joining Eurofins Group he was Deputy Managing Director and Scientific Advisor for Harlan CRS Cytotest Cell Research. He is an active and long date member of various international groups. He is convened by the expert group of the ISO/TC 194 (WG6) and Chairman of ISO Technical Committee 194 “Biological Evaluation of medical devices”.

Edwin Wen
Manager of Strategic Operating Division & Medical Device Legislation Compliance Department of CIRS (Chemical Inspection & Regulation Service) in China. Has an extensive background in China medical device regulatory activities by developing compliance procedures for medical device registration in CFDA, compliance procedures for the entry of medical device and formulated technical methods for the regulatory risk management in China.

Michael Petersen
Business Developer of Medical Device Legislation Compliance Department of CIRS (Chemical Inspection & Regulation Service) in China. He is working on the medical device market expansion, regulatory affairs extension and help foreign medical device enterprise enter the China market including also tracking and update of CFDA medical device regulations.

Enrico Perfler
CEO of Atricath, Italian start-up company developing an innovative ablation catheter for atrial fibrillation treatment. He previously was Director of Medical Device Technology at Eudax, a contract research organization focused on early stage project development for medical device and pharmaceutical companies. He is also contract professor at the University of Pavia, faculty of Engineering and he participates actively to various national and international technical working groups.

Paolo Dentis

Elena Aleotti
Regulatory Affairs Specialist at Sorin Group. Dealing with CE marking and FDA submissions of medical devices, she is charge of creation, review and maintenance of Technical Files. Following all product lifecycle, she cooperates with new product development teams, advising on risk management, product safety and relevant regulatory affairs standards and guidelines for medical devices.
Reservation Form (please complete in full):

Title, first name, surname _______________________

Company ________________________________________

Department ______________________________________

Address __________________________________________

Phone ____________________ Fax ______________________

e-mail _____________________________________________

Important: Please indicate your company’s VAT ID Number ____________________________________________

If the bill-to-address is different please fill out here:

______________________________________________________________________________________________

Registration fee:

95€ + VAT if applicable
Discount rate for second participant: 80€ + VAT
Including: Workshop documentation, lunch and refreshment.
The registration fee is payable in advance.

A certificate of attendance for professional development will be given to each participant who completes the workshop.

General terms and conditions:

If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
   - until 1 week prior to the conference 50% of the registration fee will be charged;
   - less than 1 week prior to the conference full registration fee will be charged.

Eurofins Biolab Training Center reserves the right to cancel/alter the programme, the speakers, the date or venue. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. Eurofins Biolab Training Center is not responsible for airfare, hotel or other costs incurred by registered delegates.

Terms of payment:

The registration fee is payable in advance.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
Only after we have received your payment, you are entitled to participate in the conference.

Date __________________ Signature __________________________

Date: Thursday 23rd of April 2015, 09.30h - 16.45h
(Registration 09.00h-09.30h).

Venue:

Michelangelo Hotel
Piazza Luigi di Savoia, 6 - 20124 Milan (Italy)
Tel. +39 0267551
Fax +39 026694232
http://www.michelangelohotelmilan.com/

Just steps away from Milan’s central train station and underground station MM3 - MM2.
Easy access for those who reach the venue by plane, train, underground or other public tranporation.
For logistic support please contact us at FormazioneFarma@eurofins.com.

Registration:

Via the attached reservation form, by e-mail at FormazioneFarma@eurofins.com

Bank details:

UNICREDIT SPA
ABI: 2008   CAB: 20600   CIN: N
C/C: 000004846325
IBAN: IT04 N020 0820 6000 0000 4846 325
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www.biolab.it
www.eurofins.it
http://pharma.eurofins.com/medical-device-testing.aspx

We very much look to welcoming you to the Medical Devices Workshop on Thursday 23rd of April.