2013 Global Expert Training Series
(HRDF SBL Scheme Claimable)

Biological Evaluations of Medical Devices

By Dr. Nazarena Mazzaro,
Director of Clinical Research, Biosafety and Health Economics
Ambu A/S

2-3 July 2013 (0900 – 1700)
E&O Hotel, George Town, Penang

This two-day training course is intended for manufacturers of medical devices (RA, R&D, Clinical, and Biosafety specialists), Distributors, Consultants, and interested parties in Regulatory Authorities.

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Organized for AMMI by Medsociate Medsociate Sdn Bhd (HRDF Approved Training Provider)
TRAINING COURSE
Biological Evaluations of Medical Devices

INTRODUCTION / OBJECTIVE
The regulatory scene governing the design, development and manufacturing of medical devices is constantly evolving. Biosafety and clinical data are gaining more importance. Within this context, a good understanding of the regulatory requirements and technical basics behind biosafety are important to make sound biological testing choices, document your product development appropriately, and face the regulatory framework with confidence.

In this workshop we will review several aspects within medical device biosafety, from regulations (EU and USA) to testing (ISO 10993) and reporting.

OUTLINE
- Regulation framework for medical devices with emphasis on biological safety (focus on European and USA regulations).
- The Biological Evaluation process.
- Review of main parts of ISO 10993.
- REACH Regulation (invited speaker).
- Clinical Evaluation: basic concepts.

TRAINER’S PROFILE
Nazarena Mazzaro, Ph.D, is Corporate Director of Clinical Research, Biosafety and Health Economics at Ambu A/S. She is responsible of Ambu’s overall clinical operations as well as responsible of the area of biosafety (biocompatibility) and Health Economics. She is leading an international team of clinical and biosafety specialists in the Unites States, Europe and Asia, and has been in the field of research and development of medical devices for more than 12 years.

Dr. Mazzaro has knowledge within the fields of clinical research, biosafety, health economics, product development and regulatory affairs. She is Member of the Danish Working Groups for ISO 10993 (Biological Evaluation of Medical Devices) and ISO 14155: Clinical Investigations of Medical Devices for Human Subjects, and has presented in several international scientific conferences, and training courses within clinical research.

Dr. Mazzaro is currently located in Penang (Ambu Sdn Bhd) establishing the local clinical research and biosafety function, while is still responsible of the corporate clinical and biosafety team of Ambu A/S.

Invited Speaker Session (REACH)
Ms Annette Bitz. Chair of the Danish working group for the ISO 10993 standard.

DATE & DURATION
2-3 July 2013 (Tuesday - Wednesday) 9.00 am – 5.00 pm

VENUE
Eastern & Oriental Hotel (E&O Hotel), George Town, Penang, Malaysia
TERMS AND CONDITIONS

REGISTRATION AND CLOSING DATE
Closing date for registration is 25 June 2013.
For online registration, please visit http://form.jotform.me/form/31531352669455

COURSE FEE
Public RM1,200 or USD400 per person

PAYMENT
Upon receiving the registration form, AMMI Secretariat (Medsociate Sdn Bhd) will issue Course Quotation for Confirmation and follow by Invoice with payment instruction.

CONTACT:
For enquiry, please email to secretariat@ammi.com.my or ccs@medsociate.com

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CANCELLATION
The organizer reserves the right to cancel or postpone any training / event but with due notice to the registered participants / company(s). Cancellation of attendance and refund will not be entertained as all bookings would have been reserved and confirmed.

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