STERILE MEDICAL PACKAGING- REGULATIONS, STANDARDS, DESIGN & DEVELOPMENT AND VALIDATIONS

Date: 31 July 2019   Time: 9.00am – 4.00pm   Venue: G Hotel Kelawai, Penang

The one-day seminar covers:

1. The new EU Medical Device Regulation (MDR)
   - A summary of key features and issues
   - The Impact on Global Sterile Packaging Standards
   - Harmonized standards – new EU requirements

2. Sterile Packaging Standards
   - The essentials of sterile packaging validation
   - ISO 11607- Packaging for sterile medical devices- latest revisions Feb 2019
   - EN 868 series
   - ISO TS 16775 – the guidance for the application of ISO 11607-1/2

3. The clinical aspects of medical packaging
   - Aseptic presentation – risks and aspects to consider
   - Usability evaluation for aseptic presentation – a new ISO 11607 requirement
   - New requirements for labelling of sterile packaging, new symbols

4. Considerations on Packaging Science, Design and Validation
   - Packaging design tips
   - Sealing process development
   - The science behind peel strength testing using different ASTM F88 techniques
   - Basics of microbial barrier and particulate filtration testing
   - Organising validation protocols to support future revalidations

DURATION
One (1) day

TARGET AUDIENCE
This training is recommended for those who are involved in Quality Control and Regulatory Affairs, Microbiologists, R&D and Manufacturing Operations, Packaging and Process Engineering, Procurement and Supply Chain Management, Quality Control and Regulatory Affairs, Marketing and Product Management as well as Sterilization Professionals
SPEAKER’S PROFILE

Thierry Wagner has spent over 30 years working for DuPont in its polyester films and nonwovens businesses in a variety of assignments ranging from process development and project management to operations and business management. He is convenor of ISO TC198/WG7 “Sterilization of Health Care Products—Packaging” (ISO 11607), chairman of the Sterile Barrier Association (SBA), member of the Parenteral Drug Association (PDA) and actively involved in various ISO and CEN technical committees on medical and pharmaceutical packaging like CEN TC102 “Sterilizers for Medical Purposes—Packaging” (EN868) and ISO TC76 “Transfusion, infusion and injection equipment for medical and pharmaceutical use”. Thierry is also a member of ISO/TC 210 in charge of ISO 13485, medical device symbols, ASTM Committee F02 and of the CEN Advisory Board for Healthcare Standards-Europe (CEN ABHS).

Thierry Wagner earned a master’s degree in mechanical and process engineering from ETH Zürich in Switzerland. He is a featured speaker at international conferences and seminars on medical and pharmaceutical packaging regulatory aspects.

COURSE FEES

COMPLIMENTARY FOR AMMI MEMBERS
Full members – 2 seats, Associate members- 1 seat
Additional seats at RM159 per pax.

PUBLIC / NON MEMBERS
Seminar fees at  RM530 per pax

REGISTRATION DETAILS
Register online at www.ammi.com.my

PAYMENT AND CONFIRMATION OF REGISTRATION

All payment is due immediately upon receipt of invoice. Please note that a confirmation letter for HRDF submission will only be issued upon receipt of payment.

Option 1: Direct Bank-in or via E-Banking upon receipt of Invoice
An invoice will be sent to you within 3 working days upon your registration. Please note that any Early Bird Discounts (for registration within validity period) will be reflected in the invoice. Please email us (admin@medsociate.com) the bank-in slip / remittance slip once the payment
MEDICAL DEVICE PACKAGING

is made. A confirmation letter for your HRDF submission will be issued to you upon receipt of payment.

Please refer the following bank account details:
Beneficiary Name: Medsociate Sdn Bhd
Bank Account Number: 800 3930 348
Bank: CIMB Bank
Swift Code: CIBB MYKL

For Government Sector - A Local Order (LO) or letter of approval to participate must be submitted before your registration can be confirmed.

Option 2 : Direct Online Payment
You may choose to make direct online payment, via Paypal or your credit/ debit card. A tax invoice and confirmation letter will be sent to your email address within 3 working days, when you choose this option.

CANCELLATION / REFUND POLICY
AMMI reserves the right to cancel or postpone any training or event but with due notice to the registered participants / company(s). Any payment made will be refunded in full if the cancellation is made by AMMI. No shows and cancellations made by participants/ companies within the specified period will incur the specified costs as per below schedule.

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<th>Prior to Training Date</th>
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SUBSTITUTION
Replacement of participant is allowed at no additional cost if you are unable to attend. Please inform us of the replacement in writing at least 3 working days before the training date.

CONTACT
For enquiries, please email to secretariat@ammi.com.my
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