eurofins | Medical Device Testing

Li-MED RA & QA Experts



Conference:
Sterilization validation and cleaning validation of Medical Devices

February 27th, 2018
Leonardo City Tower Tel Aviv Hotel

Speakers:

Paolo Pescio
Medical Devices Specialist
Biocompatibilty & Toxicological expert
Eurofins Medical Devices Testing Italy

Harry Leinwand
M.Sc; CQE
Managing Director
R&Q Consulting Ltd

Sally Berkovich
QA/RA Expert at Li- Med

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Introduction

Manufacturers of finished medical devices should provide clear, understandable and reproducible cleaning and sterilization protocols that have been validated to be effective. Due to the development of more complex devices, the biggest challenge for reusable medical devices is an appropriate design process not only to facilitate the use of the device, but to facilitate the eventual reuse through an adequate cleaning and disinfection/sterilization process.

Many medical devices need to be able to function safely after hundreds of cleaning and disinfection or sterilization cycles.A thorough understanding of device cleaning, disinfection, and sterilization issues is therefore essential in the design phase of any reusable medical device.

This conference will provide a wide and comprehensive overview of critical aspects of cleaning and sterilization validation of Medical devices.

By attending, participants will gain valuable insight on current regulatory expectations and latest industry practices. Benefit from the strong expert advice on how to overcome challenges and implement successfully your cleaning and sterilization decision making and activity planning strategy.

Who should attend

This conference offers a rewarding experience and is particularly relevant to those directly involved or supporting the development of cleaning/sterilization validation programs and plans, also those responsible for cleaning validation protocols and execution activities. This includes validation, engineering, operations, consultants also Quality Control and Quality Assurance personnel.

Programme

9.00 - 9.30: Registration

9.30 - 10.30: ETO Sterilization of Medical Devices
Harry Leinwand (M.Sc, CQE, Managing Director, R&Q Consulting Ltd)

10:30-10:45: Coffee break and refreshments

10:45 – 12:45: Cleaning & reprocessing validation
Paolo Pescio (Eurofins Medical Device Testing Italy)

12:45 – 13:45: Lunch

13:45- 14:45: Endotoxin contamination after sterilization: FDA expectation
Paolo Pescio (Eurofins Medical Device Testing Italy)

14:45 – 15:00: Coffee break

15:00-15:30: ISO 10993-7: Ethylene Oxide Sterilization Residuals
Sally Bercovich (Li-Med)

15:30-16:00: Q & A session

16:00-17:30: One on One Personal meeting

Workshop language

The official workshop language will be English.

Speakers

Paolo Pescio
With more than 10 years of experience performing pre-clinical evaluation for medical devices earned a M.S. in Biomedical Engineering from Polytechnic University of Milan (Italy). Former Chairman of the UNI U4201 Committee for non-active medical devices for transfusion and biological evaluation is an active member of ISO TC194 and CEN TC206 groups.
He also has a successful background as Test Facility Manager, and his expertise lies in:
Toxicological evaluation and risk assessment
Biological evaluation of medical devices
Integrated Testing Strategies
Validation of sterilization process
E&L assessment
PDE evaluation.

Harry Leinwand
An expert in Quality Systems, Sterilization and Regulatory Affairs for companies in the medical device industry. For nearly 30 years Harry has been focusing on preparation and implementation of QA systems compliant with the international standard ISO 13485, the EC Directives and Regulations, Canadian Medical Device Regulations and the FDA Quality System Regulations, as well as in controlled environments & sterilization processes. In the field of sterilization, Harry has helped medical device companies by preparing protocols and reports for aseptic processing and steam, EtO and Gamma irradiation terminal sterilization processes according to consensus/ harmonized standards. On top of that, he assisted in sterilization validation files and preparation of expert reports for DEKRA Certification B.V, The Netherlands.

Sally Bercovich
Sally is QA\RA expert with more than 12 years of experience. She has vast experience in leading quality processes and regulatory projects for companies in the field of medical devices and agriculture. Her main expertises are sterilization validation and biocompatibility. Sally's strongest suit is her broad understanding of processes and her ability to drill down to the smallest detail.

: Registration

Online registration: https://goo.gl/forms/2KNFUHx4O4Ut9zfu2

Registration fee:

Early bird registration fee (Valid until 1.2.2018): 490 NIS
Full registration fee: 690 NIS

The registration fee includes:
Conference documentation, lunch, refreshment and parking.
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.

Organizers reserve 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. Organizers are not responsible for airfare, hotel or other costs incurred by registered delegates.

Terms of payment:

The registration fee is payable in advance.

Means of Payment:

On-line credit card:
https://secure.cardcom.co.il/e/uJg/

Bank transfer:
Top Li-Med Technology
Bank: Hapoalim
Branch: 537
Account No. 187391

Please send a reference of the transfer by email at sivan@li-med.com. Invoice will be issued and emailed separately.

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:

February 27th 2018, 09.30h - 17.30h
(Registration 09.00h-09.30h).

Leonardo City Tower Hotel
Zisman Shalom St 14, Ramat Gan, Israele
https://www.google.it/maps/place/Leonardo+City+Tower/@32.084689,34.7995847,15z/data=!4m2!3m1!1s0x0:0x625d346a3c96efdf?sa=X&ved=0ahUKEwju1bmTz6LWAhUEIJoKHWQGAIcQ_BIInwEwCg

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We very much look to welcoming you to the Sterilization validation and cleaning validation of Medical Devices on February 27th in Tel Aviv.