



Conference: Biological evaluation of medical devices

November 16th, 2017
Leonardo City Tower Tel Aviv Hotel
Zisman Shalom St 14, Ramat Gan, Israel

Speakers:

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

Ayelet Geva
CEO
Li-Med Israel

Sally Bercovich
QA/RA Expert
Li-Med Israel

Organisation and Contact:

Li-Med
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Introduction

The main scope of ISO 10993 is to protect patients from biological risks arising from the use of medical devices. The standard states that the biological evaluation of a medical device (or a material component of such) should be conducted within the framework of a risk management process. Such a process should generally begin with assessment of the device, including the material components, the manufacturing processes, the clinical use of the device including the intended anatomical location, and the frequency and duration of exposure.

Considering this information, the potential risks from a biocompatibility perspective should be identified. Such risks might include chemical toxicity, unacceptable biological response to physical characteristics of the device, and aspects of manufacturing and processing that could alter the physicochemical characteristics of the device, which could lead to changes in the biocompatibility response. The data coming from the chemical characterization should be toxicologically assessed to elucidate the need for further tests to address the relevant biological endpoints for the device under evaluation.

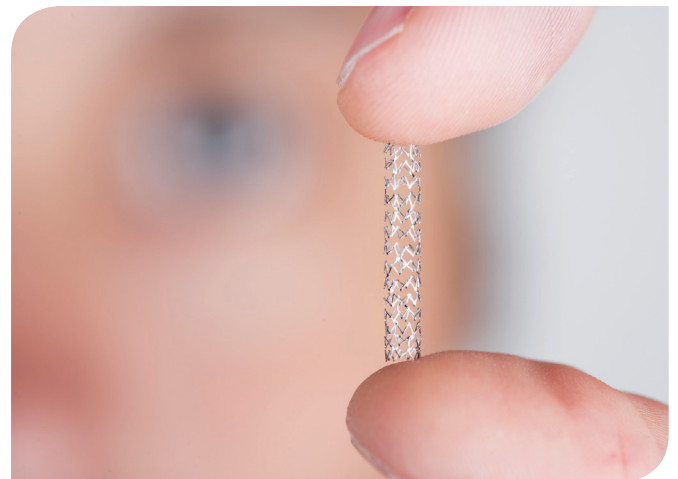
This Conference will provide a wide and comprehensive overview of critical aspects and latest updates on ISO 10993 and the impact that these upcoming changes will reflect on the medical devices industry.

By attending, participants will gain valuable insight on how to plan and conduct the biological evaluation, and, more importantly, how such an evaluation sits within the activities of design control and risk management by giving practical hints for the definition of pathways based on scientific rationales.

The Conference led by the biocompatibility expert in Eurofins and TC member of ISO TC194 and CEN TC206 groups will also give the opportunity to bring your specific questions and case studies along to the Conference for discussion. Benefit from the strong expert advice on how to overcome challenges and implement successfully your biocompatibility testing strategy.

Who should attend

This Conference offers a rewarding experience and is particularly relevant to both specialist or beginner within biocompatibility, product safety, material specialist, material characterization, R&D, production, process development or Quality Assurance/Regulatory Affairs.



Programme

9.00h - 9.30h: Introduction and general overview
(*Ayelet Geva*)

9.30h - 10.15h: ISO 10993 standard series: approaching biocompatibility within a risk management process
(*Paolo Pescio*)

10.15h - 10.45h: Introduction to the new FDA guidance
(*Paolo Pescio - Sally Bercovich*)

10.45h - 11.00h: Coffee break

11.00h - 11.45h: Chemical characterization of the materials: what does it mean in practice
(*Paolo Pescio*)

11.45h - 12.15h: Toxicological assessment (ISO 10993-17) application in order to evaluate obtained data from chemical chemical characterization
(*Paolo Pescio*)

12.15h - 13.00h: Bridge approach and change management optimization thanks to chemical characterization
(*Paolo Pescio*)

13.00h - 14.00h: Lunch break

14.00h - 15.30h: Biocompatibility tests overview:
In vivo tests
In vitro tests
(*Paolo Pescio*)

15.30h - 16.00h: What's new in ISO Technical Committee 194 "Biological and clinical evaluation of medical devices": an update from October 2017 meeting in Seoul
(*Paolo Pescio*)

16.00h - 18.00h: One on One meetings

Conference language

The official Conference 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.

Ayelet Geva

Ayelet's background stems from the High Tech industry where she was a product owner and a consultant for entrepreneurs and startups of different sizes. She has more than 16 years of managerial experience. Ayelet has a proven business insight, vast software development experience, managerial and communication skills alongside an in-depth experience facing clients and managing large scale products of both in Israel (Motorola, SintecMedia, BioGaming etc.) and Internationally (TEVA, FOX, ESPN CTV etc.). Ayelet's current position is Li-Med CEO.

Sally Bercovich

Sally is QA/RA expert with vast experience in leading quality processes and regulatory projects for companies in the field of medical devices and agriculture. Her main expertise is sterilization validation and biocompatibility. She holds a BSC in life sciences and MSC in Biotechnology. Sally's strongest suit is her broad understanding of processes and her ability to drill down to the smallest detail.

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:

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 released to each participant.

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.

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:

November 16th 2017, 09.00h - 18.00h
(Registration 08.30h - 09.00h).

Venue:

Leonardo City Tower Hotel
Zisman Shalom St 14, Ramat Gan, Israele

Registration:

Via the attached reservation form, by e-mail at **sivan@li-med.com**

or online at:

<https://secure.cardcom.co.il/e/E9G/>

Payment method:

Wire Transfer:

Top LIMED Technologies LTD

Bank: POALILIT

IBAN:IL 10-0125-3700-0000-0187-391

or online at:

<https://secure.cardcom.co.il/e/E9G/>

You'll receive confirmation, payment and invoicing details via e-mail after submission.

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www.eurofins.com/Medical-Device

We very much look to welcoming you to the Biological evaluation of medical devices Conference on November 16th in Tel Aviv.