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Workshop:
ISO 10993-1 and Chemical Characterization of Medical Devices

June 12th, 2019 - Lyon

Speaker:

Paolo Pescio
Eurofins Medical Device Testing Italy

Organisation and Contact:

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Introduction

The new ISO 10993-1:2018 “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” has significantly impacted the approach to biocompatibility. This approach is now based on the review of relevant established scientific data, physico/chemical characterization and in vitro testing; in vivo testing is carried out only to fill gaps in our understanding. All device types will require a chemical characterization as a prerequisite for the risk assessment.

Data obtained from chemical characterization should be toxicologically assessed to elucidate the need for further tests to address the relevant biological end-points. In line with the risk management, the biological evaluation should be planned in advance (“Biological Evaluation Plan”), carried out and documented (“Biological Evaluation Report”) by knowledgeable and experienced professionals. Characterization studies are performed in order to gain a more complete understanding of a device, and of the risk factors associated with using a device. Also FDA is placing a greater emphasis on these studies – to better ensure patient safety.

This Workshop will provide a wide and comprehensive overview of critical aspects and latest updates on ISO 10993 series and the impact that on the medical devices industry. By attending, participants will gain valuable insight on how to plan and conduct the biological evaluation plan, and, more importantly, how such an evaluation sits within the activities of design control and risk management.

This Workshop, led by the biocompatibility industry expert in Eurofins, will also give the opportunity to bring your specific questions and case studies along to the workshop for discussion. Benefit from the strong expert advice on how to overcome challenges and implement successfully your biocompatibility testing strategy.

Workshop language

The official workshop language will be English.

Agenda

09:30-11:15 What’s new in ISO 10993-1

11:15-11:30 Coffee break

11:30-13:00 Chemical characterization as a preliminary step for risk assessment (ref. ISO FDIS 10993-18)

13:00-14:00 Lunch break

14:00-15:00 Toxicological evaluation of data (ref. ISO 10993-17)

15:00-15:30 Biological Evaluation Plan and Biological Evaluation Report

15:30-16:15 Case study

16:15-16:30 Q&A

Who should attend

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

Speaker

Paolo Pescio, ERT
European Registered Toxicologist with a M.S. in Biomedical Engineering has over 13 years of experience in biological evaluation of medical devices with a successful background as Test Facility Manager.
He is Senior Consultant in Eurofins Medical Device Testing Italy, Healthcare Engineering HAS consultant for EU Commission and adjunt professor in “Regulatory aspects in toxicology - Legislation in European Union” at the University of Milan.
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.

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Reservation Form (please complete in full):

Title, first name, surname _____

Company _____

Department _____

Adress _____

Phone _____

e-mail _____

Important: Please indicate your company's VAT ID Number

_____

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

_____

_____

_____

Registration fee: 100€
The registration fee includes:
Workshop documentation, refreshment and certificate of attendance.
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:

June12th 2019, 09.30h - 16.30h
(Registration 09.00h - 09.30h).

Venue: To be defined. Confirmation will be delivered to participants by e-email.

Registration:

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

Payment method:

Wire Transfer:
Eurofins Pharma Quality Control
Bank: BNP Paribas Pays De La Loire
IBAN: FR76 3000 4024 0800 0112 6249 558
BIC: BNPAFRPPXXX

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

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We very much look to welcoming on June12th in Lyon.