Conference:
Best Practices for Extractables and Leachables Studies in the Pharmaceutical and Medical Devices Industry

March 14th, 2019
Leonardo City Tower Hotel, Tel Aviv

Key Note Speakers:

Simone Carrara
Extractables and Leachables Laboratory Manager
Eurofins BioPharma Product Testing Italy

Chiara Picotti
Senior Consultant and Team Leader
Eurofins Medical Device Testing Italy

Organisation and Contact:

Eurofins BPT & MDT Italy
Via Bruno Buozzi, 2
20090 Vimodrone, Italy
website: www.eurofins.com/BPT
website: www.eurofins.com/Medical-Device

Edu-Med
24 Imber st. Kiryat Arie
Petach Tikva 4951158, Israel
e-mail: office@edu-med.info
website: www.edu-med.info

Introduction

The importance of extractables and leachables testing in the pharmaceutical and medical device industry has grown significantly in the last few years driven by a substantial growth in global regulatory requirements.

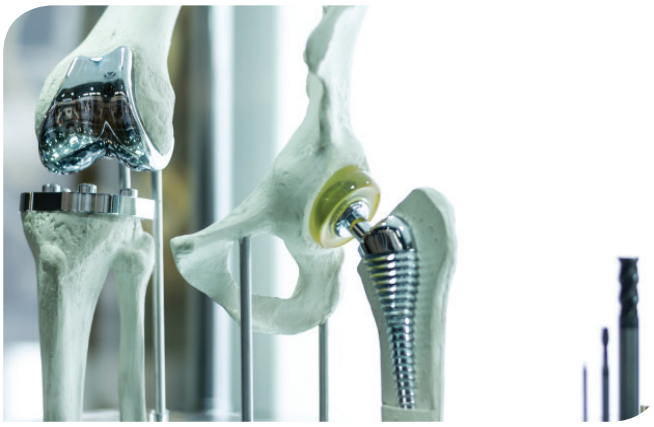
A drug product container-closure system should not release chemicals that can accumulate in the drug product in quantities sufficient to present a risk of toxicity, or affect its stability or efficacy. Extractables and leachables testing is also an important component in establishing the biocompatibility of a medical device as required by ISO 10993.

Substances may migrate from different materials and patients may be exposed through different routes of administration. During the drug development process and medical devices study design it is important to evaluate the potential for various chemicals to migrate. Risk assessment of product configuration or manufacturing chain should be performed as well as a proper toxicological evaluation.

Regulatory agencies require extractables and leachables testing to identify any risks of product adulteration. FDA and international regulators are also placing an increasing emphasis on characterizing the chemical components of devices, including colorants and polymers. Failure to demonstrate material safety could result in failure to receive regulatory approval for a product from authorities such as FDA and EMA. Consequently, extractables and leachables studies are now a crucial component of product release.

This conference will provide a wide and comprehensive overview of critical aspects, technical considerations and strategies for establishing an extractables study design that provides meaningful data, including the advantages and disadvantages of various analytical techniques for the pharmaceutical and medical device industry. The normative approach according to USP, ISO 10993-1 and ISO/DIS 10993-18) will be discussed in detail.

By attending, participants will gain valuable insight from our first class expert's comprehensive expertise on how to conduct risk assessment and toxicological evaluation recommending testing options that are up to current industry and regulatory standards and expectations.



Who should attend?

This course offers a rewarding experience and is particularly relevant to the following key figures: R&D Manager, CQ Manager, QA Manager, Regulatory Manager, Production Manager, Packaging Manager, CMC manager and Validation Manager.

Programme

(9:30 - 10:00) Introduction and general overview:
- Extractables and leachables definition
- The difference between extractables and leachables
- Guidelines regulatory requirements (USP<1663> <1664>; ISO 10993-1; ISO/DIS 10993-18)

Simone Carrara; Chiara Picotti

(10:00 - 11:15) Extractables studies:
- When and how to set up an extractable study
- Critical evaluation of the packaging system, process components and drug properties (Risk Based Approach)
- Setting up an extractables study (Design of Experiment):
  - Selection of extraction conditions
  - Selection of extractive solvents
  - Selection of extractive techniques (HS/GC/MS-GC/MS HPLC/MS/UV-ICP/OES-ICP/MS-Ion Chromatography)
  - Definition of screening methods and minimum sensitivity request
- Specific case study

Simone Carrara

(11:15 - 11:30) Coffee break

(11:30 - 12:30) Peculiar feature of extractables and leachables for medical devices

Chiara Picotti

(12:30 - 13:00) BPOG

Simone Carrara

(13:00 - 14:00) Lunch break

(14:00 - 15:45) Toxicological evaluation: Integrated approach:
- Maximum Daily Intake (MDI)
- Threshold of Toxicological Concern (TTC)
- Different approaches to the interpretation of data of known and unknown compounds
- Tolerable Intake (TI)/Tolerable Exposure (TE)
- NOAEL-LOAEL: Definition and selection criteria
- Uncertainty factors
- In silico predictions
- Cramer scheme, ToxTree Benigni/Bossa
- Specific case study

Chiara Picotti

(15:45 - 16:00) Coffee break

(16:00 - 16:30) Leachables studies:
- When and how to set up a leachablee study
- The approach on known and unknown extractables
- Targeted & non-targeted leachable screening
- Method development and validation
- Leachables studies stability plan
- Specific case study

Simone Carrara

(16:30 - 17:15) Final case study step by step (prefilled syringe and administration set):
- Extractables studies
- Toxicological approach
- Leachables studies

Simone Carrara; Chiara Picotti

(17:15 - 17:30) Final questions and answers

Speaker Profile

Simone Carrara

Simone holds a Biotechnology degree from the University of Milan and has a vast experience as bio-analytical researcher through LC/MS method development for Pharmacokinetics analysis and ADMET profiling. In his previous role as Project Leader he has successfully managed different projects in a wide range of areas including analytical method development and validation with LC/MS-GC/MS, and drug product impurities characterization. For the last 5 years he has been focusing on extractables & leachables studies to support drug-manufacturing companies to fulfill regulatory requirements. He is currently extractables & leachables and impurity characterization laboratory Manager in Eurofins BioPharma Product Testing Italy.

Chiara Picotti

With a degree in Biomedical Engineering she gained strong experience in the biological evaluation of medical devices field as senior consultant and Toxicological and Biological Evaluation Group Leader in Eurofins Medical Device Testing Italy. She manages a dedicated team for the calculation of the Permitted Daily Exposure in shared Facility and toxicological evaluations of extractables & leachables studies on medical devices, pharmaceutical packaging and process components.

Conference language

The official conference language will be english.

Registration:

Online registration: **https://goo.gl/forms/Dt6BK1uMpmlJp7Po2**

Registration fee:

Early bird registration fee (Valid until February 28th): 790 NIS
Full registration fee: 990 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:

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Please send a reference of the transfer by email at office@edu-med.info. 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:

March 14th 2019, 09.30h - 17.30h
(Registration 09.00h-09.30h).

Leonardo City Tower Hotel
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Organisation and Contact:

Edu-Med
9 Hagilad St. Ramat Gan
P.O Box 11530, Israel
e-mail: office@edu-med.info
website: www.edu-med.info

Eurofins BPT & MDT Italy
Via Bruno Buozzi, 2
20090 Vimodrone, Italy
e-mail: FormazioneFarma@eurofins.com
website: www.eurofins.com/Medical-Device
website: www.eurofins.com/BPT

We very much look to welcoming you to the Extractables and Leachables Conference on March 14th in Tel Aviv.