eurofins | BioPharma Product Testing

BEST PRACTICES FOR CONDUCTING EXTRACTABLES AND LEACHABLES STUDIES

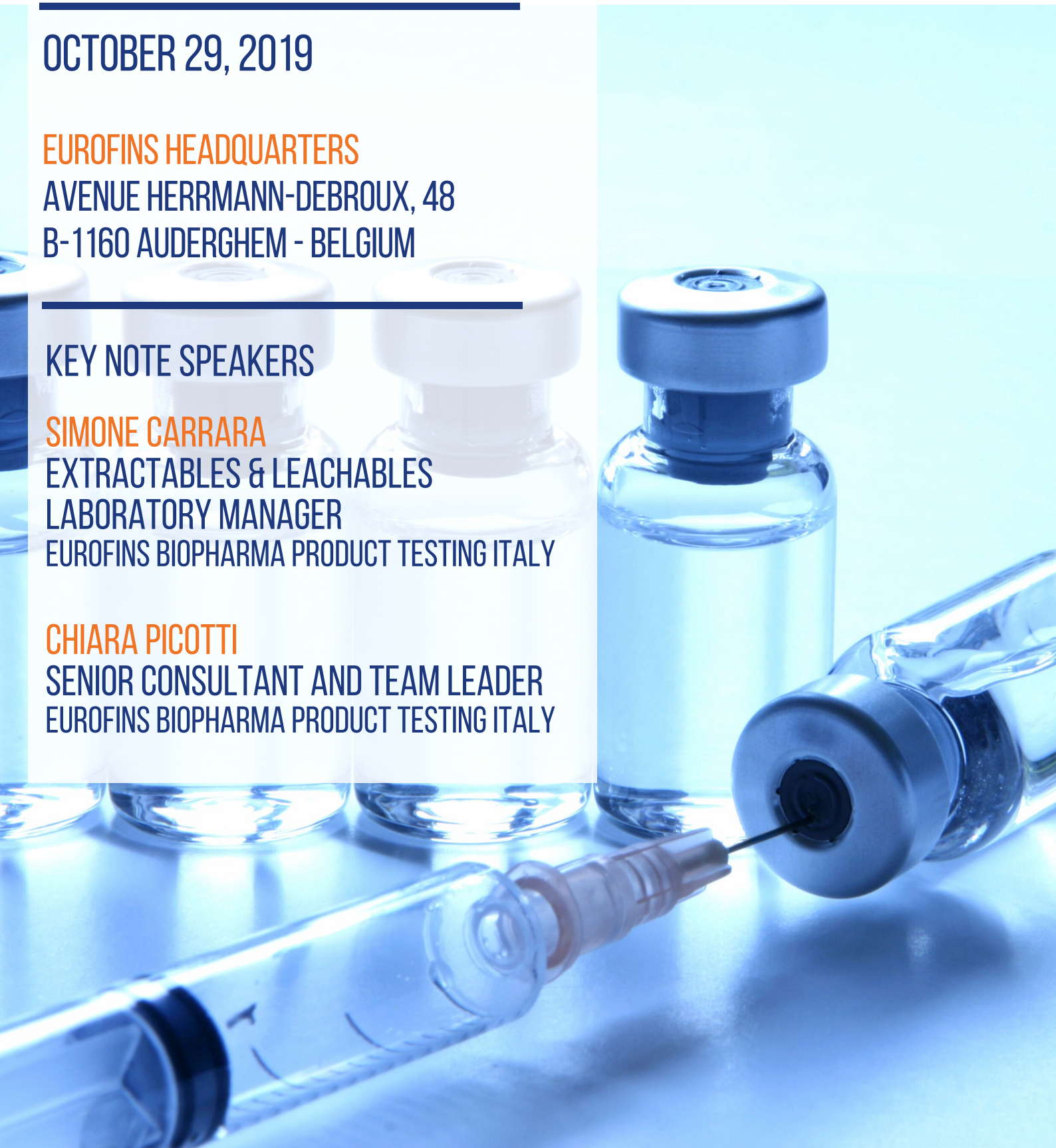
OCTOBER 29, 2019

EUROFINS HEADQUARTERS
AVENUE HERRMANN-DEBROUX, 48
B-1160 AUDERGHEM - BELGIUM

KEY NOTE SPEAKERS

SIMONE CARRARA
EXTRACTABLES & LEACHABLES LABORATORY MANAGER
EUROFINS BIOPHARMA PRODUCT TESTING ITALY

CHIARA PICOTTI
SENIOR CONSULTANT AND TEAM LEADER
EUROFINS BIOPHARMA PRODUCT TESTING ITALY



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 the chemical characterization of 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, E&L studies are now a crucial component of product release.

This course will provide a wide and comprehensive overview of the most relevant and critical aspects, technical considerations and strategies for establishing an extractables study design that provides meaningful data, including advantages and disadvantages of various analytical techniques for the pharma 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 keynote expert's comprehensive expertise on how to correctly approach risk assessment and toxicological evaluation by also recommending testing options that are up to current industry 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.

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AGENDA (9.30AM - 5.30PM)

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

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 sensivity request
- Specific case study

Peculiar feature of extractables and leachables for medical devices

BPOG approach

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

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

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

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 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 has gained strong experience in the biological evaluation of medical devices and toxicological evaluations of extractables & leachables studies on medical devices, pharmaceutical packaging and process components. In her previous role she managed a dedicated team for the calculation of the Permitted Daily Exposure in shared Facility. She is currently Senior Consultant and Team Leader in Eurofins BioPharma Product Testing Italy.

SUBMISSION FEE

- First delegate: 125€
- Second delegate: 100€

Including: Course documentation, lunch and refreshment.
The registration fee is payable in advance.

Send this reservation form by e-mail at:
LoreSchoutteten@eurofins.com

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

RESERVATION FORM (PLEASE COMPLETE IN FULL):

TITLE, NAME, SURNAME:

COMPANY:

DEPARTMENT:

COMPANY ADDRESS:

BILLING ADDRESS (IF DIFFERENT):

VAT ID:

PHONE NUMBER:

E-MAIL:

DATE:

SIGNATURE:

DATE AND VENUE

October 29, 2019
9.30am - 5.30pm
Registration 9.00am - 9.30am

Venue:
Eurofins Headquarters
Avenue Herrmann-Debroux, 48
B-1160 Auderghem
Belgium

PAYMENT METHOD AND TERMS

Payment method: Wire transfer
Company name: Eurofins Biolab srl
Bank details: UNICREDIT SPA
IBAN: IT04 N020 0820 6000 0000 4846 325
VAT ID: 00762140960

ORGANIZATION

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website: www.eurofins.it/Pharma

GENERAL TERMS AND CONDITIONS:

If you cannot attend the course 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 event 50% of the registration fee will be charged;
- less than 1 week prior to the event full registration fee will be charged.

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.