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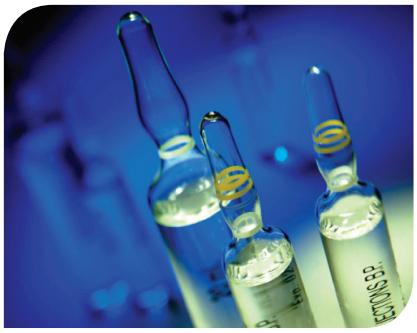


Best Practices for Conducting Extractable and Leachable Studies

March 20th, 2018
Parc Cientific de Barcelona
Ed. Cluster – Sala Felix Sarratosa
C/Baldiri Reixac, 4-12-15
08028 Barcelona

Speakers:

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

Chiara Picotti
Toxicological and Biological Evaluation Group Leader
Eurofins BioPharma Product Testing Italy

Introduction

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.

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

Substances may migrate from different materials (polymers, metals, glass etc.) and patients may be exposed through different routes of administration. Every type of container or closure has its own approach and testing strategy. During the drug development process, it is important to evaluate the potential for various chemicals to migrate from container closure or manufacturing systems into pharmaceuticals and biologics. 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. Failure to demonstrate material safety could result in failure to receive regulatory approval for a product from authorities such as FDA and EMA.

This course 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.

By attending, participants will gain valuable insight from our expert's comprehensive expertise on how to conduct risk assessment and toxicological evaluation 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 and Validation Manager.

Programme

Introduction and general overview:
- Extractables & leachables definition
- The difference between extractables & leachables
- Guidelines regulatory requirements

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

Close the gap between extractables & leachables

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
- Extractables studies
- Toxicological approach
- Leachables studies

Course language

The official course language will be English.

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. She is currently Toxicological and Biological Evaluation Group Leader in Eurofins BioPharma Product 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.

Company Profile

Whether you are evaluating container closure systems, delivery devices, single-use systems or manufacturing equipment, Eurofins BioPharma Product Testing offers a broad range of services to support extractables and leachables testing. With more than 50 scientists and 12 years of experience testing bottles, caps, stoppers, tubing, filters, syringes, bioprocess bags and packaging, and hundreds of controlled extraction studies completed along with associated leachables work, we have established a variety of extraction and testing options to meet your extractables and leachables needs.

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Reservation Form (please complete in full):

Title, first name, surname _____

Company _____

Department _____

Adress _____

Phone _____ *Fax* _____

e-mail _____

Important: Please indicate your company's VAT ID Number

_____

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

_____

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Registration fee:

Early bird for submission within January 26th, 2018:
400€ + VAT (if applicable)
Discount rate for second participant: 350€ + VAT

Registration fee after January 26th, 2018:
500€ + VAT (if applicable)
Discount rate for second participant: 350€ + VAT

Including: Course documentation, lunch and refreshment.
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 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 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 attend the course.

Date:

March 20th 2018, 09.30h - 17.30h
(Registration 09.00h - 09.30h).

Venue:

Parc Cientific de Barcelona
Ed. Cluster – Sala Felix Sarratosa
C/Baldiri Reixac, 4-12-15
08028 Barcelona
www.pcb.ub.edu

Registration:

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

Payment method:

Wire Transfer:
Eurofins BioPharma Product Testing Spain S.L.U.
BANCO SABADELL
IBAN: ES29 0081 5098 66 0001111318

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

Organisation and Contact:

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We very much look to welcoming you on March 20th in Barcelona!