eurofins | BioPharma Product Testing

WORKSHOP

EXTRACTABLES AND LEACHABLES AND CONTAINER CLOSURE INTEGRITY TESTING

A JOURNEY THROUGH THE PHARMACEUTICAL PACKAGING TESTING

20 May 2026

DOUBLETREE BY HILTON MANCHESTER – PICCADILLY
ONE PICCADILLY PLACE, 1 AUBURN STREET,
MANCHESTER, M1 3DG

ORGANISATON AND CONTACTS

EUROFINS BIOPHARMA PRODUCT TESTING UK

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INTRODUCTION

PACKAGING TESTING: WHY IS IT IMPORTANT?

Over the last few years, the requirements on the assessment of substances that could leach into the drug product over its life cycle have increased significantly. Substances may migrate from different materials and patients may be exposed through different routes of administration. On the other hand, 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.

Join this workshop to embark on a journey through the pharmaceutical packaging testing. By attending you will be able to implement a successful strategy to ensure the safety of your products.

LEARNING OBJECTIVES

DURING THIS WORKSHOP YOU WILL LEARN:

- Regulatory requirements and expectations on E&L
- How to prepare a successful E&L study
- Practical approaches for E&L testing
- Evaluation of E&L data
- Toxicological assessment
- E&L testing for single-use systems
- Container Closure Integrity Testing (CCIT)

WHO SHOULD ATTEND

THIS WORKSHOP IS RELEVANT FOR:

- Pharmaceutical packaging and device engineers
- Analytical chemists that perform E&L testing
- Toxicologists
- R&D Manager
- QC Manager, QA Manager
- Regulatory Manager
- Production Manager
- Packaging Manager
- CMC Manager and Validation Manager

AGENDA

REGISTRATION: 9.00 – 9.30
COFFEE BREAK: 11.00 – 11.30
LUNCH: 12.30 – 14.00
CLOSING AND NETWORK: 17.00

OPENING SESSION

WELCOME AND INTRODUCTION

REGULATORY OVERVIEW

REGULATORY REQUIREMENTS: UNDERSTANDING AUTHORITY PERSPECTIVE AND EXPECTATIONS ON EXTRACTABLES & LEACHABLES:

- Testing strategy on primary packaging, process materials, combination products, medical devices
- General overview on USP chapters <1663>, <1664>, <665>
- Experiences in regulatory submissions: deficiencies, remarks, warning letters
- Risk based approach: creation of a risk assessment and management of risk assessment outcome

DESIGN OF EXPERIMENT

EXTRACTABLES STUDIES:

- Selection of materials and components to be tested
- Selection of extraction conditions
- Selection of extraction solvents
- Analytical methods
- The adequate reporting threshold to be applied (based on total daily intake, safety concern thresholds, uncertainty factors)
- Unidentified compounds management

DESIGN OF EXPERIMENT

TOXICOLOGICAL ASSESSMENT:

- Calculation of the total daily intake of the compounds of potential concern:
  - Derivation of toxicological threshold, TTC, permitted daily exposure
  - Derivation of margin of safety and impact to patient
- Case study

AGENDA

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CLOSING AND NETWORK: 17.00

DESIGN OF EXPERIMENT

LEACHABLES STUDIES:

- The targeted leachables screening
- The non-targeted leachables screening
- The limit test vs full method validation for the products of concern
- The fingerprint approach for the management of small changes in the packaging configuration
- The design of the experiment of a leachables study (strategy and time points definitions)
- How to manage the leachables raising between the stability check points

CONTAINER CLOSURE INTEGRITY TESTING

CONTAINER CLOSURE INTEGRITY TESTING (CCIT):

- The life cycle risk assessment for the container closure systems
- The probabilistic and deterministic methods of analysis
- The peculiarities and features of the most used CCIT methods (dye ingress, microbial ingress testing, pressure decay, vacuum decay, high voltage leak detection, laser-based gas head space analyser)
- The choice of the most proper analytical testing based on the product-container coupling
- Method setup and validation
- Case studies

CASE STUDIES

HANDS-ON TRAINING

Attendes will be given space to actively discuss and problem-solve together. Examples of a primary packaging, a single use-system and a combination product will be showcased and their testing strategy will be discussed with the attendees.

Q&A SESSION

SPEAKERS

FRANCESCO TESSARI

Francesco graduated in pharmaceutical chemistry and technologies with a focus on analytical chemistry and method development. he started working in Johnson & Johnson as QC technician. He then moved to Cambridge (UK) working for 4 years in a C.R.O. as an analytical specialist and study director specialised in analytical method development and validation. In 2021 he started working as a Project Leader for the E&L department in Eurofins BioPharma Product Testing Italy providing his expertise on chemical screenings and analytical techniques. He is currently supporting the E&L department as a Technical Manager in order to provide Eurofins approach on E&L studies and upcoming regulatory challenges.

DANIELE ZARINI

Daniele earned a bachelor's and master's degree in industrial biotechnology (bioinformatics field) in 2014 and 2016, respectively, and he started working as a toxicologist in the electronic cigarette industry from 2017 to 2021. Daniele joined Eurofins BioPharma Product Testing Italy in 2021 as a toxicologist in the E&L sector of the pharmaceutical industry, holding also the role of project manager (E&L, biological, chemicals). Daniele is currently Technical Manager and Senior Consultant for the pharma consulting group.

ELEONORA LOSTAGLIO

With a degree in Toxicology and Safety Assessment from Milan, she joined Eurofins BioPharma Product Testing Italy in 2020 after gaining experience in in silico toxicology research and in the pharmaceutical industry as Quality Assurance. Initially working as a toxicologist at Eurofins, Eleonora currently holds the position of Project Manager at Eurofins Regulatory & Consultancy Services Italy, with a particular focus on the pharmaceutical area. In this role, she manages complex projects, coordinates multidisciplinary teams, and supports companies in complying with regulations and safety standards.

WORKSHOP LANGUAGE: ENGLISH

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REGISTRATION FEE: 195£

TO REGISTER PLEASE CONTACT: SOPHIE.KILLICK@BPT.EUROFINSEU.COM

THE REGISTRATION FEE IS PAYABLE IN ADVANCE BY BANK TRANSFER.
FEE INCLUDES: DOCUMENTATION, COFFEE BREAK AND LUNCH.
YOU'LL RECEIVE CONFIRMATION, PAYMENT AND INVOICING DETAILS VIA E-MAIL AFTER SUBMISSION.

VENUE

DOUBLETREE BY HILTON MANCHESTER – PICCADILLY
ONE PICCADILLY PLACE, 1 AUBURN STREET, MANCHESTER, M1 3DG
HTTPS://WWW.HILTON.COM/EN/HOTELS/MANPDDI-DOUBLETREE-MANCHESTER-PICCADILLY/

- 0.2 MILES FROM MANCHESTER PICCADILLY STATION
- 10 MINUTE DRIVE FROM THE AIRPORT
- ONSITE PARKING AVAILABLE

GENERAL TERMS AND CONDITIONS:

IF YOU CANNOT ATTEND THE WORKSHOP 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:
- BEFORE 1 WEEK PRIOR TO THE WORKSHOP 50% OF THE REGISTRATION FEE WILL BE CHARGED;
- LESS THAN 1 WEEK PRIOR TO THE WORKSHOP FULL REGISTRATION FEE WILL BE CHARGED.

EUROFINS BIOPHARMA PRODUCT TESTING RESERVES THE RIGHT TO CANCEL OR 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. EUROFINS BIOPHARMA PRODUCT TESTING IS NOT RESPONSIBLE FOR AIRFARE, HOTEL OR OTHER COSTS INCURRED BY REGISTERED DELEGATES.

TERMS OF PAYMENT:

THE REGISTRATION FEE IS PAYABLE IN ADVANCE BY BANK TRANSFER. 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 WORKSHOP.

ONE STOP-SHOP SOLUTION FOR YOUR PACKAGING TESTING NEEDS

- EXTRACTABLES & LEACHABLES
- CONTAINER CLOSURE INTEGRITY TEST
- QC TESTING ON GLASS, PLASTIC AND RUBBER
- STATE-OF-THE-ART INSTRUMENTATION
- GMP/GLP/ISO 17025 METHODS AND PROTOCOLS
- PROPRIETARY LC-MS DATABASE
- UNKNOWN COMPOUNDS IDENTIFICATION CAPABILITY
- DETERMINISTIC AND PROBABILISTIC METHODS AVAILABLE
- IN-HOUSE TOXICOLOGY EXPERT TEAM
- CONSULTING SUPPORT TO DEFINE THE OPTIMAL TESTING STRATEGY THROUGH A RISK-BASED APPROACH
- TRAINING

WWW.EUROFINS.IT/EXTRACTABLES-LEACHABLES