EXTRACTABLES AND LEACHABLES AND CONTAINER CLOSURE INTEGRITY TESTING

A JOURNEY THROUGH PHARMACEUTICAL PACKAGING TESTING

26 March 2026
Thu

SHERATON HSINCHU HOTEL
NO. 265, SECTION 1, DONGXING ROAD, ZHUBEI CITY, HSINCHU COUNTY, TAIWAN

ORGANISATON AND CONTACTS

EUROFINS ANALYTICAL SCIENCE LABORATORIES, KYOTO

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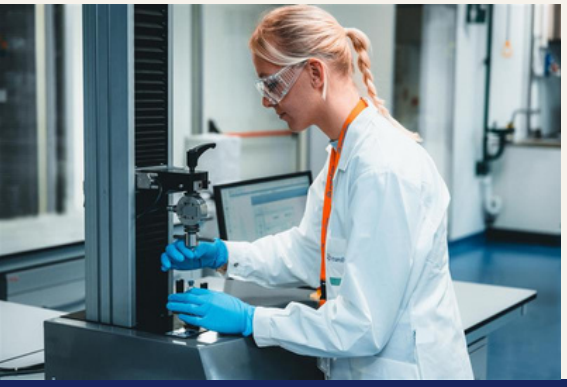
VISIT OUR EXTRACTABLES & LEACHABLES WEBPAGE HERE



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

8:45 - 9:15

REGISTRATION

9:15 – 9:30

WELCOME AND INTRODUCTION

9:30 – 10:15
EXTRACTABLES & LEACHABLES AND CONTAINER CLOSURE INTEGRITY TESTING
SPEAKER: SIMONE CARRARA

- Overview of the most common CCIT technologies and their selection based on packaging and product
- Qualification of packaging systems through material assessment and packaging–product compatibility
- Key updates from USP <382> and their impact on system-level functional testing

10:15 – 11:00
A RISK-BASED APPROACH FOR E&L DETERMINATION
SPEAKER: DANIELE ZARINI

- Application of a risk-based strategy to structure and prioritize the E&L program
- Identification of critical components requiring focused analytical attention
- Alignment with major regulatory guidelines (ICH Q3E, USP <1663>/<1664>/<1665>/<665>)

11:00 - 11:20

COFFEE BREAK

11:20 - 12:20
EXTRACTABLES REGULATORY REQUIREMENTS AND DESIGN OF EXPERIMENT
SPEAKER: FRANCESCO TESSARI

- Design of Extractables studies using worst-case, high-coverage conditions
- Use of orthogonal solvents and stress factors to maximise extraction
- Tailored workflows for packaging, combination products, and single-use systems

12:20 - 13:30

LUNCH BREAK

AGENDA

13:30 – 14:00
TOXICOLOGICAL RISK ASSESSMENT IN E&L WORKFLOW
SPEAKER: ELEONORA LOSTAGLIO

- Role of toxicology in interpreting E&L data and supporting risk-based decisions
- Establishment of PDE, TTC, and AET values
- Identification of critical impurities and strategies to mitigate patient risk

14:00 – 14:30
LEACHABLES REGULATORY REQUIREMENTS AND DESIGN OF EXPERIMENT
SPEAKER: FRANCESCO TESSARI

- Design of Leachables studies using real-time and accelerated conditions
- Lifecycle monitoring to ensure safety and stability over shelf-life
- Method development and validation targeting relevant leachables

14:30 - 15:10

EXCERCISES SECTION

15:10 - 15:30

COFFEE BREAK

15:30 - 16:10
STRATEGIES TO OPTIMISE NUMBER OF TESTING AND THE TIMELINE
SPEAKER: ELEONORA LOSTAGLIO
DANIELE ZARINI

- Practical approaches to reduce testing volume and streamline timelines
- Use of equivalency matrices and expert review to eliminate redundant studies
- Accelerated roadmaps supported by effective planning and project management

16:10 - 16:30

CLOSING & NETWORKING

SPEAKERS

SIMONE CARRARA

Simone joined Eurofins BioPharma Product Testing Italy in 2012. He is the Business Unit Manager of the Extractables & Leachables and Packaging Testing Department. He is also E&L Senior Scientific Director in Eurofins. Starting from a biotechnology degree at the University of Milan in 2005, he built his experience as a bio-analytical researcher through LC/MS method developing for pharmacokinetics analysis and ADME profiling. He has led projects in a wide range of areas of the analytical chemistry including method developing/validation by LC/MS-GC/MS and drug product impurities characterisation. In the last 10 years, his job was focused on extractables & leachables testing to support drug-manufacturing companies in the fulfillment of the regulatory requirements.

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.

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 Technical Manager supporting the E&L department in order to provide Eurofins approach on E&L studies and upcoming regulatory challenges.

DANIELE ZARINI, ERT

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.

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WORKSHOP LANGUAGE: ENGLISH

ORGANISATION CONTACTS:

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GENERAL TERMS AND CONDITIONS:

IF YOU CANNOT ATTEND THE WORKSHOP WE ARE HAPPY TO WELCOME A SUBSTITUTE COLLEAGUE AT ANY TIME.

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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

VISIT OUR EXTRACTABLES & LEACHABLES WEBPAGE HERE