eurofins | BioPharma Product Testing

WORKSHOP

EXTRACTABLES AND LEACHABLES AND CONTAINER CLOSURE INTEGRITY TESTING

A JOURNEY THROUGH THE PHARMACEUTICAL PACKAGING TESTING

9 June 2026

GREFIS HOTEL - LOHENSTRASSE 5, 82166 GRÄFELFING (MUNICH), GERMANY

ORGANISATON AND CONTACTS

EUROFINS BIOPHARMA PRODUCT TESTING GERMANY

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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: 8:30-9:15
COFFEE BREAK: 11:00-11:20
LUNCH: 12:30-13:30
COFFEE BREAK: 15:10-15:30
CLOSING AND NETWORK: 16:10-16:40

8:30-9:15

REGISTRATION

9:15-9:30

WELCOME AND INTRODUCTION

9:30-10:15
SPEAKER:
FRANCESCO TESSARI

EXTRACTABLES & LEACHABLES AND CONTAINER CLOSURE INTEGRITY TESTING

- 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
SPEAKER:
DANIELE ZARINI

A RISK-BASED APPROACH FOR E&L DETERMINATION

- Application of a risk-based strategy to structure and prioritise 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
SPEAKER:
FRANCESCA CALÒI

EXTRACTABLES REGULATORY REQUIREMENTS AND DESIGN OF EXPERIMENT

- 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

12:30-13:30

LUNCH BREAK

AGENDA

REGISTRATION: 8:30-9:15
COFFEE BREAK: 11:00-11:20
LUNCH: 12:30-13:30
COFFEE BREAK: 15:10-15:30
CLOSING AND NETWORK: 16:10-16:40

13:30-14:00
SPEAKER:
DANIELE ZARINI

TOXICOLOGICAL RISK ASSESSMENT IN E&L WORKFLOW

- 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
SPEAKER:
FRANCESCO TESSARI

LEACHABLES REGULATORY REQUIREMENTS AND DESIGN OF EXPERIMENT

- 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

15.10-15.30

COFFEE BREAK

15:30-16:10
SPEAKER:
DANIELE ZARINI

STRATEGIES TO OPTIMISE NUMBER OF TESTING AND THE TIMELINE

- 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

16:10-16:40

CLOSING & NETWORKING

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 Business 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 Business Manager and Senior Consultant for the pharma consulting group.

FRANCESCA CALÒ

Francesca Calò holds the position of Project Leader E&L at Eurofins BioPharma Product Testing Italy. Francesca leads several projects and is responsible for designing technical solutions to improve workflow in various scenarios, ensuring high-quality standards. She is also responsible for presenting data to stakeholders. She earned an innovative PhD with industrial characterization in Chemistry from the Department of Biological and Environmental Sciences and Technologies at the University of Salento (IT) and a Master's degree in Medical Biotechnology and Nanobiotechnology in collaboration with Cranfield University (UK), where she conducted experimental thesis research in analytical chemistry.