

WORKSHOP



EXTRACTABLES AND LEACHABLES AND CONTAINER CLOSURE INTEGRITY TESTING

A JOURNEY THROUGH THE PHARMACEUTICAL PACKAGING TESTING



30

June
2026

HOTEL CATALONIA,
C/BERGARA 11, 08002 BARCELONA

ORGANISATION
AND CONTACTS

EUROFINS BIOPHARMA PRODUCT
TESTING SPAIN

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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: 9.30-10.00

COFFEE BREAK: 12.00-12.30

LUNCH: 14.00-15.00

CLOSING AND NETWORK: 17.00

SPEAKER:
FRANCESCO TESSARI

SPEAKER:
DANIELE ZARINI
ELISA COLOMBO

SPEAKER:
FRANCESCO TESSARI

REGISTRATION

WELCOME AND INTRODUCTION

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

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>)

COFFEE BREAK

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

LUNCH BREAK

AGENDA

REGISTRATION: 9.30-10.00

COFFEE BREAK: 12.00-12.30

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CLOSING AND NETWORK: 17.00

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

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

EXERCISES

COFFEE BREAK

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

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.



ELISA COLOMBO

Elisa Colombo graduated in Pharmaceutical Chemistry and Technology (CTF) in 2021 and joined Eurofins in the same year as an Analyst, gaining hands-on experience in laboratory activities and analytical methodologies. Since 2022, she has been part of the consultancy team within Eurofins Regulatory & Consultancy Services, where she specializes in Extractables & Leachables (E&L), supporting clients with study design, risk assessment, and regulatory compliance.

WORKSHOP LANGUAGE: ENGLISH



BioPharma
Product Testing

REGISTRATION FEE

EARLY BIRD PRICE (VALID UNTIL MAY 29, 2026): 300 EUR VAT EXCLUDED

FULL PRICE (VALID AFTER MAY 29 2026): 370 EUR VAT EXCLUDED

REGISTRATION LINK: [HTTPS://FORM.JOTFORM.COM/261190707492459](https://form.jotform.com/261190707492459)

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

HOTEL CATALONIA, C/BERGARA 11, 08002 BARCELONA

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