eurofins | BioPharma Product Testing

EUROFINS EXTRACTABLES AND LEACHABLES SUMMIT

1ST EDITION

6-7 MAY 2026

ENTERPRISE HOTEL MILAN, ITALY

Empowering E&L Excellence to Safeguard Patient Health

FROM INSIGHT TO ACTION: YOUR MOST INTERACTIVE E&L EXPERIENCE

Day 1 (full day) delivers an exceptional, insight-rich program designed to illuminate the evolving E&L landscape and equip attendees with the knowledge shaping tomorrow's standards.

WHERE CONVERSATIONS BECOME ACTIONABLE SOLUTIONS

Day 2 (half-day) is where the Eurofins E&L Summit becomes unique — the only event that gives you access to expert-moderated, small-group work tables dedicated to the three most challenging pillars of the E&L world: Regulatory, Technical, and Toxicological.

This immersive approach turns insights into action, with guided discussions that help you translate complex E&L issues into clear, practical strategies.

Led by Eurofins experts and enriched by peer exchange, Day 2 delivers a level of hands-on, real-world problem-solving you won't find at any other E&L event - so you walk away with immediately applicable strategies.

REGISTRATION LINK: HTTPS://EU.JOTFORM.COM/FORM/260390924651458

AGENDA - DAY 1

09.00 - 09.30
Registration and welcome coffee

09.30 - 09.45
Introduction and opening remarks
Setting the Scene: Why Extractables & Leachables Matter Today
Simone Carrara, Chairman - Eurofins BioPharma Product Testing Italy

SESSION 1: REGULATORY LANDSCAPE & GLOBAL HARMONISATION

09.45 - 10.30
Advancing Global E&L Harmonisation: USP's Strategic Contributions to Standards, Chapters, and Emerging Challenges

- Driving consistency in E&L science: USP's System Suitability Standards initiative
- Introduction of new dosage form–specific USP chapters (<1664.2–<1664.5>)
- Current status and future direction of <665>
- Revisions to USP <1663> and <1664>
- Oligomer evaluation as an emerging critical topic in study design

Dr. Ravi Kiran Kaja, Ph.D., FRSC - USP

10.30 - 11.15
ICH Q3E Implementation: Current Status and Industry Readiness
Speaker to be confirmed

11.15 - 11.45 Coffee Break

SESSION 2 – TECHNICAL ADVANCEMENTS, PART 1

11.45 - 12.30
Extractables & Leachables in Pharmaceutical Development. Practical Challenges, Risk-Based Strategies and Lessons Learned

- Risk-Driven Prioritization of Primary Packaging Components
- Designing E&L Studies Aligned With Risk Assessment Outcomes
- Managing Supplier and Material Variability Through Risk Evaluation

Marco Ceccolini, Angelini Pharma

AGENDA - DAY 1

12.30 - 13.15

Artificial Intelligence in Extractables & Leachables.
From Data Complexity to Smarter Risk Assessment

- Managing complex E&L datasets with advanced analytics

Alberto Bresciani, Tycho Science & Tech

13.15 - 14.15 Networking Lunch

SESSION 3 – TECHNICAL ADVANCEMENTS, PART II

14.15 - 15.00

Implementing USP <665> Requirements for Process Equipment and SUS/MUS

- Definition of a pragmatic approach for Low Risk items
- Use adequate aggravating and mitigation factors as part of the LRA
- Deep dive on current regulatory expectation during submissions
- Presentation of different type of cumulative effect to the conference room and vote on the different approaches

Marine Lepoutre, GSK Vaccines

15.00 - 15.45

Method Upgrades for E&L Studies Using Algorithmic Prediction

- Enhancing traditional E&L methodologies and study design through algorithmic tools
- Reducing false positives/negatives through *Relative Response Factor* rescaling
- Integrating predictive approaches with laboratory workflows

Francesco Tessari, Eurofins BioPharma Product Testing

15.45 - 16.15 Coffee Break

AGENDA - DAY 1

SESSION 4 – TOXICOLOGY, RISK ASSESSMENT & EMERGING APPROACHES

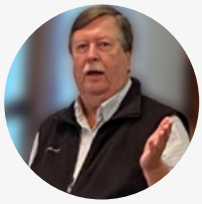
16.15 - 16.45

New regulatory developments in toxicology studies

- Evolution of toxicological expectations in E&L
- Risk-based justification strategies
- Documentation approaches for global submissions
- Regulatory convergence and divergence across regions
- Preparing for authority interactions

Paolo Pescio, ERT

Managing Director Eurofins Regulatory & Consultancy Services



16.45 - 17.15

New Approach Methodologies (NAMs) for the Safety Assessment of E&L Compounds

- Introduction to NAMs in toxicological assessment
- Application of NAMs to E&L compound evaluation
- Integration of alternative approaches with TTC frameworks
- Scientific and regulatory acceptance of emerging methods
- Future direction of safety assessment paradigms

Ron Brown, Toxicologist at Risk Science Consortium, Former FDA

KEY TAKEAWAYS & CLOSING REMARKS

17.15-17.30

- Summary of regulatory, technical and toxicological insights
- Key themes emerging from the discussions
- Preview of Day 2 interactive roundtables

Simone Carrara, Chairperson

E&L Business Unit Manager & Senior Scientific Director, Eurofins BioPharma Product Testing Italy

DAY 2 - EXPERT GUIDED WORK TABLES

A Premium Learning Environment Designed for Interaction Half Day (09.00 - 13.00)

Expert-Moderated, Work Tables

Led by Eurofins specialists with:

- Daily experience on real studies and products
- Hundreds of regulatory interactions
- Visibility across global industry trends

Participants don't just listen - they co-create solutions with those shaping the field.

Interactive • Practical • Expert-Led • Small-Group Experience

Practical, Applied, Real-World Discussions

Not theory. Not generic Q&A. Not mini-sessions.

Each table follows a structured, high-value format:

- Targeted prompts
- Real case scenarios
- Challenge questions
- Guided peer-to-peer exchange

Participants walk away with clear, actionable outcomes.

Small Groups = Big Value

Each work table can host 10–15 participants, ensuring:

- Everyone contributes
- Meaningful dialogue
- Deep expert moderation
- "Micro-communities" around key E&L challenges

This is where true connection, insight, and problem-solving happen.

Real E&L challenges. Real solutions.

DAY 2 - EXPERT GUIDED WORK TABLES

Parallel Learning at Its Best: Three Macro-Themes, Two Rooms, Unlimited Interaction

Technical

Design, Data Interpretation & Analytical Challenges:

- Study design strategies aligned with USP <665> and dosage form considerations
- Interpretation of complex chromatographic and spectral data
- Managing false positives/false negatives
- Oligomer detection and emerging analytical challenges
- Data trending, graphical evaluation and decision-making criteria
- Variability management across materials, suppliers and processes.

Three Deep-Dive Challenging Topics

Regulatory

From Guidelines to Submissions:

- Implementation of USP <665>, <1663>, <1664> in real dossiers
- Pharmaceutical and medical device expectations
- Common regulatory questions and deficiency trends
- Risk-based justification strategies
- Documentation approaches for global submissions
- Authority interaction and inspection readiness

Toxicology

Risk Assessment & Safety Evaluation

- Application of TTC in E&L risk assessment
- Grouping and read-across strategies
- Handling data gaps and uncertainty
- Cumulative exposure considerations
- Integration of New Approach Methodologies (NAMs)
- Aligning toxicological conclusions with regulatory expectations

Think, Debate, and Problem-Solve Together

LEADING AUTHORITIES AND INDUSTRY EXPERTS

MEET THE SPEAKERS

DR. RAVI KIRAN KAJA, PH.D., FRSC
Senior Principal Scientist, Complex Generics
Pharmaceutical Science, General Chapters
U.S. Pharmacopeia (USP)

RON BROWN
Toxicologist at Risk Science
Consortium, former FDA

PAOLO PESCIO, ERT
Managing Director, Eurofins Regulatory
and Consultancy Services Italy

MARINE LEPOUTRE
Global Subject Matter Expert Extractable & Leachable,
GSK Vaccines

MARCO CECCOLINI
Product Analytical Development Scientist,
Angelini Pharma, AFI Member

ALBERTO BRESCIANI
Founder and Principal,
Tycho Science and Tech

FRANCESCO TESSARI
E&L Technical Business Manager,
Eurofins Biopharma Product Testing

MORE SPEAKERS TO BE CONFIRMED SOON!

LEADING AUTHORITIES AND INDUSTRY EXPERTS

Dr. Ravi Kiran Kaja, Ph.D., FRSC
Senior Principal Scientist, Complex Generics - Pharmaceutical Science, General Chapters U.S. Pharmacopeia (USP)
Dr. Ravi Kiran Kaja is a distinguished scientific leader with over 20 years of experience in analytical chemistry and pharmaceutical R&D, specializing in formulation analytical sciences for sterile and complex drug products. With a Ph.D. in Analytical Chemistry, he is recognised for combining deep technical rigor with strategic vision to advance high-quality medicines.
In his role at USP, Dr. Kaja leads scientific strategy for complex generics and drives the development of impactful USP–NF documentary standards, including general chapters on pharmaceutical packaging and complex drug products-strengthening global quality frameworks and supporting patient safety worldwide.
Dr. Kaja's expertise spans sterile formulation analytics, complex formulation characterisation, Extractables & Leachables, manufacturing sciences, MS&T, and technology transfer. Known for his collaborative leadership, he actively promotes the sharing of scientific knowledge to elevate pharmaceutical quality across the industry.

Ron Brown
Toxicologist at Risk Science Consortium, former FDA
Ron Brown is a board-certified toxicologist with 35 years of experience in regulatory toxicology and risk assessment. He recently retired from the US FDA after 25 years of service and currently directs a small company, Risk Science Consortium, LLC, that provides consultation and training in toxicological risk assessment and computational toxicology. At the FDA, Ron was the senior toxicologist responsible for developing and reviewing toxicological risk assessments of extractable and leachable (E&L) compounds from medical devices. While at the FDA, he served in a number of leadership roles in standards development organisations.
At the international level, he served for many years as convener of ISO TC194 WG11 which is responsible for the development and revision of the ISO 10993-17 standard, Biological evaluation of medical devices-Part 17: Establishment of allowable limits for leachable substances. At the national level, he represented the United States as an expert on ISO TC194 WG11 and served as co-chair of the AAMI Biological Evaluation Committee. Prior to his position at the US FDA, Ron served as a Senior Associate at the ILSI Risk Science Institute. He is founding member and former President of the Medical Device and Combination Products Specialty Section of the Society of Toxicology and former President of the Dose-Response Specialty Section of the Society for Risk Analysis.

Marine Lepoutre
Global Subject Matter Expert Extractable & Leachable, GSK Vaccines
Marine currently holds the position of Global Subject Matter Expert in Extractable & Leachable at GSK Vaccines and is responsible for aligning all GSK Vaccines sites with current regulatory requirements.
Before this position, in his role of process expert for Belgium site, she leads process validation as homogeneity, holding time, lifetime and lyophilization. Marine is a Chemical Process Engineer with a master's degree in Chemistry from CPE Lyon in France.

Alberto Bresciani
Founder and Principal, Tycho Science and Tech
Alberto Bresciani is an Owner and CEO at Tycho s.r.l. since 2025. He has years of hands-on experience applying AI in drug discovery within the pharmaceutical and life sciences sector. His expertise includes utilizing AI models in biology, chemistry, and large language models (LLMs). More recently, he served as the Director of Project Biology at Recursion (2024 to date) and Exscientia (2022 to 2024). From 2010 to 2022, he held a significant operational role at IRBM S.p.A. as the Director - High Throughput Biology and Screening, where he was responsible for managing a team of over 50 people in discovery sciences. He has published over 50 scientific articles in peer-reviewed international journals.

LEADING AUTHORITIES AND INDUSTRY EXPERTS

Marco Ceccolini
Product Analytical Development Scientist, Angelini Pharma, AFI Member
Marco Ceccolini is an experienced Analytical Scientist specializing in product development from early-stage new chemical entities to the lifecycle of marketed projects. Currently Senior Scientist at Angelini Pharma since 2020, he leads analytical method development, impurity control strategies, statistical analysis, and coordinates team activities with external partners for early-stage projects. He holds a Bachelor and Master's degree in Pharmaceutical Chemistry and Technology from the Università di Bologna. Marco has contributed to numerous scientific publications and presented at international conferences on topics such as Analytical Quality by Design, E&L, and forced degradation studies, serving as a university lecturer for pharmaceutical stability and impurity management.

Paolo Pescio, ERT
Managing Director, Eurofins Regulatory and Consultancy Services Italy
Paolo Pescio is a Strategic Regulatory Leader and Compliance Expert with extensive experience in medical devices and pharmaceuticals, currently serving as Managing Director within Eurofins Regulatory & Consultancy Services Europe. With a strong background in regulatory strategy, quality systems and compliance, Paolo has supported numerous companies in navigating complex regulatory frameworks across EU and international markets, including medical devices, combination products and pharmaceutical products. His expertise spans regulatory pathways, risk-based approaches, authority interactions and compliance strategy, with a particular focus on translating regulatory requirements into practical, implementable solutions.
Paolo holds an MBA and is an ERT-certified expert, combining strategic vision with hands-on regulatory experience. He is frequently involved in high-level advisory projects and acts as a trusted partner for companies facing evolving regulatory expectations.

Francesco Tessari
E&L Technical Business Manager, Eurofins BioPharma Product Testing Italy
Francesco Tessari holds a degree in Pharmaceutical Chemistry and Technology with a specialization in Analytical Chemistry and method development. After contributing to the publication “Microextraction by packed sorbent and HPLC-PDA quantification of multiple anti-inflammatory drugs and fluoroquinolones in human plasma and urine,” he began his career at Johnson & Johnson as a QC Technician.
He then moved to Cambridge (UK), where he spent four years working in a CRO as an Analytical Specialist and Study Director, focusing on the development and validation of analytical methods for complex pharmaceutical programs. In 2021, Francesco joined Eurofins Biolab in Milan as a Project Leader in the Extractables & Leachables department, contributing expertise in chemical screening strategies and advanced analytical techniques.
Today, he works as Technical Business Manager for the E&L division, acting as a technical advisor and strategic link between scientific teams and commercial functions. His role focuses on supporting clients and internal stakeholders by aligning Eurofins’ analytical approaches with evolving regulatory expectations and emerging challenges in Extractables & Leachables studies.

Simone Carrara - Chairperson
E&L Business Unit Manager & Senior Scientific Director, Eurofins BioPharma Product Testing Italy

MORE SPEAKERS TO BE CONFIRMED SOON!

EVENT DETAILS AND GENERAL CONDITIONS

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REGISTRATION LINK: HTTPS://EU.JOTFORM.COM/FORM/260390924651458

REGISTRATION FEES:

EARLY BIRD PRICE - VALID UNTIL 31 MARCH 2026

- 790€ + VAT *
- 15% DISCOUNT APPLICABLE FOR 3 OR MORE PEOPLE FROM THE SAME COMPANY

- FULL PRICE - VALID AFTER 31 MARCH 2026
- 1090€ + VAT
- 15% DISCOUNT APPLICABLE FOR 3 OR MORE PEOPLE FROM THE SAME COMPANY

* VAT APPLICABLE TO ITALIAN COMPANIES ONLY

PAYMENT OPTION VALID ONLY: BANK TRANSFER

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ORGANIZATION AND CONTACTS

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WWW.EUROFINS.IT/BIOPHARMA

VENUE

ENTERPRISE HOTEL MILAN
CORSO SEMPIONE 91 - 20149 MILAN
HTTPS://WWW.ENTERPRISEHOTEL.COM/EN/

GENERAL TERMS AND CONDITIONS

THE REGISTRATION FEE MUST BE PAID IN ADVANCE THROUGH BANK TRANSFER. ONLY AFTER WE HAVE RECEIVED YOUR PAYMENT, YOU ARE ENTITLED TO ATTEND THE CONFERENCE AND/OR WORKSHOP. IF YOU CANNOT ATTEND THE CONFERENCE/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:
- 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.
EUROFINS BIOPHARMA PRODUCT TESTING ITALY RESERVES 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. EUROFINS BIOPHARMA PRODUCT TESTING ITALY IS NOT RESPONSIBLE FOR AIRFARE, HOTEL OR OTHER COSTS INCURRED BY REGISTERED DELEGATES. YOUR DATA WILL BE PROCESSED IN ACCORDANCE WITH EU REGULATION NO. 679 OF 27 APRIL 2016 AND LEGISLATIVE DECREE 30 JUNE 2003, N. 196.

VENUE: ENTERPRISE HOTEL MILAN, CORSO SEMPIONE 91, MILAN

To reach the Enterprise Hotel Milano from Milano Centrale (Central Train Station):

1. Subway: Take the Line 2 Subway from "Centrale FS" direction Assago Milano Fiori Forum or Abbiategrasso. Stop at Garibaldi station and take Line 5 Subway Direction San Siro stop at Domodossola.
2. By Taxi: A taxi ride from Milano Centrale to Enterprise Hotel Milano takes about 6 minutes.

To reach the Enterprise Hotel Milano from Milan Malpensa Airport:

1. Take the Bus or Train shuttle until Milano Centrale (Central Train Station) and follow instructions stated above.

To reach the Enterprise Hotel Milano from Linate Airport:

- Tram: Take Tram 19 from "P.za del Tricolore" to "C.so Sempione Via E. Filiberto." The journey takes about 1 hour.
- By Taxi: A taxi ride from Linate Airport to Enterprise Hotel Milano takes about 12 minutes.

To reach the Enterprise Hotel Milano from Bergamo Airport:

- Take the Bus shuttle until Milano Centrale (Central Train Station) and follow instructions stated above.

Milan Subway Map