



BioPharma  
Product Testing

# EUROFINS EXTRACTABLES AND LEACHABLES SUMMIT



1<sup>ST</sup> 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 delivers a full insight-rich day designed to illuminate the evolving E&L landscape and equip attendees with the knowledge behind tomorrow's standards.

### **WHERE CONVERSATIONS BECOME ACTIONABLE SOLUTIONS**

Day 2 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](https://eu.jotform.com/form/260390924651458)**

09.00 - 09.30	09.30 - 09.45
Registration and welcome coffee	Introduction and opening remarks
	Setting the Scene: Why Extractables & Leachables Matter Today
	<i>Simone Carrara, Chairman - Eurofins BioPharma Product Testing Italy</i>

## 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

*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:

- Integration of E&L strategy within analytical development
- Risk-based study design aligned with regulatory expectations
- Managing variability across materials and suppliers
- Lessons learned from real-life pharmaceutical case studies

*Marco Ceccolini, Angelini Pharma*



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*

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**13.15 - 14.15 Networking Lunch**

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## SESSION 3 – TECHNICAL ADVANCEMENTS, PART II



14.15 - 15.00

Method Upgrades for E&L Studies Using Algorithmic Prediction:

- Enhancing traditional E&L methodologies through algorithmic tools
- Data-driven study design optimisation
- Reducing false positives/negatives through advanced modelling
- Integrating predictive approaches with laboratory workflows
- Practical implementation in regulated testing environments

*Speaker to be confirmed*



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15.00 - 15.45

Industry Case Study – Extractables & Leachables Implementation:

- Corporate strategy for E&L management
- Cross-functional alignment (QA, RA, R&D)
- Implementation challenges of USP <665>
- Supplier and material qualification considerations
- Real-world decision-making under regulatory pressure

*Speaker from Industry to be confirmed*

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**15.45 - 16.15 Coffee Break**

## 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*

*Managing Director Eurofins Regulatory & Consultancy Services*

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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*

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## 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

## 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**

## 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.

## A Premium Learning Environment Designed for Interaction

## 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.

**Real E&L challenges. Real solutions.**

# DAY 2 - EXPERT GUIDED WORK TABLES

## 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

## 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

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

## 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

Think, Debate, and Problem-Solve Together

# 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



**SIMONE CARRARA**

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



**MARCO CECCOLINI**

Product Analytical Development Scientist, Angelini Pharma, AFI Member



**ALBERTO BRESCIANI**

Founder and Principal, Tycho Science and Tech



**PAOLO PESCI**

Managing Director, Eurofins Regulatory and Consultancy Services Italy

MORE SPEAKERS TO BE CONFIRMED SOON!

**Dr. Ravi Kiran Kaja, Ph.D., FRSC****Senior Principal Scientist, Complex Generics - Pharmaceutical Science, General Chapters****U.S. Pharmacopeia (USP), Rockville, MD 20852**

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.

**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.



**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****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.

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

Simone Carrara is the E&L and Packaging Testing Business Unit Manager at Eurofins Biolab, with over 15 years of experience in Extractables & Leachables, packaging testing and pharmaceutical project management within highly regulated environments. He currently leads the E&L and Packaging Testing activities at Eurofins Biolab, combining scientific expertise, operational leadership and client-facing responsibilities. Over the years, Simone has covered key roles including E&L Senior Scientific Director, Extractables & Leachables Laboratory Manager, and Pharma Project Leader, gaining deep hands-on experience across the full lifecycle of E&L studies – from study design and execution to data interpretation and regulatory support. His background also includes strong expertise in bioanalytical sciences, LC/MS analysis, and quality-controlled laboratory environments, supported by an Executive MBA from Politecnico di Milano and a degree in Industrial Biotechnology.

As Chairperson and Moderator of the Eurofins E&L Summit, Simone will guide discussions across technical and regulatory sessions, ensuring focused dialogue, scientific rigor and practical relevance, and facilitating effective exchange between industry, regulators and experts.

**MORE SPEAKERS TO BE CONFIRMED SOON!**



**REGISTRATION LINK: [HTTPS://EU.JOTFORM.COM/FORM/260390924651458](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

\* VAT APPLICABLE TO ITALIAN COMPANIES ONLY

- 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: BANK TRANSFER

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ABI: 2008, CAB: 20600, CIN: N

C/C: 000004846325

IBAN: IT04 N020 0820 6000 0000 4846 325

VAT ID: 00762140960

## ORGANIZATION AND CONTACTS

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[WWW.EUROFINS.IT/BIOPHARMA](http://WWW.EUROFINS.IT/BIOPHARMA)

## VENUE

ENTERPRISE HOTEL MILAN

CORSO SEMPIONE 91 - 20149 MILAN

[HTTPS://WWW.ENTERPRISEHOTEL.COM/EN/](http://WWW.ENTERPRISEHOTEL.COM/EN/)

## GENERAL TERMS AND CONDITIONS

THE REGISTRATION FEE IS PAYABLE 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 SEMPIOLE 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**

