CPHI India

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7th Edition

EXTRACTABLES & LEACHABLES FORUM

11 - 12 November 2025
Radisson Blu Plaza Hotel, Banjara Hills, Hyderabad

WORKSHOP & CONFERENCE

Driving Success in E&L Studies to Achieve Patient Safety

About the Conference

The **7th Edition of Extractable and Leachable Forum 2025** brings together industry experts for knowledge exchange through focused workshop by the Industry leader followed by informative & interactive speaker sessions. The event provides a comprehensive view of E&L across R&D, formulation, testing, packaging, regulatory compliance, and more.

The workshop, conducted on Day 1 will provide an in-depth overview of the new draft guideline ICH Q3E: Management of Extractables and Leachables (E&L), developed by the Expert Working Group (EWG) under the International Council for Harmonisation (ICH).

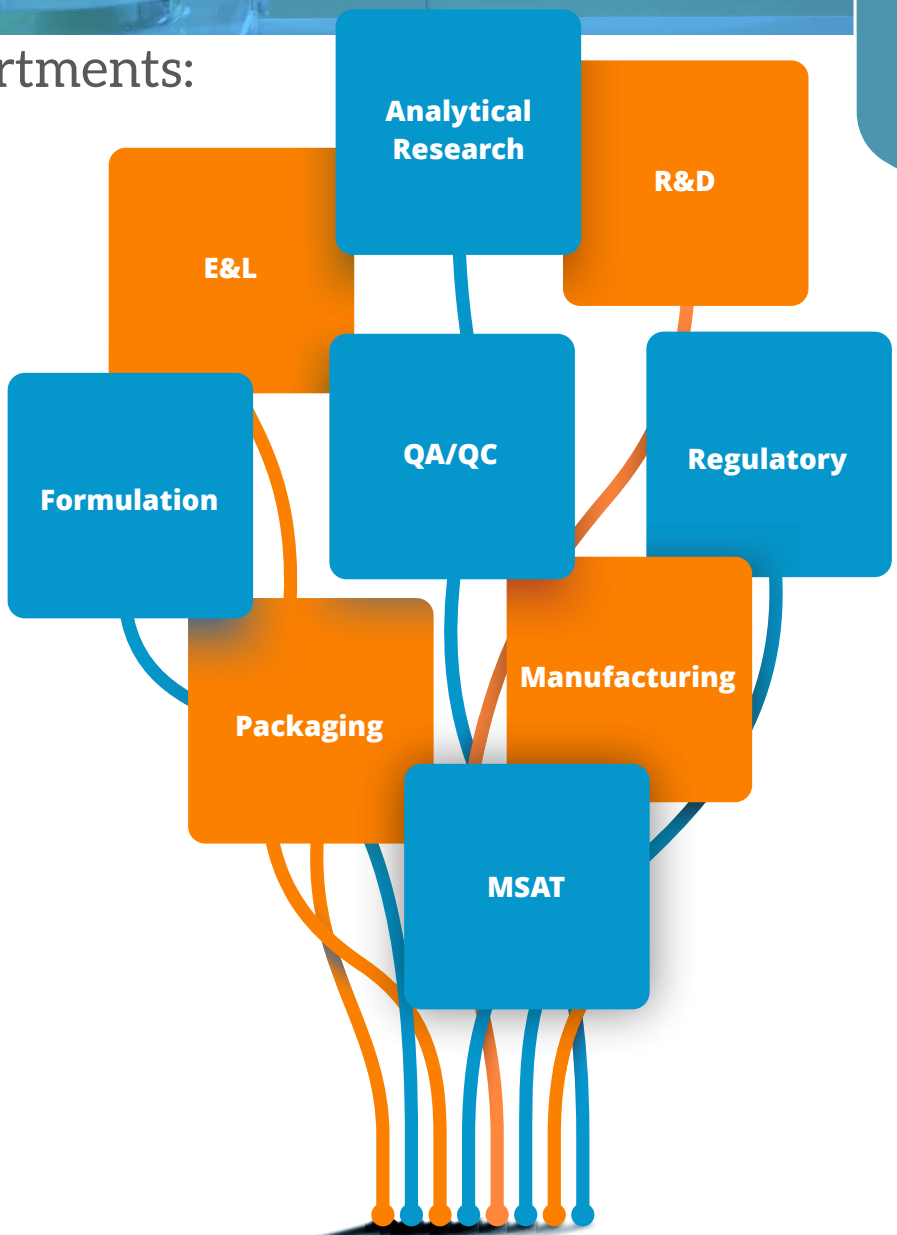
At the conference, participants will discover cutting-edge tools to equip them with the advancement in E&L and give insights into the upcoming regulatory changes, analytical methodologies, and risk assessment strategies that will shape the future of extractables and leachables management across the pharmaceutical and medical device industries.

It will also bridge the gap between international regulations from India, the US, and the UK. The forum offers valuable networking with service providers to help pharmaceutical manufacturers optimize equipment, processes, and materials for enhanced quality and patient safety.

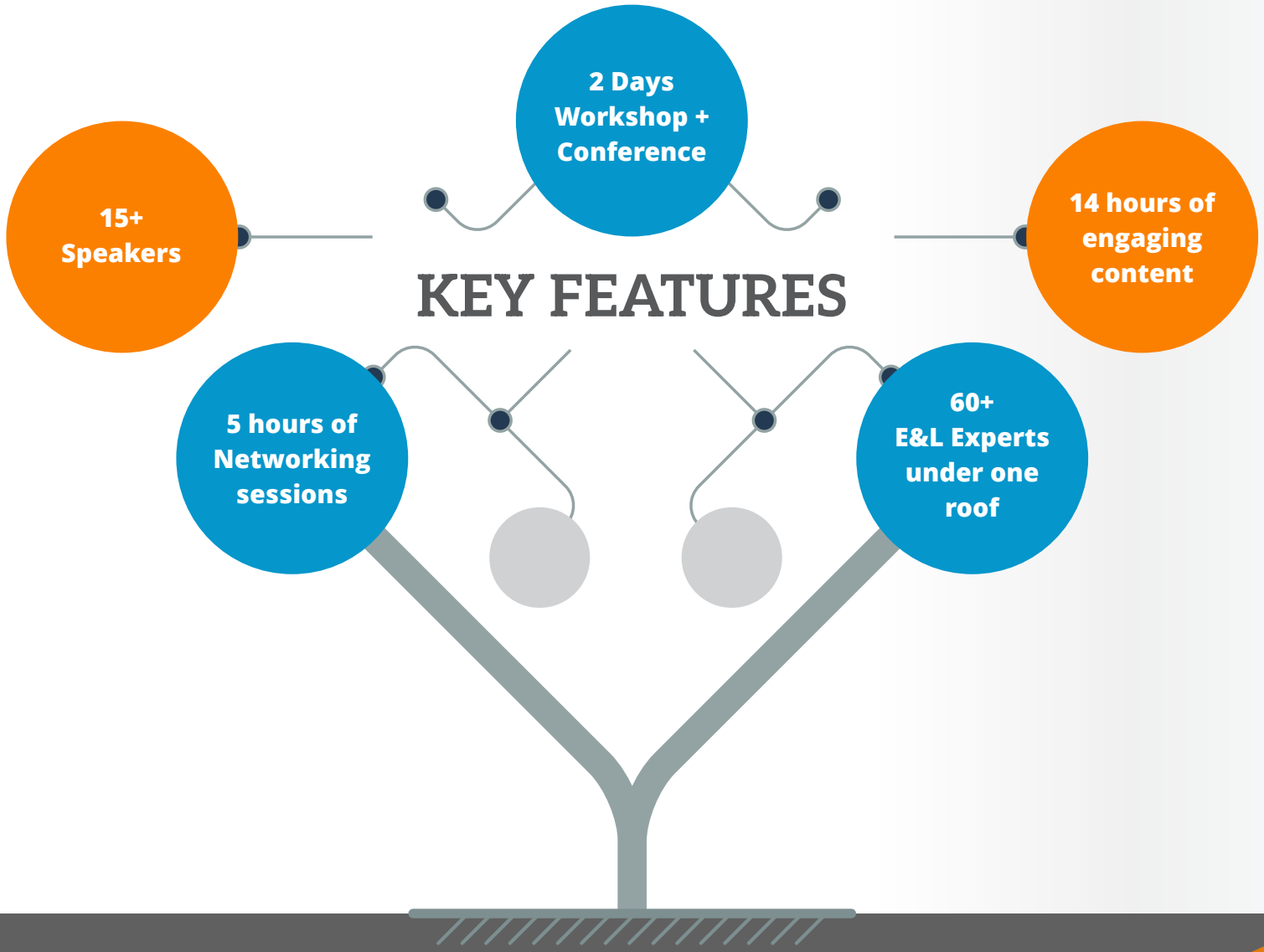
Who Will You Meet

Industries:

Departments:



KEY FEATURES



Key Topics:

- Workshop on E&Ls Risk Assessment & Analytical Evaluation Under ICH Q3E
- USP 665 Guidelines: Implementation and Compliance Strategies
- Integration of Computational Modelling in E&L Testing
- Medical Device Manufacturers - Chemical Characterization Challenges - From Analytical Hurdles to Toxicological Insights
- E&L Considerations in Emerging Biopharmaceutical & Cell & Gene Therapy Modalities
- Next-Generation Approaches to Pharmaceutical Packaging Safety and Managing Green and Biodegradable Materials
- E&L Challenges in Single-use Systems in Bio-manufacturing

Benefits of Attending:

- Meticulously curated Workshop will provide an in-depth overview of the new guidelines and regulations
- Networking opportunity with top industry leaders as speakers are from top pharma companies and research labs
- More than 15 speakers from industry
- Discusses E&L in a broad spectrum – Testing, Regulatory, Risk Assessment, Medical Devices, Sterile Products, Combination products etc
- Expert solutions to industry problems like changes in ICH Q3E guidelines, Annex 1, new EU Regulations, USP new chapters, Single container systems, toxicology impact etc.

Workshop Overview

This workshop will provide an in-depth overview of the new draft guideline **ICH Q3E: Management of Extractables and Leachables (E&L),** developed by the Expert Working Group (EWG) under the International Council for Harmonisation (ICH).

The guideline introduces a holistic risk-based framework for identifying, assessing, and controlling leachables to safeguard the safety, efficacy, and quality of finished drug products. While it addresses materials characterization and process understanding, its central focus is ensuring patient safety and product integrity through rigorous evaluation and control strategies. Recognizing rapid advances in materials science, device innovation, manufacturing technologies, and novel therapies, the guideline establishes forward-looking principles aligned with evolving scientific and regulatory landscapes.

Currently at **Step 2 (public consultation phase)**, feedback received will be reviewed by the EWG and integrated before finalization.

Key Discussion Topics:

- **Risk Assessment and Control of Extractables and Leachables**
- **Chemical Testing and Assessment**
- **Analytical Evaluation Threshold (AET) and Analytical Uncertainty Factor**
- **Few Case studies and interactive discussions with the participants**

What participants will learn:

- Distinctions in **leachable risk and qualification requirements between container closure systems (CCS)** and **production systems.**
- Methodologies for establishing and applying **Qualification Thresholds (QTs)** for leachables, including clarity on their scientific basis.
- Practical tools to help organizations meet **global regulatory expectations** for E&L management.

About the Workshop Trainer

Dr. BM Rao, Ph.D.

Chief Executive Officer

QDOT Associates, Hyderabad

Dr. B.M. Rao is an accomplished pharmaceutical quality expert with over 33 years of leadership in Analytical R&D and Quality Control at leading companies such as Dr. Reddy's, Janssen (J&J), and Novartis. A recognized authority on data integrity, regulatory readiness, and Nitrosamine assessments, he has actively supported global audits by USFDA, EMEA, and Health Canada. With 80+ scientific publications and ten Ph.D. mentees, he now serves as CEO of QDOT Associates, providing global consultancy services. Dr. Rao is also a seasoned international speaker known for delivering insightful sessions on GMP compliance and analytical excellence.

Speakers 2025

Dr. Anirban Roy Chowdhury
Executive General Manager-
Analytical R&D
Amneal

Dr. Ashutosh Kumar
Professor - Department of
Biosciences and Bioengineering
IIT Bombay

Dr. Ranjan Chakraborti
Biopharma Professional

Dr. Avinash Krishnaji Velhal
Pharma Lifescience Expert

Dr. Pushkar Kulkarni
Preclininal Expert
Dr. Reddys Laboratories

Deepak Dongare
Associate Director
Biocon Biologics

Dr. Kailas Ingle
Senior Toxicologist,
Nonclinical Drug Development
and Safety Assessment
Elanco Innovation and
Alliance Centre India LLP

Dinesh Goudar
AGM-External Manufacturing Lead
Kashiv Biosciences

Dr. Mayank Bhanti
Senior Director, Compendial
Development Laboratory
United States Pharmacopeia
India Pvt. Ltd.

Amit Mukherjee
Senior Manager- Scientific Affairs
United States Pharmacopeia
India Pvt. Ltd.

Dr. Ravikishore Saiempu
Senior Scientist III
Jodas Expoim

Dr. Ashutosh Joshi
Principal Scientist & Team Lead –
Nonclinical Development &
Risk Assessments
Dr. Reddy's Laboratories

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Day 1: 11th Nov 2025, Tuesday

08:30 – 09:30	**Registration & Networking**
09:30 – 09:40	**Opening Remarks by Informa Markets in India**
09:40 – 11:30	**Workshop: Spotlight on ICH Q3E: Overview of ICH Guideline for Extractables and Leachables (Q3E), Step 2 Guideline** • Risk Assessment and Control of Extractables and Leachables • Chemical Testing and Assessment **Dr. BM Rao,** Chief Executive Officer**, QDOT Associates**
11:30 – 12:00	**Tea/Coffee & Networking Break**
12:00 - 13:30	**Workshop: Spotlight on ICH Q3E: Overview of ICH Guideline for Extractables and Leachables (Q3E), Step 2 Guideline** • Analytical Evaluation Threshold (AET) and Analytical Uncertainty Factor • Few Case studies and interactive discussions with the participants **Dr. BM Rao,** Chief Executive Officer **, QDOT Associates**
13:30 - 14:30	**Lunch & Networking Break**
Conference Day 1	
14:30 – 15:20	**Panel Discussion : Global Approaches to E&L Testing** • Risk Assessment through-out the product life-cycle since initial development phase • Harmonization of global guidelines • Understanding regional variations in E&L Standards • Data management & interpretation to facilitate regulatory submissions **Moderated By:** **Dr.Ranjan Chakrabarti**, Biopharma Professional

	Panelists: **Dr. Kailas Ingle,** Senior Toxicologist, Nonclinical Drug Development and Safety Assessment **Elanco Innovation and Alliance Centre India LLP** **Dr.Pushkar Kulkarni,** Preclinical Expert**, Dr.Reddy's Laboratories** **Dr. Mayank Bhanti**, Senior Director, Compendial Development Laboratory, **United States Pharmacopeia India Pvt. Ltd.**
15:20 – 15:50	**Health-Based Exposure Limit Determination for Extractable and Leachable Risk Assessment** • Overview Permitted Daily Exposure (PDE) Determination Strategy • Understanding Toxicological Concepts : Critical Effect Selection and Uncertainty Factor Application • Basic Principles of Read-Across and Route-to-Route Extrapolation **Dr. Kailas Ingle,** Senior Toxicologist, Nonclinical Drug Development and Safety Assessment **Elanco Innovation and Alliance Centre India LLP**
15:50 – 16:20	**Toxicological Assessment of Leachables with Limited Data** • Utilize established safety thresholds (TTC, SCT, QT) to determine which compounds require further evaluation • Apply route-specific exposure limits to efficiently focus resources on compounds of genuine concern • Leverage worst-case extractables data as surrogate information • Structure-Based Risk Assessment • Using regulatory guidance & resources like USP, PQRI. **Pushkar Kulkarni,** Preclinical Expert**, Dr.Reddy's Laboratories**
Tea/ Coffee Networking and End of Workshop & Conference Day 1	

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Day 2: 12th Nov 2025, Wednesday

Conference Day 2	
08:30- 09:30	**Networking Breakfast**
09:30 – 10:00	**Opening Remarks by Informa Markets, India**
10:00- 10:30	**Optimizing your Extractables and Leachable Study and Strategy for Faster Assessment** • Crafting a structured procedure for E&L assessments integrating regulatory expectations • Initiating E&L Studies from the initial stages of Drug Development • Techniques for faster assessment to help go to market strategies **Deepak Dongare,** Associate Director**, Biocon Biologics**
10:30 – 11:00	**Navigating E&L Challenges in Inhalation Drug Products with Advanced Analytics and Regulatory Risk Mitigation.** • Route-specific challenges for inhalation products – more components, lower AETs, lower LOQs • Managing custom components and high number of additive universe. • Study design strategies for maximum E&L coverage • Rapid identification pathways for unknown leachables using structured decision making • Synchronizing extractables with leachables control strategies • Minimizing regulatory queries and post-approval changes through proactive lifecycle management **Dr. Anirban Roy Chowdhury**, Executive General Manager- Analytical R&D, **Amneal**
11:00 – 11:30	**Networking Break**
11:30– 12:00	**E&L Challenges in Single-Use Systems : Lessons from Real-World Case Studies** • E&L concerns in disposable bioprocessing equipment & SUS • Focus on their impact on product quality **Dinesh Goudar**, AGM- External Manufacturing Lead, **Kashiv Biosciences**
12:00 – 12:30	**Role of USP in the Evolving Framework of Extractable/Leachable Assessment** **Amit Mukherjee,** Senior Manager- Scientific Affairs**, United States Pharmacopeia India Pvt. Ltd.**

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12:30– 13:00	**E &L: Novel Analytical Solutions that Meet ICH Q3E Guidelines and Beyond** • Key considerations in extractable analysis with modern tools such as mass spectrometry • Decision drivers and leachable characterisation & quantification • Reporting the right way adhering Q3E guidelines • Keys to unlock the challenges through advanced analytical tools **Dr. Ravikishore Saiempu,** Senior Scientist III**, Jodas Expoim**
13:00- 14:00	**Lunch & Networking Break** 
14:00 – 15:00	**Round table Discussion** **Table A** : **Topic: Adopting Adequate Testing Strategy to Meet Regulatory Aspects** **Moderated By: Dr.Avinash Krishnaji Velhal, Pharma Lifescience Expert** **Table B** : **Topic: E&L Challenges in Biopharma** **Moderated By: Dinesh Goudar**, External Manufacturing Lead, **Kashiv Biosciences** **Table C**: **Topic: Optimizing E&L Risk Management with Vendor Diversification Strategies** **Moderated By: Dr. Ashutosh Kumar,** Professor - Department of Biosciences and Bioengineering, **IIT Bombay**
15:00 – 15:30	**E&L Risk Mitigation in Pharma Formulation Space** **Dr.Avinash Krishnaji Velhal, Pharma Lifescience Expert**
15:30 – 15:50	**Networking Break** 
15:50 – 16:20	**Extractable and Leachable Risk to Parenteral Drug Formulations from Primary Packaging System** • Understanding the hidden risks posed by extractables and leachables (E&L) in Parenteral Formulations • Parenteral formulations bypass first-pass metabolism, making any contaminants introduced through leachables immediately bioavailable, thereby increasing toxicological risk • Lack of standardized protocols hinders comparisons of stopper types • Exploring the Study focused on identifying and quantifying both organic and inorganic extractables and leachables using a multi-technique analytical platform

	• Tailored testing strategies to ensure the safety of biopharmaceuticals **Dr. Ashutosh Kumar,** Professor - Department of Biosciences and Bioengineering**, IIT Bombay**
16:20- 17:00	**Strengthening WoE Justifications in Risk Assessment of E&L- Exploring NAMs** • NAMs - Principals and Types • Regulatory Scenario • Currently Used and Upcoming NAMs • Case examples **Dr Ashutosh Joshi,** Principal Scientist & Team Lead – Nonclinical Development & Risk Assessments**, Dr. Reddy's Laboratories**
END OF CONFERENCE	

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Delegate Pricing:

For Pharmaceutical Drug Manufacturers

	INR PER DELEGATE
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**Note:*
(Mandatory 18% GST will be applicable on all bookings.)

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