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7th Edition



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



Driving Success in E&L Studies to Achieve Patient Safety



About the Conference

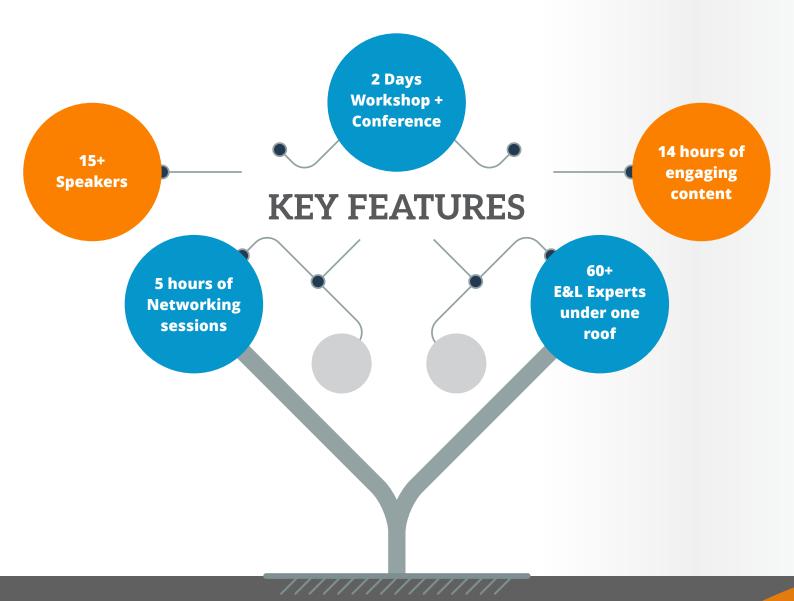
The **7**th **Edition of Extractable and Leachable Forum 2025** brings together industry experts for knowledge exchange through focused workshop by the Industry leader followed by informative & interactive speaker sessions. The event provides a comprehensive view of E&L across R&D, formulation, testing,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





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



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. Venkat ManoharDirector **IICMS**



Dr. Anirban Roy Chowdhury
Executive General ManagerAnalytical R&D
Amneal



Dr. Ashutosh KumarProfessor - Department of
Biosciences and Bioengineering **IIT Bombay**



Dr. Ranjan Chakraborti Biopharma Professional



Dr. Pushkar KulkarniPreclininal Expert **Dr. Reddys Laboratories**



Dr. Avinash Krishnaji Velhal Pharma Lifescience Expert



Deepak Dongare Senior Manager **Biocon Biologics**



Dinesh GoudarAGM-External Manufacturing Lead **Kashiv Biosciences**



Dr. Kailas Ingle
Senior Research
Scientist-Toxicology,
Non-Clinical Development
Elanco Innovation and
Alliance Centre India LLP



Dr. KMV Narayana Rao Head of Analytical R&D (API) NATCO Research Centre



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.

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Driving Success in E&L Studies to Achieve Patient Safety

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 – 15:10	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 Panelists: Dr. Ranjan Chakrabarti, Biopharma Professional Dr. Kailas Ingle, Senior Research Scientist-Toxicology, Non-Clinical Development Elanco Innovation and Alliance Centre India LLP Dr. KMV Narayana Rao, Head of Analytical R&D (API), NATCO Research Centre

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15:10 – 15:40	Simplifying the Screening Workflow for Extractables Testing • Efficient approaches to initial material screening • Prioritization strategies for further testing Reserved for Sponsors
15:40 - 16:10	Tea/Coffee & Networking Break
16:10 – 16:40	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 Research Scientist-Toxicology, Non-Clinical Development Elanco Innovation and Alliance Centre India LLP
16:40 – 17:10	 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
	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	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.Venkat Manohar, Director, IICMS
10:30 – 11:00 11:00 – 11:30	 Al and Advanced Analytics applications Enhancing drug safety and efficacy through computational approaches Reserved for Sponsors 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, Senior Manager, Biocon Biologics
11:30 – 12:00	Networking Break
12:00– 12:30	 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

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	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
12:30 – 12:45	Toxicological evaluation and risk assessment
	Reserved for Sponsors
12:45– 13:15	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
13:15- 14:15	Lunch & Networking Break
14:15 – 15:20	Round table Discussion
	Table A : Topic: Adopting Adequate Testing Strategy to Meet Regulatory Aspects
	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
15:20 – 15:50	E&L Risk Mitigation in Pharma Formulation Space
	Dr.Avinash Krishnaji Velhal, Pharma Lifescience Expert
15:30 – 16:00	Networking Break
16:00 – 16:30	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

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	 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	ed
16:30- 17:00	Sustainability Fireside: Managing Green and Biodegradable Materials The trade-offs between sustainability goals and E&L safety when using eco-friendly materials How emerging biodegradable plastics and biopolymers fare in E&L testing The challenge of ensuring environmental responsibility while minimizing leachable risks Regulatory hurdles and public perception of E&L in sustainable packaging materials	<u>ф</u>

END OF CONFERENCE

Event Partners

Exhibit Partner





Delegate Pricing:

For Pharmaceutical Drug Manufacturers

INR PER DELEGATE

Standard Rate

33,000

*Note:

(Mandatory 18% GST will be applicable on all bookings.)

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