CPHI India

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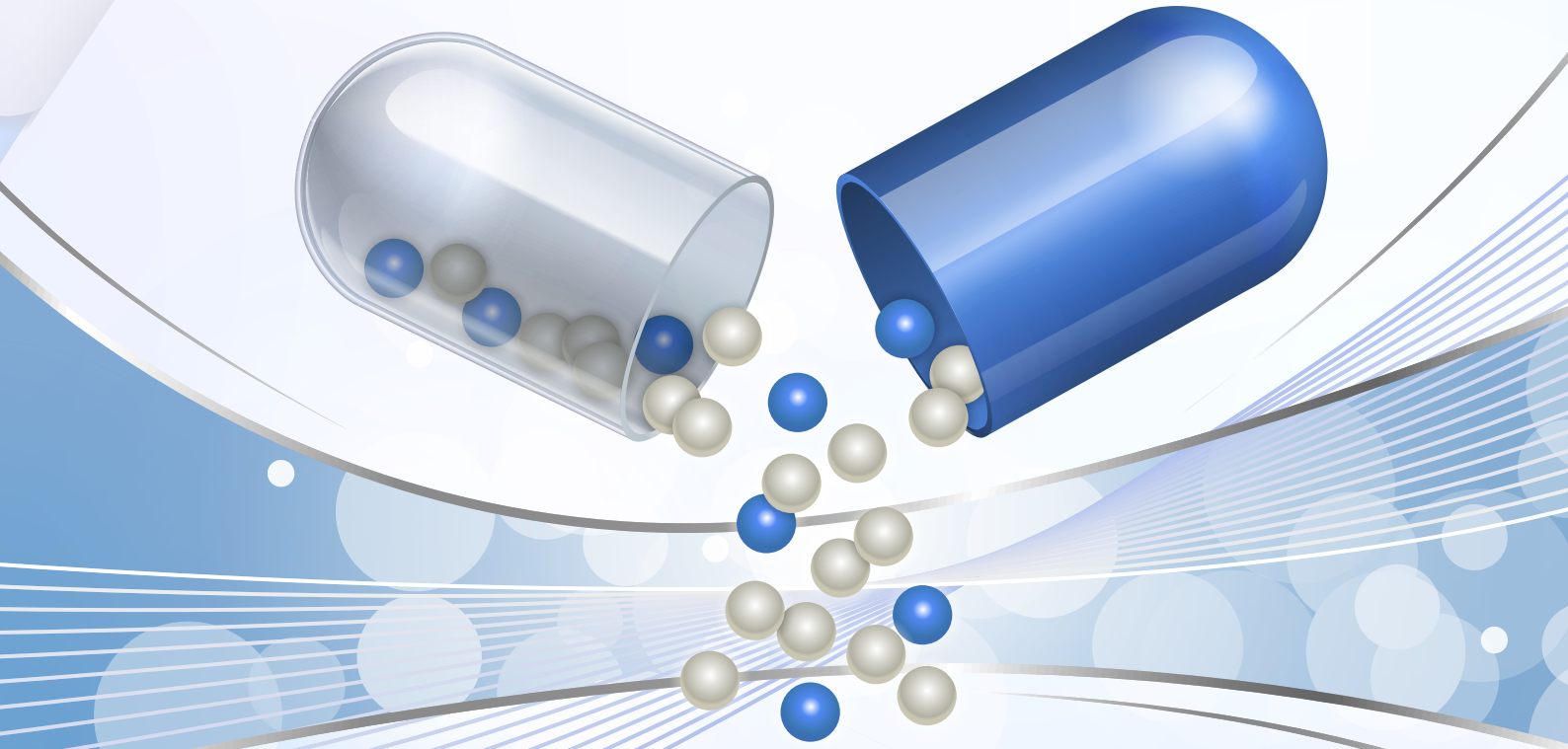
8th Edition

NITROSAMINES IMPURITIES FORUM

20 - 21 August 2025
Novotel HICC, Hyderabad

1 Day Workshop + 1 Day Conference

Nitrosamine Safety Developments, Guidelines, and Challenges



www.nitrosamineimpurities.com

Industry Landscape & Course Overview

The Eighth edition of the Nitrosamine Impurities Forum scheduled from 20 - 21 August 2025, in Hyderabad, will have one day workshop and one day conference. The forum aims at bringing industry participants up to date on the constantly evolving nitrosamines saga with a focus on regulatory requirements and their impact on the supply chain of essential medicines in international pharmaceutical markets.

The first day entails the workshop hosted by the leading experts of nitrosamines impurities Dr. Raphael Nudelman and Dr. Muzaffar Khan focusing on the latest trends and challenges in nitrosamines, safety assessments, regulatory frameworks including ICH M7, NDSRI risk assessment models with various case studies.

The second day is focused on imparting a deep understanding of various aspects of nitrosamines impurities backed by multiple speaker sessions and panel discussions from distinguished industry experts.

Why this Forum?

The Eighth edition of Nitrosamines Impurities Forum will focus on the challenges to any molecule containing the nitroso functional group while discussing the below:

- *Understanding current regulatory requirements to tackle nitrosamine impurities in pharmaceuticals*
- *How to calculate & derive acceptable intake limits for nitrosamine impurities*
- *Gain clarity on choosing the correct analytical methods & tools to address these impurities*
- *How nitrosamines are formed – The chemistry behind this*
- *How to restrict nitrosamine impurities in the development phase and in commercialized products*
- *Understand what toxicological studies can be performed to qualify nitrosamines*
- *Discuss the results from toxicological studies and their use to determine the mutagenic/carcinogenic potency of nitrosamines*

Who Will Attend?

Industries

- Pharmaceuticals
- Life sciences
- API Manufacturers
- Bio-Pharmaceuticals

Departments

- Quality Assurance
- Quality Control
- R&D
- Production & Manufacturing
- Analytical
- Deputy General Manager
- Regulatory

Designation:

- Vice Presidents
- Associate Vice Presidents
- Directors
- Associate Directors
- Head/ Plant Head
- Deputy General Manager
- General Manager
- Senior Managers
- Managers
- Assistant Managers
- Senior Executives

The Eighth edition of Nitrosamines Impurities Forum will focus on the challenges, including:

Get awareness and understanding of current regulatory guidelines, the similarities, and differences across guidelines, and their impact.

Learn how to derive acceptable intake limits, and the challenges associated with this from both a technical and regulatory perspective

Learn how nitrosamines are formed – The chemical mechanism behind this, the risk factors, and modeling to understand the extent of formation

Key Benefits of Attending

Deeply understand the potential strategies to reduce nitrosamine contamination risk, and develop orthogonal control strategies for nitrosamines in drug substances and products.

Experience know-hows of developing sensitive and accurate analytical methods and associated challenges with the testing of nitrosamines and NDSRIs

Get in-depth knowledge on Toxicological studies for nitrosamines and the use of data emerging from such studies to set limits for nitrosamines, particularly for NDSRIs

About the WORKSHOP TRAINER

Dr. Muzaffar Khan

Assistant Vice President - Regulatory Affairs

Laurus Labs Limited

Muzaffar Khan, Assistant Vice President at Laurus Labs Limited is a seasoned regulatory affairs expert with a PhD in Chemistry and 25 years of industrial experience. He specializes in impurity profiling and assessment and control of mutagenic and nitrosamine impurities in pharmaceutical products.

Khan has presented extensively on mutagenic and nitrosamine impurities at international forums, including Lhasa's ICH M7 Indian Roadshows and webinars alongside noted industry experts like Dr. Mike Urquhart, Dr. Andrew Teasdale and Dr. Raphael Nudelman. His insights have also been featured at key industry events like Informa Markets Nitrosamine Impurities Forums & the Intensive Course on Pre-clinical toxicology and risk assessment at University of Hyderabad. Khan is also an active scientific contributor, having reviewed for esteemed scientific journals including Talanta, CHROMB, Central European Journal of Chemistry, Bentham Science etc.

About the WORKSHOP TRAINER

Dr. Raphael Nudelman

Chief Executive Officer

Nudelman ChemTox Consulting

Raphael (Raphy) Nudelman is an accomplished chemical toxicologist with more than 20 years of experience in the pharmaceutical industry. He earned his PhD in organic chemistry from the Weizmann Institute of Science in Israel and completed postdoctoral fellowships at the US Air Force Research Laboratory and Duke University Medical Center. During his two decades at Teva Pharmaceuticals, Raphy held a variety of positions, including roles in medicinal chemistry, patents, non-clinical safety, and ultimately served as the company's Impurity Expert. His areas of expertise include the qualification of impurities and excipients in both drug substances and drug products, with a particular emphasis in recent years on the risk assessment of nitrosamine impurities. After retiring from Teva in September 2024, Raphy established Nudelman ChemTox Consulting, where he now offers consulting services to the pharmaceutical sector.

Speakers 2025

Dr. Arvind Kumar
Head - Analytical R&D
Viatris

Dr. Ashok Chaudhari
Associate Director- Head of the Sophisticated Instruments facility
Emcure Pharmaceuticals Limited

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

Dr. B.M. Rao
Chief Executive Officer
QDOT Associates

Dr. B.V. Ravichandra
Head -Global Toxicology & Nonclinical Development
Amneal Pharmaceutical

Dheeraj Handique
Manager GC/GCMS (Product Marketing)
Shimadzu Analytical (India) Pvt Ltd

Dr. Mrunal Jaywant
Vice President of Research and Development
USP India

Dr. Rajendra S. Chavan
Group Leader – Analytical Research
Wockhardt Research Centre

Samata Karwarkar
Head - CQA
ACG - Associated Capsules

Dr. Santosh Bhardwaj
Manager-Business Development - Pharma (LC / LCMS) & Consumables Market
Shimadzu Analytical (India) Pvt Ltd

8th Edition of Nitrosamines Impurities Forum
20th- 21st August 2025, Hyderabad

Shaping the Future of Nitrosamine Control

Day 1: 20th August 2025

08:15 AM – 09:15 AM	**Registration & Networking**
09:15 AM – 09:30 AM	**Opening Remarks by Informa Markets in India**

09:30 AM – 10:15 AM	**Introduction to N-Nitrosamines**
	• What are N-nitrosamines
	• N-Nitrosamines in Pharma (NDSRIs)
	• Market impact
	• The Nitrosamines Saga
	  ○ Important occurrences related to NAs in pharmaceuticals
	  ○ Nitrosamines from food and endogenous formation
	  ○ Why secondary amines in APIs cannot be avoided and why pharmaceuticals cannot be made "nitrosamine-free"
	  ○ The value of data sharing initiatives
	
	Dr Raphael Nudelman, Chief Executive Officer, **Nudelman ChemTox Consulting**.

10:15 AM – 10:30 AM	**Q&A Session**
10:30 AM – 11:00 AM	**Tea/Coffee & Networking Break**
11:00 AM – 11:40 AM	**Risk Assessment of N-Nitrosamine Impurities in API** • Scope of N-Nitrosamine risk assessment • Identified Sources of Formation/Contamination • Chemistry of Formation of N-nitrosamines • Risk Assessment of Formation – Industry Perspective • Performing Nitrosation Assay Procedures • Work-flow for N-nitrosamine Risk Assessment in APIs **Dr Muzaffar Khan**, Assistant Vice President - Regulatory Affairs, **Laurus Labs Limited**
11:40 AM – 11:50 PM	**Q&A Session**
11:50 AM – 12:25 PM	**N-Nitrosamine Guidelines** • Introduction to nitrosamine guidelines • Carcinogenicity Potency Categorization Approach (CPCA) • Enhanced Ames Test (EAT) • Ames test for N-Nitrosamines • Less Than Lifetime (LTL) for N-Nitrosamines • Molecular Weight Adjustment to Set AIs for NDSRIs **Dr Raphael Nudelman**, Chief Executive Officer, **Nudelman ChemTox Consulting**.
12:25 PM – 12:35 PM	**Q&A Session**

12:35 PM – 13:30 PM	**Lunch & Networking Break** 

13:30 PM – 14:10 PM	**Purge Assessment of Mutagenic Impurities (MIs) & N-Nitrosamines**
	• ICH M7 Control Options for MIs
	• Important Takeaways from ICH M7 on Option 4 Controls
	• Purge factors calculations
	• Regulatory Requirements of Purge Assessments
	• Purge Assessment of Nitrosamine Impurities
	  ○ Reactivity & Solubility of Nitrosamines
	  ○ Case Studies - *N*-nitrosamine Purge Assessments
	• Work-flow for *N*-nitrosamine Risk Assessment in APIs
	
	Dr Muzaffar Khan, Assistant Vice President - Regulatory Affairs**, Laurus Labs Limited**

14:10 PM – 14:20 PM	**Q&A** 
14:20 PM – 15:00 PM	**Nitrosamine Limits** • Limits according to Health Authorities guidelines • Discrepancies between guidelines from different regions • Inconsistencies within the guidelines **Dr Raphael Nudelman**, Chief Executive Officer, **Nudelman ChemTox Consulting**
15:00 PM – 15:10 PM	**Q&A** 
15:10 PM - 15:30 PM	**Tea/Coffee & Networking Break** 
15:30 PM – 16:10 PM	**Risk Assessment of N-Nitrosamine Impurities in Drug Products** • Identified root causes for nitrosamines presence in DP • Quantitative Risk Assessment of NAs in DP • Controlling multiple nitrosamines • Control Strategies & Risk mitigation measures • Workflow for *N*-Nitrosamine risk assessment in DP **Dr Muzaffar Khan**, Assistant Vice President - Regulatory Affairs**, Laurus Labs Limited**
16:10 PM – 16:30 PM	**New Methods to Determining Mutagenicity/Carcinogenicity Potency** • Setting limits using in vivo mutagenicity data for NDSRIs that don't have carcinogenicity data • Quantum mechanical (QM) docking and CYP P450 binding prediction of NDSRIs **Dr Raphael Nudelman**, Chief Executive Officer, **Nudelman ChemTox Consulting**.
16:30 PM - 16:40 PM	**Q&A** 

16:40 PM – 17:10 PM	**Case studies on N-Nitrosamines** • Industry based case studies & regulatory experiences **Dr Muzaffar Khan**, Assistant Vice President - Regulatory Affairs**, Laurus Labs Limited**
17:10 PM – 17:40 PM	**The Near and Far Future for Nitrosamines** • HESI working groups • Summary of methods for setting nitrosamine limits • Outlook for the future **Dr Raphael Nudelman**, Chief Executive Officer, **Nudelman ChemTox Consulting**.
17:40 PM - 17:50 PM	**Q&A** 
18:00 PM	**End of Day 1**

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Shaping the Future of Nitrosamine Control

Day 2: 21st August 2025

09:15 AM – 09:45 AM	**Registration & Networking**
09:45 AM – 10:00 AM	**Opening Remarks by Informa Markets in India**
10:00 AM – 10:40 AM	**Current Regulatory Challenges Related to "Nitrosamines in Product Manufacturing, Testing, Re-established Process Submissions, and Recalls"** **Dr. B.M. Rao,** Chief Executive Officer**, QDOT Associates**
10:40 AM – 11:10 AM	**Precision in Safety: Shimadzu Cutting edge UFMS Technologies for Pharma Impurities Challenges by GCMS/MS** **Dheeraj Handique,** Manager – GC/GCMS Product Marketing, **Shimadzu Analytical (India) Pvt Ltd**
	Addressing pharmaceutical impurity challenges with Shimadzu's cutting edge UFMS Technologies by LCMS/MS **Dr. Santosh Bhardwaj,** Manager-Business Development - Pharma & Consumables Market**,** **Shimadzu Analytical (India) Pvt Ltd**
11:10 AM – 11:30 AM	**Tea/Coffee & Networking Break**
11:30 AM - 12:00 AM	**Regulatory Perspective on Nitrosamine and Safety Standards** • Everyday Exposure and Historical Overview of Nitrosamines • Key Industry Challenges and Practical Constraints • Evolving Regulatory Guidance Across Global Regions • Analytical Method Development: Critical Parameters • Defining and Harmonizing Safety Standards **Dr. Rajendra S. Chavan,** Group Leader – Analytical Research, **Wockhardt Research Centre**
12:00 PM – 12:20 PM	**Nitrosamines Risk assessment – Role of Excipient** • Contribution of nitrite from capsules / excipient in formation of Nitrosamines • Control strategy for nitrosamine impurities **Samata Karwarkar,** Head- CQA, **ACG - Associated Capsules**
12:20 PM - 13:00 PM	**Complex Nitrosamine (NDSRI) and its Control Strategy in API – Key Highlights** • Overview of Nitrosamine Impurities, Classification of NDSRIs, and Evolving Global Regulatory Expectations. • Exploration of How API structure, Synthesis Routes, Reagents, and Process conditions influence NDSRI formation

	• Implementation of Risk Assessment, Synthesis Optimization, Preventive Controls, and Advanced Analytical Methods. • Case Study **Dr. Ashok Chaudhari**, Associate Director- Head of the Sophisticated Instruments facility, **Emcure Pharmaceuticals Limited**
13:00 PM – 14:00 PM	**Lunch & Networking Break** 
14:00 PM - 14:30 PM	**Safeguarding Quality: USP's Analytical Framework for Nitrosamine Control** • USP's comprehensive analytical framework to address nitrosamine impurities threatening pharmaceutical quality and patient safety • Essential tools including documentary standards, validated methods for small nitrosamines, NDSRI characterization, and risk assessment resources by USP • Access to USP's Analytical Hub and the Nitrosamine Exchange Community, supporting stakeholders in addressing analytical challenges and safeguarding pharmaceutical quality **Dr. Mrunal Jaywant ,** Vice President- R&D**, USP India**
14:30 PM - 15:00 PM	**Development of Sensitive Analytical Methods of NDSRI - Strategy & Challenges** • NDSRI Method development Approach • How to enhance sensitivity • Key Challenges in Method development & Routine Testing at Quality Control. • False positive Results • Troubleshooting **Dr. Arvind Kumar,** Head - Analytical R&D**, Viatris**
15:00 PM - 15:30 PM	**Regulatory Discord Between FDA and EMA on NDSRIs: A Safety and Toxicological Perspective** • Contrasting FDA and EMA limits for complex nitrosamines • How discord impacts submissions and global timelines • Unified guidance, clarity on data expectations, and safety margins **Dr B.V. Ravichandra,** Head -Global Toxicology & Nonclinical Development**, Amneal Pharmaceuticals**
15:30 PM – 16:00 PM	**Critical (Re-)Considerations for Applying ICH-S9 Based Relaxations to NDSRIs in Advanced Anti-Cancer Agents** • Science' Behind the 'Guidance' of Relaxation • Current Regulatory Framework in Different Geographies • Possible Scope for modification in Current Guidance documents • How to (and more importantly – How Not to) use S9 relaxations - Examples of commonly used and misused relaxations

	• Situations where S9 applications can be avoided in-spite being an anti-cancer agent for advanced cancer • Scope for regulatory re-consideration for applying 'S9-like relaxations' for 'Life Saving' Drug Products. **Dr Ashutosh Joshi**, Principal Scientist & Team Lead – Nonclinical Development & Risk Assessments, **Dr. Reddy's Laboratories**
16:00 PM	**Closing Remarks by Informa Markets in India**
End of Forum	

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CONTACT

For Speaking Opportunities, contact:

Archana Shantaram

M: +91 93431 97703 | E: archana.shantharam@informa.com

For Partnerships, Exhibits & Speaking Opportunities, contact:

Anuksha Hivarkar

M: +91 77770 88340 | E: anuksha.hivarkar@informa.com

For Delegates Registrations, contact:

Saleem Pasha

M: +91 9986768672 | E: saleem.pasha@informa.com

For Marketing & Communications, contact:

Shrushti Kamath

M: +91 91672 26207 | E: shrushti.kamath.IN@informa.com

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Informa Markets India Private Limited, 1st Floor B wing, Unit No 3 and 4, Solitaire XIV, Guru Hargovindji Marg, Chakala, Andheri East, Mumbai Suburban, Maharashtra, 400093