6th

NITROSAMINES

Genotoxic Impurities & Beyond Summit 2026

online | December 2nd– 3rd, 2026

Key Speakers:

3:30pm IST / 12:00pm CET / 6:00am EST

Crystal D'Silva, BE
Associate Director – Preclinical Toxicology
Baxter

Raphael Nudelman, IL
Chemical Toxicologist
Nudelman ChemTox Consulting

Andrew Teasdale, UK
Former Head of Impurity Management & CMC Strategy
AstraZeneca

George Johnson, UK
Associate Professor
Swansea University

Robert Jolly , USA
Risk Assessment Toxicologist
Eli Lilly

6th NITROSAMINES

Genotoxic Impurities & Beyond Summit 2026

December 2nd – 3rd, 2026

Conference Overview

Join industry leaders, regulatory experts and scientific innovators at the **6th Genotoxic Impurities: Nitrosamines & Beyond Summit**. This premier two-day virtual event is dedicated to the latest developments, regulatory expectations and technical challenges in global impurity control.

Day 1 establishes the strategic framework for risk assessment. It features expert-led sessions on 2026 regulatory updates from the FDA and EMA, the qualification of drug substances and integrated in silico modeling. Discussions will highlight the newest structural risks, including the February 2026 Lhasa data-sharing initiative, CPCA potency categories and the ICH M7 purge factor strategy.

Day 2 focuses on the practical execution of testing and manufacturing. Sessions cover advanced trace-level analytical validation, high-sensitivity detection at ppb levels and formulation-based mitigation. Attendees will explore unique challenges in biologics, packaging leachables and cross-contamination risks, concluding with best practices for lifecycle management and post-approval change control.

We Will Talk About

2026 Regulatory & Strategy

Key takeaways from EMA's early 2026 Appendix 1 and the integration of nitrosamine oversight into routine inspection frameworks.

Establishing safety-based limits and utilizing ICH M7 purge factors to justify reduced batch testing.

Predictive Risk & Data Sharing

Using integrated in silico modeling (Derek/Sarah Nexus) and amine precursor mapping to identify DNA-reactive groups early.

Applying updated insights from the Lhasa initiative and CPCA frameworks to categorize complex NDSRIs.

Analytical Precision & Validation

High-resolution LC-MS/MS and GC-MS strategies capable of quantifying impurities at the parts-per-billion (ppb) level.

Validating trace-level methods to ensure specificity and accuracy for 2026-2027 audit standards.

Manufacturing & Lifecycle Controls

Mitigation through smart formulations, packaging E&L screening and managing cross-contamination from cleaning pitfalls or NOx levels.

Addressing unique risks in Biologics and maintining compliance during post-approval site transfers and supplier changes.

Who Is It For?

This summit is designed for professionals involved in impurity profiling, risk assessment, regulatory compliance and pharmaceutical development, including:

- Regulatory Affairs Professionals
- Analytical Scientists and Chemists
- Toxicologists and Safety Assessors
- CMC and QA/QC Experts
- Formulation and Process Development Scientists
- Computational Toxicology Specialists
- Biologics and Device Developers
- Clinical Affairs

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Genotoxic Impurities & Beyond Summit 2026

December 2nd, 2026

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12:00 - 12:05 Registration

12:05 - 12:10 Opening Address from the Organizer

Regulations, Risk Assessment and In Silico Modeling

12:10 - 12:40

Session 1: Global Regulations & 2026-2027 Guideline Updates

- Thematic Focus: Both Nitrosamines & General Mutagenic Impurities.
- Description: Reviewing early 2026 EMA Appendix 1 additions and how FDA and EMA are integrating nitrosamine oversight into routine, standard inspection frameworks.

12:40 - 12:50 Short Break

12:50- 13:20

Robert Jolly, USA
Risk Assessment Toxicologist
Eli Lilly

Session 2: Qualification of Impurities in Drug Substances and Drug Products

- Thematic Focus: Both Nitrosamines & General Mutagenic Impurities.
- Description: Establishing safety-based limits and navigating the transition from ICH Q3A/B to mutagenic thresholds for stability-related impurities.

13:20 - 13:30 Short Break

13:30 - 14:00

George Johnson, UK
Associate Professor
Swansea University

Session 3: Using genetic toxicity data for risk assessment purposes

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14:00 - 14:10 Short Break

14:10 - 14:40

Session 4: Collaborative Data & Complex Nitrosamine Profiles

- Thematic Focus: Nitrosamines & NDSRIs.
- Description: Utilizing February 2026 Lhasa data-sharing initiative to speed up safety profiles and categorize NDSRIs.

14:40 - 15:00 Break

15:00 - 15:30

Session 5: Conducting a Nitrosamine Risk Assessment

• Thematic Focus: Nitrosamines & NDSRIs.
• Description: A practical walkthrough of the assessment process focusing on evaluating complex NDSRIs within multi-ingredient pharmaceutical formulations.

15:30 - 15:40 Short Break

15:40 - 16:10

Raphael Nudelman, IL
Chemical Toxicologist
Nudelman ChemTox Consulting

Session 6: Nitrosamine Potency Categories (CPCA & EAT)

• Thematic Focus: Nitrosamines & NDSRIs.
• Description: Step-by-step guidance on using the CPCA framework for complex nitrosamines and interpreting data from the Enhanced Ames Test (EAT).

16:10 - 16:20 Short Break

16:20 - 16:50

Session 7: The «Purge Factor» Strategy (ICH M7)

• Thematic Focus: General Mutagenic Impurities.
• Description: Using the ICH M7 framework to prove that manufacturing processes naturally eliminate impurities justifying the reduction of routine batch testing.

16:50 - 17:00 Organizer's closing remarks and end of day one

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Genotoxic Impurities & Beyond Summit 2026

December 3rd, 2026

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12:00 - 12:05 Registration

12:05 - 12:10 Opening Address from the Organizer

Testing, Formulations and Manufacturing

12:10 - 12:40

Session 1: Advanced Lab Testing at Ultra-Low Levels (Parts Per Billion)

- Focus: Nitrosamines & NDSRIs.
- Description: Advanced LC-MS/MS and GC-MS strategies to quantify trace impurities while eliminating sample-prep artifacts.

12:40 - 12:50 Short Break

12:50- 13:20

Session 2: Analytical Method Validation for 2026 Standards

- Focus: Both Nitrosamines & General Mutagenic Impurities.
- Description: Key requirements for validating trace-level methods. Ensuring specificity and accuracy at the Limit of Quantitation (LoQ) to satisfy 2026-2027 audit standards.

13:20 - 13:30 Short Break

13:30 - 14:00

Session 3: Stopping Nitrosamines with Smart Formulations

- Focus: Nitrosamines & NDSRIs.
- Description: Practical mitigation using nitrite scavengers and pH modifiers to block nitrosation in finished dosage forms.

14:00 - 14:10 Short Break

14:10 - 14:40

Session 4: Impurities in Packaging and Single-Use Systems

- Focus: Both Nitrosamines & General Mutagenic Impurities.
- Description: E&L screening for primary packaging and single-use processing tools used in modern manufacturing.

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14:40 - 15:00 Break

15:00 - 15:30

Session 5: Unique Challenges in Biologics

- Focus: General Mutagenic Impurities.
- Description: Assessing genotoxic risks in large molecules and peptides originating from synthetic reagents and single-use manufacturing equipment.

15:30 - 15:40 Short Break

15:40 - 16:10

Session 6: Unexpected Impurities: Cleaning Pitfalls and Particulates

- Focus: Both Nitrosamines & General Mutagenic Impurities.
- Description: Preventing cross-contamination in shared facilities and managing environmental factors like air quality (NOx) during production.

16:10 - 16:20 Short Break

16:20 - 16:50

Session 7: Lifecycle Management & Post-Approval Change Control

- Focus: Both Nitrosamines & General Mutagenic Impurities.
- Description: Managing impurity risks during site transfers, supplier changes and scale-up to ensure continuous compliance throughout the product lifecycle.

16:50 - 17:00 Organizer's closing remarks and end of day two

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Speakers Biographies

December 2nd – 3rd, 2026

Crystal D'Silva

Associate Director – Preclinical Toxicology

Baxter

Crystal D'Silva is a Preclinical subject matter expert at Baxter International and based in Brussels, Belgium. She is actively involved in standard development as a national expert in the ISO/TC 194 Biological and Clinical Evaluation of Medical Devices technical committee and she is part of several working groups within Medicines for Europe, MedTech Europe, and the International Generic and Biosimilars Association. She is also a European Registered Toxicologist (ERT) and a Diplomate of the American Board of Toxicology (DABT). She has a PhD in Medical Biophysics from the University of Toronto in collaboration with the Princess Margaret Cancer Centre and the Hospital for Sick Children (Ontario, Canada).

George Johnson, UK

Associate Professor

Swansea University

George is an Associate Professor at Swansea University, Wales UK. He continues to work with the in vitro Toxicology group in the Institute of Life Science. He is co-chair of the Health and Environmental Sciences Institute (HESI) Genetic Toxicology Technical Committee (GTTC) and co-chair of the quantitative workgroup, working on projects including nitrosamine impurities.

George has worked on projects with US-FDA-NCTR, BfArM, European Medicines Agency (EMA), Health Canada, RIVM-Netherlands, Food Standards Agency along with the pharmaceutical industry and many other companies.

George was President of the EEMGS society in 2021-2023. George has consulted with clients including the pharmaceutical, food additive, fragrances, agrochemical and chemical industries. A major aspect of many of these projects has been the derivation of point of departure metrics for use in human health risk assessments.

Raphael Nudelman

Chemical Toxicologist

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.

Andrew Teasdale, UK

Former Head of Impurity Management & CMC Strategy

AstraZeneca

Andrew Teasdale is an expert in the field of mutagenic impurities other impurity related matters. He has advanced a number of key scientific advancements in the control of impurities as the inventor of the purge factor concept and the instigator of the development of Elemental Impurities database for excipients. With over 50 scientific papers, he has also written 3 books focused on impurity related matters including most recently. Mutagenic Impurities – Strategies for Identification and Control Second Edition. Editor A Teasdale. Publisher Wiley. ISBN 978-1-119-55121-8

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REGISTRATION DATE:

COUPON CODE:

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PACKAGE NAME	2 Days Ticket + Recording - €595 per person ☐	1 Day Ticket + Recording - €415 per person ☐	2 Days Recording - €495 ☐
	Full access to the 2 days online event.	Full access to the 1 day online event.	Recording of 2 days event sessions.
	Digital certificate, List of participants.	Digital certificate, List of participants.	List of participants.
	Recording of 2 days event sessions, PDF.	Recording of 1 day event sessions, PDF.	PDF presentations.

1st Attendee

Full Name:
Job Title:
Company:
Country: Phone:
Email:

2nd Attendee

Full Name:
Job Title:
Company:
Country: Phone:
Email:

3rd Attendee

Full Name:
Job Title:
Company:
Country: Phone:
Email:

4th Attendee

Full Name:
Job Title:
Company:
Country: Phone:
Email:

SEND

INVOICE DETAILS

Full Name:
Job Title:
Company:
Country: City:
Address:
Postcode: Phone:
EU VAT #:
Email:

PAYMENT METHOD

Bank Transfer: ☐ Credit Card: ☐ PayPal: ☐

Signature: «I agree to be bound by Terms and Conditions of registration»

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Discount for additional passes	10%	20%	25%	30%
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Logo on the event webpage	◊	◊	◊	◊
Recognition on our social channels		◊	◊	◊
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Recognition in chairman's opening address		◊	◊	◊