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
Independent Consultant
ATCMC Solutions Limited,
Principle Consultant
Nelson Labs



George Johnson, UK
Consultant
GTOX Ltd
Honorary Associate Professsorship
Swansea University



Robert A. Jolly, USA
Senior Advisor
Eli Lilly and Company



Olivier Dirat, UK
Senior Director, Global Regulatory Sciences CMC Advisory Office
Pfizer



Jan Wenzel, DE
Senior Principal Scientist - Applied Digital Toxicology Expert
Sanofi-Aventis Deutschland GmbH



Stephanie Simon, DE
Associate Scientific Director
Merck Healthcare KGaA



Arianna Bassan, IT
Principal Consultant
Innovatune



Jason Brown, USA
Founder
Brown Pharma Consulting



Maria Chapela, UK
Senior Principal Scientist
GSK



Ian Ashworth, UK
Principal Scientist
AstraZeneca



Gemma Packer, UK
Senior Scientist
Lhasa Limited



Sanghamitra Mishra, IN
Co-founder and Managing Director
NexGenTox

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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.

Our Sponsor



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.

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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



Andrew Teasdale, UK
Independent Consultant
ATCMC Solutions Limited,
Principle Consultant
Nelson Labs

The Nitrosamines journey - current status and future expectations / hopes

o The good news - progress in terms of
• Understanding what is and isn't a risk. • Control options in both API and DP.
• Analysis of Nitrosamines • Adoption of the Less than Lifetime principle.
o The challenges remaining
• Other risk factors - Nox and complexity.
• The CMC rabbit - how many more times will he come to our rescue?
• Is safety science going to provide the answers we need?

12:40 - 12:50 Short Break

12:50- 13:20



George Johnson, UK
Consultant
GTOX Ltd
Associate Professor
Swansea University

Deriving Human Safety Limits for Nitrosamine Impurities Using In Vivo Mutation Data

• Investigating in vivo mutation data for derivation of BMDL metrics.
• Using in vivo mutation BMDl in different mutation derived acceptable intake calculations.
• Future directions in this area...

13:20 - 13:30 Short Break

13:30 - 14:00



Stephanie Simon, DE
Associate Scientific Director
Merck Healthcare KGaA

Practical example how in vivo mutagenicity data can be used to derive human safety limits
• N-Nitroso bisoprolol as case study.
• Applying BMD modeling to identify a PoD.
• Using the relative potency (anchor) approach for calculating an Acceptable Intake (AI) limit.
• Considerations for human risk assessment.

14:00 - 14:10 Short Break

14:10 - 14:40



Raphael Nudelman, IL
Chemical Toxicologist
Nudelman ChemTox Consulting

Nitrosamine Potency Categories (CPCA & EAT)

• A holistic approach to setting acceptable intakes for NDSRIs.
• Other N-nitroso-compounds (o-NNOs).

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14:40 - 15:00 Break

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15:00 - 15:30



Sanghamitra Mishra, IN
Co-founder and Managing Director
NexGenTox

Building a defensible read-across justification for NDSRI acceptable intakes

- Deriving substance-specific acceptable intakes beyond CPCA-based values: practical examples of when read-across supports an alternative intake.
- Establishing a robust read-across justification beyond structural similarity: evaluating multiple criteria relevant to analogue suitability and applying expert judgement to support surrogate selection.
- Preparing a clear justification for regulatory submission: explaining the proposed acceptable intake and addressing uncertainties.

15:30 - 15:40 Short Break

15:40 - 16:10



Robert A. Jolly, USA
Senior Advisor
Eli Lilly and Company

Qualification of Impurities in Drug Substances and Drug Products

- Setting limits for impurities in Development, normal and genotoxic.
- Predicting nitrosamine formation.
- Challenges in setting limits for nitrosamines.

16:10 - 16:20 Short Break

16:20 - 16:50



Olivier Dirat, UK
Senior Director, Global Regulatory Sciences CMC Advisory Office
Pfizer

Nitrosamines – Purge Considerations in Drug Substance Assessments for Nitrosamines

- 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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6th NITROSAMINES

Genotoxic Impurities & Beyond Summit 2026

December 3rd, 2026

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11:20 - 11:25 Registration

11:25 - 11:30 Opening Address from the Organizer

Testing, Formulations and Manufacturing

11:30 - 12:00

Baxter

Beyond the Default: An In Vitro Weight-of-Evidence Framework for Challenging CPCA-Based Nitrosamine AI Limits

- Default CPCA-based potency categorization often assigns nitrosamine impurities a conservative lifetime AI limit.
- A three-pillar in vitro alternative — hepatocyte metabolism/reactive-metabolite ID, an enhanced Ames test, and a TK6 mammalian gene mutation assay — can build a mechanistic weight-of-evidence case without in vivo data.
- The 3Rs-aligned framework generalizes across NDSRI-containing drug products and offers a resource-efficient and data-driven pathway to justify alternative AI limits.

12:00 - 12:10 Short Break

12:10 - 12:40



Jan Wenzel, DE
Senior Principal Scientist - Applied Digital Toxicology Expert
Sanofi-Aventis Deutschland GmbH

In silico risk assessment of NAs using quantum chemistry to estimate ethe reactivity and mutagenicity of NAs

- Computational toxicology/chemistry support of Nitrosamines de-risking.
- In silico risk assessment of Nitrosamines using quantum chemistry to estimate the reactivity and mutagenicity of Nitrosamines.
- Demonstrating recent examples.

12:40 - 12:50 Short Break

12:50- 13:20



Maria Chapela, UK
Senior Principal Scientist
GSK

Analytical Method Validation for 2026 standards

-
-

13:20 - 13:30 Short Break

13:30 - 14:00



Arianna Bassan, IT
Principal Consultant
Innovatune

Metabolism of Selected N-Nitrosamine Drug Substance-Related Impurities: Insights from In Silico Predictions

- Metabolic insights from in silico predictions for selected NDSRIs.
- CYP-mediated bioactivation, α-hydroxylation, and detoxification pathways.
- Selected examples.

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14:00 - 14:10 Short Break

14:10 - 14:40



Gemma Packer, UK
Senior Scientist
Lhasa Limited

In Silico and Data Sharing to Understand N-Nitrosamine Formation and Clearance

- This presentation will demonstrate the applicability of in silico tools and data sharing in identifying and informing risk mitigation strategies for nitrosamines.

14:40 - 15:00 Break

15:00 - 15:30



Jason Brown, USA
Founder
Brown Pharma Consulting

Nitrosamine Risks and Controls for Large Molecules and Synthetic Biologics

- What is in scope? From a regulatory standpoint and understanding the science, which product types and possible nitrosamines are of concern?
- What are the unique differences in risks with these product types?
- Why are active nitrosamine controls more important for large molecules and synthetic biologics? What are the key components to keep your product safe?

15:30 - 15:40 Short Break

15:40 - 16:10



Ian Ashworth, UK
Principal Scientist
AstraZeneca

N-Nitrosamine Formation & Degradation in Pharmaceutical Drug Products: The Application of Models Based on Aqueous Kinetics

- General kinetic models of aqueous nitrous acid-based nitrosamine formation.
- Modelling nitrosamine formation in a solid drug products.
- Stability of nitrosamines.

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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6th NITROSAMINES Genotoxic Impurities & Beyond Summit 2026

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

Consultant GTOX Ltd
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.



Olivier Dirat

Senior Director, Global Regulatory Sciences CMC Advisory Office
Pfizer

Olivier Dirat is Senior Director within Pfizer Global Regulatory Sciences CMC Advisory Office where he provides technical and regulatory guidance on a wide array of topics, including CMC regulatory strategies, the development and articulation of control strategies, impurities management, nitrosamines, continuous manufacturing, starting materials, ADCs, peptides, mRNA vaccine lipids and other special cases. External to Pfizer, Olivier is involved with ICH as rapporteur for ICH Q6(R1) (PhRMA) and was deputy topic lead for ICH Q13 IWG (PhRMA), IQ consortium Board of Directors and various working groups including Nitrosamines and EFPIA for CMC topics including Nitrosamines, ICH M7, and ICH Q6. He has co-authored 45 publications and is a regular conference speaker. Olivier is based in Sandwich, UK.



Gemma Packer

Senior Scientist
Lhasa Limited

Dr. Gemma Packer is a Senior Scientist at Lhasa Limited, where she leads the nitrosamine quality initiatives, including the Lhasa Nitrites database and Nitrosamine Formation database. Gemma earned her PhD in Chemistry from the University of Southampton in 2016 and Masters from the University of Leeds in 2013. She has experience in drug discovery and R&D, having worked as a Medicinal Chemist in an R&D department for a pharmaceutical company before joining Lhasa. Her primary interest lies in applying chemical theory to support decision making within industry. Additionally, Gemma serves as a scientific consultant for Consult Lhasa, a subsidiary of Lhasa Limited.



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

Independent Consultant / ATCMC Solutions Limited
Principle Consultant / Nelson Labs

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.
As of since October 1st of 2025, Nelson Labs Europe announced the appointment of Dr. Andrew Teasdale as Principal Consultant.



Jan Wenzel

Senior Principal Scientist - Applied Digital Toxicology Expert
Sanofi-Aventis Deutschland GmbH

Jan Wenzel studied chemistry at the Goethe University Frankfurt, focusing research projects in computational quantum chemistry. His PhD was received from the University of Heidelberg, where he conducted fundamental research for simulation of X-ray absorption spectroscopy. Afterwards, Jan started as PostDoc at Sanofi in Frankfurt. The project's focus was on artificial intelligence methods and deep learning in the field of safety analytics, to advance the capabilities to analyze, predict and optimize safety parameters of novel drug candidates. Currently, Jan is a Senior Principal Scientist in the Toxicology Innovations group at Sanofi. Besides QSAR and artificial intelligence topics in the field of preclinical safety, Jan also supports the analysis of the genotoxic potential of N-Nitrosamine impurities with computational quantum chemical methods.



Maria Chapela

Senior Principal Scientist
GSK

Maria Chapela holds a degree in Chemistry from the University of Santiago de Compostela and a PhD in Organic Chemistry from the University of Vigo, Spain. She has over 20 years of experience in the pharmaceutical industry. At GSK, she has held various roles in Analytical Development within the CMC area, focusing on forced degradation studies and the development and validation of trace analytical methods for mutagenic impurities and nitrosamine drug substance-related impurities (NDSRIs). Maria contributes to mutagenic impurity control strategies for pharmaceutical products, supporting projects from early phase to market application, including contributions to regulatory submissions.

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Speakers Biographies

December 2nd – 3rd, 2026



Stephanie Simon
Associate Scientific Director
Merck Healthcare KGaA

Stephanie Simon is a molecular biologist and board certified toxicologist (ERT) with over 20 years of industry experience at Merck Healthcare KGaA in Darmstadt, Germany. She has a diploma degree in biology from the Technical University of Darmstadt and earned her PhD in Natural Sciences from the University of Heidelberg. Throughout her career at Merck, she has held multiple roles within the Department of Chemical and Preclinical Safety, spanning quality assurance, study direction and laboratory management, and several years leading the Genetic Toxicology group. In her current position as Senior Toxicologist within Chemical Toxicology, she has a particular focus on the risk assessment of impurities including nitrosamines and supports workplace safety and manufacturing processes by deriving health based exposure limits. She is recognized both internally and externally as an expert in genetic toxicology and nitrosamine assessment and actively contributes to national and international scientific working groups, including the HESI GTTC, ICH M7 or Lhasa's data sharing initiatives. Additionally, she contributed to the USP Nitrosamine Conversations.



Robert A. Jolly
Senior Advisor
Eli Lilly and Company

Robert A. Jolly graduated with a degree in pharmacology and toxicology from the University of Wisconsin, Madison. He later received a CPH and an MPH in Environmental Science from the University of Indiana. Bob has worked in the field of Toxicology for over thirty years starting his career in investigative toxicology and moving to human health risk assessment toxicologist in 2010. He is currently a Senior Advisor in the Toxicology group at Eli Lilly and Company where he has worked since 2002. He is a "Diplomate of the American Board of Toxicology (DABT)" with certification since 2012. Bob has coauthored over 50 peer reviewed publications and most recently has published several manuscripts on the toxicology of nitrosamines.



Sanghamitra Mishra
Co-founder and Managing Director
NexGenTox

Sanghamitra Mishra, a European Registered Toxicologist (ERT) and Diplomate of the American Board of Toxicology (DABT), is co-founder and Managing Director of NexGenTox Pvt. Ltd., a Bengaluru-based toxicology consultancy. She has over 18 years' experience in hazard characterisation, human and environmental risk assessment and regulatory toxicology across chemicals, cosmetics, biocides and pharmaceuticals.
Her work applies new approach methodologies, including QSAR, read-across, in vitro methods and AOP-informed strategies, to reduce animal testing. This extends to her doctoral research at Liverpool John Moores University on PBK modelling and QIVIVE.
Prior to NexGenTox, she established the India operations of ToxMinds BV and currently serves as its technical adviser. She has prepared dossiers under REACH, BPR and the EU Cosmetics Regulation, derived exposure limits under ICH guidelines, and engaged directly with EMA, ECHA, SCCS and the CIR Expert Panel.



Arianna Bassan
Principal Consultant
Innovatune

Arianna Bassan is a consultant and European Registered Toxicologist (ERT) with a multidisciplinary background in chemistry, biology, and toxicology. She holds a degree in Chemistry from the University of Padova and a PhD in Chemical Physics from Stockholm University. Her experience spans academia, industry, and regulatory science, including roles at Stockholm University, MSD/Merck & Co., and the European Commission. As co-founder of Innovatune, she specializes in human health hazard assessment, (Q)SAR, read-across, data curation, and computational toxicology. She has coordinated international expert groups on in silico methods and is increasingly focused on the application of artificial intelligence to toxicological risk assessment.



Jason Brown
Founder
Brown Pharma Consulting

Jason Brown is an experienced end to end nitrosamine expert, E&L strategist, and analytical CMC leader. Successful analytical support for development projects, clinical batches, and regulatory submissions including NDA, ANDA, and tech transfers. Leadership of Extractables & Leachables studies from initial risk assessment to study design. Navigating the scientific challenges and frequent regulatory updates to ensure compliance.
Proven knowledge in nitrosamine risk assessments, structural identification, analytical techniques, root cause analysis, reformulation, and control strategies. Author of July 2025 AAPS Newsmagazine Cover Article, «Nitrosamine Control Strategies: From Risk Identification to Implementation.» Recognized innovator with a patent application for reformulation techniques and research articles concerning inhibition techniques and gastric nitrosamine formation in addition to numerous panel discussions, speakerships, posters, articles, and co-host of the USP Nitrosamine Conversations.



Ian Ashworth
Principal Scientist
AstraZeneca

Career summary: Over thirty years of experience of applying physical organic chemistry to solve problems within a process chemistry environment, initially in speciality chemicals and agrochemicals, before moving to pharmaceuticals. Throughout an interest in pH dependent reactions and hydrolytic stability has been a recurring theme. Most recently this has been applied to the building mechanism-based models of nitrosamine formation in aqueous solution as tools to support drug substance and drug product risk assessments.
Academic Background: BSc in Chemistry from Durham University followed by a D Phil in Chemistry at Cambridge University with Tony Kirby, which provided an introduction to pH dependent kinetics.

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	Digital certificate, List of participants.	Digital certificate, List of participants.	List of participants.
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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:
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SEND

INVOICE DETAILS

Full Name:
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Company:
Country: City:
Address:
Postcode: Phone:
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