5TH Annual Summit

GENOTOXIC & NON-GENOTOXIC IMPURITIES

NITROSAMINES & BEYOND

VIRTUAL | DECEMBER 4TH- 5TH, 2025

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

Reinhard Stidl, AT
Senior Toxicologist - Managing Director
Safetree Consulting e.U.

Olivier Dirat, UK
Senior Director – Global Regulatory Sciences
Pfizer

Teresa Wegesser, USA
Scientific Director
Amgen

Lukas Jost, DE
PhD student
Fresenius Medical Care

Patrick Reichl, AT
Toxicology and Non-clinical Consultant
ATGC e.U.

Mike Urquhart, UK
Scientific Director
GSK

Susanne Glowienke, CH
Head Impurity Safety
Novartis Pharma AG

George Johnson, UK
Associate Professor & Vice-President
Swansea University

Malcolm Ross, CH
Consultant
Generapharm

Jason Brown, USA
Director, Analytical Sciences
Adare Pharma Solutions

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

Jack Lupton, UK
Senior Application Scientist
Lhasa Limited

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5TH Annual Summit

virtual | December 4 - 5, 2025

GENOTOXIC & NON-GENOTOXIC IMPURITIES

NITROSAMINES & BEYOND

CONFERENCE OVERVIEW

Join industry leaders, regulatory experts and scientific innovators at the **5th Genotoxic and Non-Genotoxic Impurities: Nitrosamines and Beyond Summit**, a premier two-day virtual event focused on the latest developments, regulatory expectations and technical challenges in impurity control.

Day 1 delves deep into the evolving landscape of nitrosamine impurities, featuring expert-led sessions on global regulatory updates, risk assessment strategies, toxicological evaluation and advanced analytical techniques. Discussions will cover nitrosamine drug substance-related impurities (NDSRIs), predictive assessments using in silico tools and the impact of formulation, manufacturing and stability on impurity formation.

Day 2 expands the focus to genotoxic and non-genotoxic impurities, highlighting computational tools for early hazard identification, common profiling pitfalls and unique challenges in biologics and medical devices. With dedicated sessions on qualification and regulatory perspectives, the summit provides a comprehensive view on managing both mutagenic and non-mutagenic impurity risks across the pharmaceutical lifecycle.

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 and In-Silico Modeling Specialists
- Biologics and Medical Device Developers

This event is relevant to professionals in pharmaceutical, biotechnology, medical devices, contract manufacturing and regulatory agencies seeking to stay ahead of current impurity challenges and compliance requirements.

WHAT WE WILL DISCUSS

- Global nitrosamine regulations, risk assessment tools and control strategies.
- In-silico models and SAR tools for predicting nitrosamine formation pathways.
- Analytical advances for detecting low-level nitrosamines and NDSRIs in products.
- Formulation and manufacturing factors influencing nitrosamine impurity levels.
- Strategies for identifying and controlling genotoxic and non-genotoxic impurities.
- Regulatory and toxicological approaches to qualify elemental and unknown impurities.

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12:00 - 12:05 Registration

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

NITROSAMINES – CURRENT CHALLENGES AND FUTURE DIRECTIONS

12:10 - 12:40

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

AstraZeneca

N-Nitrosamines - Past, present and future a personal reflection

- Current situation - level of risk.
- Risk Assessment - what are the main areas of concern / risk.
- What we have learnt from scientific Collaboration control and analysis.
- Safety Science and Acceptable Intakes - strengths and limitations of CPCA and EAT.
- What next for Nitrosamines - What would success look like.

12:40 - 12:50 Short Break

12:50- 13:20

George Johnson, UK
Associate Professor & Vice-President
Swansea University

Swansea University Prifysgol Abertawe

Using In Vivo Mutation Data in Risk Assessments of Nitrosamines

- Use of genetic toxicity data for assessing nitrosamines.
- Calculating BMD and AI using in vivo mutation data.
- Recent considerations from the ICH M7.

13:20 - 13:30 Short Break

13:30 - 14:00

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

Baxter

Toxicological Risk Assessment of N-Nitrosamines: Challenges and Perspectives

- Overview of toxicological risk assessment of nitrosamines.
- Comparison between agency- and literature-published acceptable intake values.
- Challenges with the current state of affairs and future perspectives.
- Weight-of-evidence approach in setting acceptable intake limits – NDBzA as a case study.

14:00 - 14:10 Short Break

14:10 - 14:40

Lukas Jost, DE
PhD student
Fresenius Medical Care

FRESENIUS MEDICAL CARE

Facing the Analytical Challenge – Nitrosamines in Large Volume Parenterals

- Analytical challenges in Large Volume Parenterals.
- Method development at ppt range.
- Method validation in an international laboratory network.

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14:40 - 15:00 Break

15:00 - 15:30

Raphael Nudelman, IL
Chemical Toxicologist
Nudelman ChemTox Consulting

Updates on Setting Limits for NDSRIs

Using holistic weight-of-evidence to set acceptable intake (AI) limits for NDSRIs including:
- Anchor approach based on positive in vivo mutagenicity data.
- QM and CYP 450 binding to categorize potency.

15:30 - 15:40 Short Break

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16:10 - 16:20 Short Break

16:20 - 17:00

Malcolm Ross, CH
Consultant
Generapharm

Nitrosamine strategies - prevention or cure?

- Avoidance of risk.
  a. The drug substance; b. The drug product process; c. The drug product formulation
- Risk reduction (amelioration).
  a. Process change; b. Low nitrite strategies; c. Scavengers - a last resort?
- The regulatory implications involved in risk reduction.
  a. Stability; b. Bioavailability and biowaivers;

17:00 - 17:10 Short Break

17:10 - 17:55

Jason Brown, USA
Director, Analytical Sciences
Adare Pharma Solutions

Effective Strategies for Nitrosamine Control and Inhibition

- Processes from initial risk identification through control strategy implementation.
- Product control vs. testing requirements.
- Mitigation techniques, when active change is needed.

17:55 - 18:00 Chairman's closing remarks and end of day one

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12:00 - 12:05 Registration

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

GENOTOXIC AND NON-GENOTOXIC IMPURITIES – BROADER IMPLICATIONS

12:10 - 12:40

Susanne Glowienke, CH
Head Impurity Safety
Novartis Pharma AG

NOVARTIS

Understanding safety limits for nitrosamine impurities in pharmaceuticals

- Regulatory expectation of very low default limit for NDSRIs.
- Nitrosamines and carcinogenic potency.
- CPCA / EAT / MutaMouse – main elements in nitrosamine limit setting.
- Predictivity of the EAT (Enhanced Ames test).

12:40 - 12:50 Short Break

12:50 - 13:30

Mike Urquhart, UK
Scientific Director
GSK

GSK

Enhancements to the N-nitrosamine risk assessment process

- Background to N-nitrosamines and impurities
- Publication of the EFPIA / IQ DS and DP workflows within OPRD.
- An enhancement to the risk assessment process through the development of additional workflows for potential amine impurities for DS and DP.
- Focus areas for science – based on CMC wish list from external health authorities.
- Summary, Reflections and looking forward.

13:30 - 13:40 Short Break

13:40 - 14:10

Patrick Reichl, AT
Toxicology and Non-clinical Consultant
ATGC e.U.

ATGC

Toxicological Risk Assessment of Impurities in Medical Devices

- Regulatory updates in the new ISO 10993-1 and impact on toxicological risk assessment.
- Practical challenges in applying ISO 10993-17:2023 for medical devices.
- Case studies.

14:10 - 14:20 Short Break

14:20 - 14:50

Olivier Dirat, UK
Senior Director – Global Regulatory Sciences
Pfizer

Pfizer

Non-mutagenic impurities: Recent advances, regulatory challenges, impact of global divergence and possible solutions via ICH Q6(R1) revision

- Overview of recent advances for non-mutagenic impurities.
- Potential impact of the EMA reflection paper on non-mutagenic impurities.
- Impact of global regulatory divergence and what it means in the real world.
- Possible alternative framework for non-mutagenic impurities.
- ICH Q6(R1) revision: opportunities for increased harmonisation and use of science and risk-based approaches.

14:50 - 15:10 Break

15:10 - 15:40

Reinhard Stidl, AT
Senior Toxicologist - Managing Director
Safetree Consulting e.U.

Toxicological Risk Assessment of Impurities from Packaging and Manufacturing Equipment: Extractables and Leachables

- Current standard approaches in toxicological risk assessment of E&L.
- Route to route extrapolation and read across.
- Update on ICH guideline Q3E on the assessment and control of E&L.

15:40 - 15:50 Short Break

15:50 - 16:20

Teresa Wegesser, USA
Scientific Director
Amgen

Qualification of Non-Mutagenic Impurities

- Overview of approaches for qualifying non-mutagenic impurities.
- Key considerations from the EMA Draft Reflection Paper on the Qualification of NMIs.
- Establishing acceptable limits based on safety data and exposure levels.

16:20 - 16:30 Short Break

16:30 - 17:00

Jack Lupton, UK
Senior Application Scientist
Lhasa Limited

Unlock robust elemental impurities data for harmonised ICH Q3D risk assessments and an efficient in silico workflow

- Achieve confident decision making through pre-competitive data sharing initiatives, driven by industry collaboration.
- Automate the identification and calculation of elemental impurities with a high-quality database and user-friendly software.
- Transforming ICH Q3D risk assessments into streamlined in silico workflows.

17:00 - 17:10 Chairman's closing remarks and end of day two

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Speakers Biographies

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Crystal D'Silva
Associate Director – Preclinical Toxicology
Baxter

Crystal D'Silva is based in Brussels, Belgium and currently holds the position of Pre-Clinical Technical Lead at Baxter. She is responsible for contributing to strategic Pre-Clinical R&D cross-function, cross-region, and cross-disciplinary programs with global impact across Baxter's business segments and innovation platforms. She provides industry expertise in shaping external scientific committee guidelines (e.g., ISO 10993, FDA, ICH) and regional compendia in the areas of Pre-Clinical Sciences. She is also a European Registered Toxicologist (ERT) and a member of the European Society of Toxicology In Vitro (ESTIV) and the Belgian Society of Toxicology and Ecotoxicology (BELTOX). 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).

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.

Jason Brown
Director, Analytical Sciences
Adare Pharma Solutions

Jason Brown brings a wealth of knowledge and practical experience to his role as Director of Analytical Sciences at Adare Pharma Solutions, where he serves as the global nitrosamine subject matter expert. He has led Adare's innovative approaches to understanding nitrosamine formation, measurement, and mitigation to ensure regulatory compliance internally and for our customers. Jason has led numerous dialogues on the subject of nitrosamines through panel discussions, webinars, posters, articles, and regular contributions to the USP Nitrosamine Forum. He can be contacted at jason.brown@adareps.com

Patrick Reichl
Toxicologist and Non-Clinical Consultant
ATGC e.U.

Patrick Reichl is a non-clinical consultant with extensive experience in the pharmaceutical and medical device industries. He is a European Registered Toxicologist (ERT) with a PhD in Biology and a Master's degree in Toxicology. He began his career as a Toxicological Risk Assessor at Baxter and later served as Toxicology Lead at Croma Pharma before transitioning to independent consulting and founding ATGC e.U. in 2025. His expertise includes in silico toxicology, genotoxicity assessment as well as the evaluation of devices, excipients, materials and impurities, with a focus on developing non-clinical strategies to support global regulatory submissions.

Mike Urquhart
Scientific Director
GSK

Mike Urquhart (Ph.D.) works for GSK and has over 25 years' experience within the Pharmaceutical industry, working mainly in research and development as a Synthetic Organic Chemist. Mike is a Scientific Director, having mutagenic impurity risk assessment expertise, who co-chairs both the Genotoxic Impurity Risk assessment and Impurities Oversight Panels at GSK. Mike works across industry within trade associations around aspects of ICH M7 and presents externally on best practice for mutagenic impurity control strategies for pharmaceutical products.

Susanne Glowienke
Head Impurity Safety
Novartis Pharma AG

Dr. Susanne Glowienke graduated at the University of Stuttgart-Hohenheim, Germany, in Food Chemistry/Technology. She then undertook research in the area of analytical chemistry and obtained her PhD degree from the Faculty of Food Technology (Cereal Chemistry) in 1997 at the same university. She joined Novartis, Basel, Switzerland, in 2000 as a postdoc in the area of Q(SAR) for toxicological endpoints. Susanne was working as a lab head for bacterial mutagenesis in Genetic Toxicology, Preclinical Safety and is responsible for the QSAR predictions and impurity/excipient assessments at Novartis. Currently, Susanne is a Director in Preclinical Safety at Novartis, Basel, Switzerland. She held several positions at Novartis including positions in Genetic Toxicology and QSAR modelling. She is currently head of the Impurity Safety group and as such responsible for contaminant issues including nitrosamines. Susanne is part and has led a number of industry expert groups within DruSafe IQ (US), European Federation of Pharmaceutical Industries and Associations (EFPIA), the Extractables and Leachables Safety Information Exchange (ELSIE) and several data sharing initiatives.

George Johnson
Associate Professor & Vice-President
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.

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Speakers Biographies

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Olivier Dirat
Senior Director – Global Regulatory Sciences
Pfizer

Olivier Dirat completed his PhD in organic chemistry at Paris University, followed by a post-doctoral position at Stanford University. Olivier has over 20 years of industrial experience in discovery and late-stage API process development at Merck and Pfizer and currently holds the position of Senior Director within Pfizer Global Regulatory Sciences CMC Advisory Office where he provides technical and regulatory guidance and direction to teams on a wide array of topics, including CMC regulatory strategies, the development and articulation of control strategies, impurities management, N-nitrosamines, continuous manufacturing, starting materials, ADCs, mRNA vaccine lipids and other special cases. He also leads a CMC team focussing on post approval marketed products. He chairs one of Pfizer's Impurities Councils, a multidisciplinary council that provides advice to teams regarding impurities (including nitrosamines) from safety, quality and regulatory perspectives. External to Pfizer, Olivier is involved with ICH as co-rapporteur for ICH Q6 EWG (PhRMA) and deputy topic lead for ICH Q13 IWG (PhRMA), IQ consortium Board of Directors, and also on N-Nitrosamines, Starting Materials, ADCs, Co-processed APIs, Novel Excipients and EFPIA MQEG CMC team and on N-Nitrosamines, ICH M7, and ICH Q6. Olivier is based in Sandwich, UK.

Jack Lupton
Senior Application Scientist
Lhasa Limited

Jack Lupton is a Senior Application Scientist at Lhasa Limited, a leading not-for-profit organisation responsible for the creation of in silico software solutions which support confident decision making on chemical safety.
Jack has hands-on clinical pathology expertise, as well as a Master's degree in Medical Biochemistry, both of which help to support a range of clinical and preclinical studies in drug development.
As Senior Application Scientist at Lhasa Limited, Jack works closely with industry stakeholders and regulatory representatives to ensure Lhasa's data sharing initiatives continue to provide the robust data required to solve challenges in chemical safety. This includes helping to reduce the need for duplicated testing and driving the refinement of Structure Activity Relationships (SAR).
Lhasa is at the forefront of industry and regulatory collaboration, providing several successful proprietary data sharing initiatives and software solutions which facilitate expert chemical safety assessments that meet regulatory compliance.

Reinhard Stidl
Senior Toxicologist - Managing Director
Safetree Consulting e.U.

Reinhard has more than 16 years of experience as Toxicological Risk Assessor in the pharmaceutical and medical device context. He works as an independent toxicology consultant and founded Safetree Consulting e.U. (since 2018). Reinhard holds a Master and PhD in Chemistry, a Master of Advanced Studies Toxicology, is Certified European Risk Assessor (TRISK) and EUROTOX registered toxicologist (ERT). He started his career as Toxicological Risk Assessor and team leader at Baxter, later Baxalta and Shire, where his last assignment was Associate Director Toxicological Risk Assessments, responsible for the global design and toxicological risk assessment strategy in a global context. Reinhard is specialized in chemical safety assessment, with focus on impurities (including extractables and leachables), active ingredients (carry-over PDEs, OELs), excipients and quality defects. Today, he provides his expertise to clients around the world, assisting to make pharmaceutical and medical products safe for patients.

Malcolm Ross
Consultant
Generapharm

A pharmacist and medicinal chemist working in the pharmaceutical industry for over 30 years. Worked in the generic industry for over 30 years in Israel, USA and Poland.
From 2016, based in Switzerland, has acted as a consultant and trainer for many companies in Europe and Asia and has been an external employee of Novartis in various roles including QA, Technical services and as a member of the Nitrosamine task force.

Teresa Wegesser
Scientific Director
Amgen

Teresa Wegesser, PhD, is a Scientific Director in Translational Safety & Risk Sciences at Amgen and a recognized subject matter expert in impurity safety assessment, including ICH Q3A/B, M7, Q3C, Q3D, nitrosamines, excipients, and CMC mitigation strategies. External to Amgen, Teresa is also involved in impurity and excipient related roles in PhRMA, EWG ICH Q3D, IQ DruSafe, IPEC Americas, and EFPIA working groups, and has published on impurities and excipient safety. As a Nonclinical Safety Project Team Representative, Teresa provides strategic guidance on cross-functional development teams for both small and large molecules, spanning all phases of development, with expertise in safety liability assessment, nonclinical study design and interpretation, and regulatory submissions.

Lukas Jost
PhD student
Fresenius Medical Care

Lukas Jost studied pharmacy at Saarland University from 2017 to 2022. After completing the first half of a pharmacy internship in a public pharmacy (May–October 2022), he joined Fresenius Medical Care for the second half, working in Product Line Quality Management & Regulatory Affairs for "Solutions and PD Accessories" (November 2022–April 2023). In June 2023, he obtained a license to practice as a pharmacist.
Since then, Lukas Jost has been pursuing a PhD in the Chemical Analytical Laboratory at Fresenius Medical Care, in cooperation with Johannes Gutenberg University Mainz and the University of Applied Sciences Trier. Hisresearch focuses on nitrosamine impurities and non-targeted screening using high-resolution LC-MS/MS techniques.

Andrew Teasdale
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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1st Attendee

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Company:
Country: Phone:
Email:

2nd Attendee

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

3rd Attendee

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Company:
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