March **15-16**, 2023 | Milan, Italy & Online (CET) | **#VLgenotoxic**

CONFERENCE & EXPO

7th IMPURITIES:
Genotoxic, Nitrosamine & Beyond Summit

The recall of Valsartan has proved a critical need of a rational risk assessment strategy for potential nitrosamines in pharmaceutical products.

At the **#VLgenotoxic 2023**, along with focussing on the N-nitrosamines, we will explore the most important aspects around the detecting and reporting of genotoxic impurities, current investigations and regulatory, toxicological, analytical, pharmaceutical relevant prospects related to GTIs, as well as recent advances and further development and future considerations towards the different types of impurities present in drugs.

Join the keynote presentations and case studies, participate in the interactive panel discussions and Q&As, visit exhibitions, and extend partnership opportunities while learning about the advanced strategies and perspectives in the landscape of impurities and E&L at the **7th Impurities: Genotoxic, Nitrosamine & Beyond conference** on **March 15-16, 2023**.

Key Practical Learning Points:

- Critical considerations on compliant implementation of ICH M7 and Q3D
- Assessment and control of DNA reactive (mutagenic) N-nitrosamines impurities to limit potential carcinogenic risk
- Uncertainties, misalignment, investigations, observations, and experiences related to nitrosamine
- New frontiers in techniques, technologies and partnerships in genotoxic impurities identification, monitoring, and control
- Recent developments in risk assessment and recommendations on the safety qualification of impurities
- Ongoing advancements on the potential gaps affecting impurities identifying and control
- Genotoxic impurities CMC regulatory requirements, pitfalls, and expectations in the field
- Efficient strategies to assess, test, and control impurities in pharmaceutical products, drug substances/APIs, and excipients
- Evaluation of extractables and leachables (E&L) for genotoxic potential
- Analytical, regulatory, and toxicology achievements and prospects for compliant mutagenic and elemental impurities identification, monitoring, and control

Dr. Susanne Glowienke, CH
Director, Preclinical Safety
Novartis Pharma AG

Dr. Andrew Teasdale, UK
Senior Principal Scientist / Head of Impurity Management & CMC Strategy
AstraZeneca

Dr. Carla Landolfi, IT
European Registered Toxicologist (ERT) / CEO - Toxicology Risk Assessor
ToxHub

Dr. Rodney Parsons, US
Executive Director, Chemical Development
Bristol Myers Squibb

Dr. Joerg Schlingemann, DE
Director, Principal Expert Quality Control Systems
Merck Healthcare KGaA

Dr. George Johnson, UK
Associate Professor
Institute of Life Science at Swansea University

Dr. Arianna Bassan, IT
Principal Consultant
Innovatune

Dr. Raphael Nudelman, IL
Senior Director of Impurity Expert, R&D Operations
Teva Pharmaceutical Industries Ltd.

Irene Cecchini, IT
Senior Principal Scientist
Healthcare Business of Merck

Dr. Paulo Eliandro da Silva Junior, BR
Technical and Regulatory Director
Integra Consultancy

Dr. Aloka Srinivasan, US
Principal and Managing Partner
RAAHA LLC

Dr. Dana Lena Budde, DE
Scientist Biocompatibility Testing Product Development Bioreactor Characterisation
Sartorius Stedim Biotech GmbH

Marina Couva, CY
QPPV
Medochemie Ltd

SPONSORSHIP SPEAKING &
EXHIBITION OPPORTUNITIES AVAILABLE

Event Sponsor & Partner

INNOVATUNE

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March **15-16**, 2023 | Milan, Italy & Online (CET) | **#VLgenotoxic**

7th IMPURITIES: Genotoxic, Nitrosamine & Beyond Summit

Sponsorship-related questions to: **emma.rosenberg@vonlanthen-conferences.com**

Who Should Attend

Chief Executives, Vice Presidents, Directors, Heads, Leaders, and Managers specialising in:

- Analytical Science
- Active Pharmaceutical Ingredient (API) Development
- Assay Development
- Carcinogens
- Chemistry (Analytical, Organic, Medicinal, Protein)
- Drug Safety
- Elemental Impurities
- Extractables & Leachables (E&L)
- Genetic Toxicology
- Genotoxic Impurities (GTIs)
- Genotoxicity
- Good Manufacturing Practices (GMP)
- Good Laboratory Practice (GLP)
- Impurities
- In Silico
- Microscopy
- Mutagenic Impurities
- Mutagenicity
- N-Nitrosamine
- Organic Synthesis
- Permitted Daily Exposure (PDEs)
- Purification
- Quality Assurance
- Quality by Design (QbD)
- Quality Control
- Regulatory
- Toxicology
- Validation
- Quantitative Structure-Activity Relationships (QSAR)

Company type:

- Pharmaceutical
- Biotechnologies
- Clinical Research & Development
- Tech/Service Providers

Geographic Distribution:

- Europe
- United States
- Other

VONLANTHEN CONFERENCES

7th IMPURITIES: Genotoxic, Nitrosamine & Beyond Summit

Schedule

DAY 1 | March **15**, 2023 | MILAN, ITALY & ONLINE (CET) | #VLgenotoxic

08:30 Registration and Welcome Coffee/Networking/Exhibition Break

09:00 Opening by Moderator

09:10

Current developments related to nitrosamines and strategies for control of nitrosamine in pharmaceuticals

- Gaps in communications between different regulatory agencies
- NDSRIs and the related challenges; are they all carcinogenic?
- Dilemma with acceptable intakes; what makes a good surrogate?
- Challenges with analytical methods; is mass spec the only solution?
- Challenges of reformulation using nitrite scavengers; what about IID?

Dr. Aloka Srinivasan, US | Principal and Managing Partner | RAAHA LLC

09:50 SPEED NETWORKING

10:20

Recent updates on nitrosamines: Areas of uncertainty and misalignment

- Quality-related issues
- Safety issues
- Regulatory issues

Dr. Andrew Teasdale, UK | Senior Principal Scientist | Head of Impurity Management & CMC Strategy | AstraZeneca

11:00 NETWORKING/COFFEE/EXHIBITION BREAK

11:30

High-throughput cell-painting assay to assess E&L genotoxicity

- The mode of action of E&L on cells is difficult to investigate
- An unbiased high throughput screening (cell painting) with a human U2OS cell line was used to study 45 different compounds
- Comparison of the read-outs with a reference library allows prediction of the mode of action of E&L on cells

Dr. Dana Lena Budde, DE | Scientist Biocompatibility Testing | Product Development Bioreactor Characterization | Sartorius Stedim Biotech GmbH

12:10 **Supporting N-nitrosamine risk assessments for drug products**

12:40 OPEN SPONSORSHIP OPPORTUNITIES 15-20-30 MIN

Sponsorhip-related questions to:
emma.rosenberg@vonlanthen-conferences.com

13:10 BUSINESS LUNCH

14:10 NETWORKING/COFFEE/EXHIBITION BREAK

14:30

Risk assessment for pharma and biotech products

Irene Cecchini, IT | Senior Principal Scientist | Healthcare Business of Merck

15:10

Analytical challenges

Dr. Joerg Schlingemann, DE | Director, Principal Expert Quality Control Systems | Merck Healthcare KGaA

15:50 SPONSORSHIP SPEAKING SLOT

Defining AI limits of N-nitrosamines based on structure activity relationship (SAR) analysis

- SAR analysis workflow for data-poor nitrosamines
- Local and global similarity
- Potency categories and read-across

Dr. Arianna Bassan, IT | Principal Consultant | Innovatune

INNOVATUNE

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16:10	NETWORKING/COFFEE/EXHIBITION BREAK
16:40	 **Genotoxicity evaluation of a valsartan-related complex N-nitroso-impurity/safety assesment** • Genotoxicity assessment of a complex N-nitrosamine • Structural considerations • Ames test and in-vivo transgenic rodent assay to address mutagenicity Dr. Susanne Glowienke, CH | Director, Preclinical Safety | Novartis Pharma AG
17:20	 **End-to-end nitrosamine assessment and control** Dr. Rodney Parsons, US | Executive Director, Chemical Development | Bristol Myers Squibb
18:00	Q&A/PANEL DISCUSSION (All Speakers of the Day Are Invited) & MODERATOR'S CLOSING REMARKS
18:30	NETWORKING/EXHIBITION BREAK | 30min

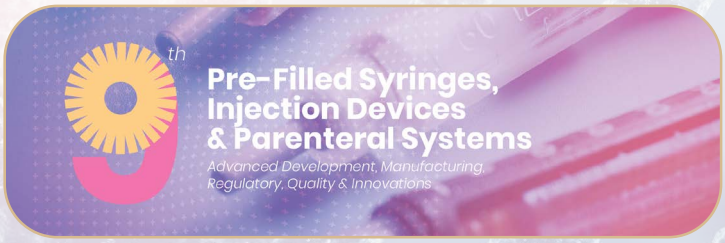
Find Out More About Our
Event Sponsor

Innovatune is a science- and technology-based company providing consultancy services for the hazard assessment of chemicals mainly focusing on human health. The services make the most of in silico methods, which aim at predicting toxicity from the molecular structure of chemicals. Hazard assessment of chemicals builds on the combination of information from different sources in an efficient and informed way; when available, standardised protocols are followed to integrate relevant data (in vitro, in vivo, human) with adequate in silico predictions. Innovatune is committed in advancing the use of new approach methodologies and, in particular, in silico approaches in regulatory contexts.

INNOVATUNE

Check Our
Upcoming Event

9th Pre-Filled Syringes, Injection Devices & Parenteral Systems
March 01-02, 2023 | Vienna, Austria | #VLpfs



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08:30 Registration and Welcome Coffee / Networking / Exhibition Break

09:00 Opening by Moderator

09:05

Nitrosamines in APIs – Quantitation according to USP General Chapter <1469> and beyond

- Nitrosamine testing according to USP monograph
- Expanding the scope beyond USP materials
- Certification of relevant reference standards
- API nitrosamine derivatives

Dr. Markus Obkircher, CH | Director, Research & Development | Merck Life Science

09:40

OPEN SPONSORSHIP OPPORTUNITIES 15-20-30 MIN

Sponsorhip-related questions to:
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10:00

Setting limits for NDSRIs

Dr. Raphael Nudelman, IL | Senior Director of Impurity Expert, R&D Operations | Teva Pharmaceutical Industries Ltd.

10:40

Setting limits for novel N-nitrosamines in active pharmaceutical ingredients

- State-of-the-art strategies and approaches for assessing acceptable intakes

Dr. Carla Landolfi, IT | European Registered Toxicologist (ERT) | CEO - Toxicology Risk Assessor | ToxHub

11:15 NETWORKING/COFFEE/EXHIBITION BREAK

11:45

Risk assessment of nitrosamines

Dr. George Johnson, UK | Associate Professor | Institute of Life Science at Swansea University

12:15

Considerations around NDMA in ranitidine

Marina Couva, CY | QPPV | Medochemie Ltd

12:35

Understanding the chemistry and risk of forming nitrosamines in drug products: From key starting material synthesis through drug product manufacturing and product stability

- Evaluation of the chemical environment of drugs to assess the formation of mutagenic impurities and determine strategies to measure their risk

Dr. Paulo Eliandro da Silva Junior, BR | Technical and Regulatory Director | Integra Consultancy

13:05 Q&A/PANEL DISCUSSION (All Speakers of the Day Are Invited) & MODERATOR'S CLOSING REMARKS

13:35 NETWORKING/COFFEE/EXHIBITION BREAK

14:00 BUSINESS LUNCH

Dr. Susanne Glowienke, CH | Director, Preclinical Safety | Novartis Pharma AG

Dr. Susanne Glowienke graduated from 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. In 2000, she joined Novartis in Basel, Switzerland, 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 of 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.

Dr. Raphael Nudelman, IL | Senior Director of Impurity Expert, R&D Operations | Teva Pharmaceutical Industries Ltd.

Raphael Nudelman holds a master's of pharmaceutical sciences from the Hebrew University of Jerusalem and a PhD in organic chemistry from the Weizmann Institute of Science in Rehovot, Israel. He held research fellow positions in the US Air Force Research Lab in Aberdeen Proving Ground, Maryland, USA, and at the Duke University Medical Center, North Carolina, USA. He has been with Teva Pharmaceutical Industries in Israel since 2003 and has held research positions in the medicinal chemistry department and the patent department. Since 2010, he has been the head of chemical and computational toxicology in Teva's non-clinical safety department. From 2011-16, Raphael also served as the president of the medicinal chemistry section of the Israel Chemical Society.

Dr. Andrew Teasdale, UK | Senior Principal Scientist | Head of Impurity Management & CMC Strategy | AstraZeneca

Andrew Teasdale, PhD, is a senior principal scientist in impurity management and external advocacy at AstraZeneca. Andrew has over 20 years' experience in the pharmaceutical industry as an analytical chemist and within quality assurance and regulatory roles. In his current role, he chairs AstraZeneca's impurity advisory group. Andrew has published over 30 papers relating to genotoxic impurities and other impurity-related matters and has been a speaker at many international conferences. He has also led a number of industry expert groups; these include both safety and quality groups within Pharmaceutical Research and Manufacturers of America (PhRMA), European Federation of Pharmaceutical Industries and Associations (EFPIA), Product Quality Research Institute (PQRI), and the Extractables and Leachables Safety Information Exchange (ELSIE). Andrew led the recent development of the ICH M7 addendum table from an industry perspective and was the inventor of the purge tool concept, Mirabilis™. He also published a book addressing genotoxic impurities, 'Genotoxic Impurities Strategies for Identification and Control,' (Wiley and Son) and is soon to publish as editor a book focussed on practical implementation of ICH quality guidelines.

Irene Cecchini, IT | Senior Principal Scientist | Healthcare Business of Merck

Irene Cecchini works as Principal Scientist in Merck Biotech Product Development division based in Guidonia Site, close to Rome - Italy. She graduated in Analytical Chemistry at the University of Rome in 2003 and joined former Serono as an analytical methods development junior researcher in the same year. In the following years, she devel-oped her expertise, particularly in Extractables & Leachables (E&L), elemental impurities, and sub-visible particles (SbVP) fields. In 2016 she was appointed Lab Manager of the E&L group, where she managed E&L studies on the final biotech products containers, as well as for manufacturing processes materials (Single Use Systems) and coordinated analyti-cal investigations linked to manufacturing processes issues. Starting June 2019, she has been appointed Principal Scientist in the Impurity Analytics Unit of Analytical Development Biotech Department dealing with chemical and biological process impurities. She is a member of ELSIE, BPOG, and SbVP industry consortia.

Dr. Carla Landolfi, IT | European Registered Toxicologist (ERT) | CEO - Toxicology Risk Assessor | ToxHub

Dr. Carla Landolfi graduated in chemistry and pharmaceutical technology from Rome University. She has more than 20 years of experience in the toxicology field gained in the pharmaceutical industry, 10 of them as manager to the toxicology group. She's the main or co-author of several papers and posters, has published in peer-reviewed journals, and she's an invited speaker at international conferences as well as the founding editor of archives of clinical toxicology. In 2020, she founded the ToxHub, a consultancy company specialised in toxicological risk assessment and regulatory toxicology.

Dr. George Johnson, UK | Associate Professor | Institute of Life Science at Swansea University

George Johnson is an associate professor of genetic toxicology at Swansea University. He has expertise in the quantitative use of genetic toxicity data for hazard and risk assessment purposes and has an interest in high content and multiplex in-vitro test systems. He currently has active roles in the HESI-GTTC, IWGT 2022, COM and EEMGS-EXCOM, and carries out teaching, research, and consultancy at Swansea.

Dr. Paulo Eliandro da Silva Junior, BR | Technical and Regulatory Director | Integra Consultancy

Dr. Paulo Eliandro da Silva Junior is a pharmacist-biochemist (USP) with a master's and PhD in medicinal chemistry, synthesis and drug discovery (FCFRP-USP, University of East Anglia – UEA, UK; Johannes Gutenberg University of Mainz – JGU, Germany). His experience in the pharmaceutical industry started in 2013 as a trainee at Novartis (Horsham, UK) in the global discovery chemistry department, and after that Paulo worked mainly in the regulatory affairs department with a focus on drug master file (DMF), quality audits, mutagenic impurities, purge factor calculations, and control of nitrosamines on his own consulting company, Integra Consultancy and BIND, a company that works with synthesis and characterisation of analytical standards, such as degradation product, azides, and nitrosamines.

Dr. Rodney Parsons, US | Executive Director, Chemical Development | Bristol Myers Squibb

Dr. Rodney Parsons earned his bachelor's degree in chemistry in 1986 from Trinity College and then received his PhD in 1992 from the University of Vermont under the guidance of Professor Martin E. Kuehne. His doctoral studies were focussed on the development of novel routes for the construction of indole alkaloids. He then carried out postdoctoral studies in organic chemistry with Professor Clayton H. Heathcock at the University of California at Berkeley. In 1994 he became a research scientist at Dupont-Merck Pharmaceutical Co., where he eventually rose to the rank of director. In 2001, after the acquisition of the DuPont Pharmaceuticals Co., he joined Bristol-Myers Squibb, where he is currently an executive director in the chemical process development department. He has been involved with drug development programs in a number of therapeutic areas including virology, cardiovascular, oncology, and metabolic diseases. His research interests include pharmaceutical process R&D, asymmetric synthesis, heterocyclic chemistry, and natural products total synthesis. He has been the BMS Mutagenic Impurity Assessment Committee (MIAC) chair since 2006. On the MIAC he leads an R&D-wide committee to establish control strategies for mutagenic impurities and align BMS internal practices with the evolving health authority regulations. Most recently he has led the end-to-end nitrosamine assessment and control process for the organisation. He has published over 40 papers and multiple patents in these areas.

Dr. Aloka Srinivasan, US | Principal and Managing Partner | RAAHA LLC

Aloka Srinivasan, PhD, is the principal and managing partner of RAAHA LLC (www.raahallc.com) and brings more than two decades of experience in the pharmaceutical industry, including nine years of progressive experience with the US FDA in the office of generic drugs, Lupin Pharmaceuticals, Lachman Consultants, and PAREXEL International. She provides strategic guidance to the pharmaceutical industry on regulatory and chemistry, manufacturing, and controls (CMC) for drug products and drug substances at all stages of development and for all types of regulatory submissions. Aloka has supported the development of several new drugs and generics during her tenure in PAREXEL and Lachman from the CMC and regulatory perspective. She has worked closely with the industry and FDA related to development and approval of several complex 505(b)(2) applications as well as complex generic applications. She spearheaded the foundation of a division in FDA related to review of drug master files (DMF) for drug substances under GDUFA and played a pivotal role in writing the FDA Guidance for Industry: Initial Completeness Assessments for Type II API DMFs Under GDUFA and a QbR document for drugs substance, which is part of FDA Mapp. 5015.10. She was one of the main authors of the QbR-QOS (Question-based Review-Quality Overall Summary) for ANDAs, which is the current basis of review of generis at CDER/FDA. Aloka is one of the world class experts in the area of nitrosamine impurities based on her research background and has been supporting the industry in addressing these carcinogenic impurities in the drugs. Aloka received her PhD from the University of Missouri (USA) under Dr. Richard N. Loeppky of nitrosamine fame. Her thesis was titled "A study of putative intermediates involved in the activation of beta-oxidized nitrosamines and nitrosation of N-substituted aziridines". Aloka also spent seven years as a scientist at the National Cancer Institute, working for Dr. Larry K. Keefer, researching on nitrosamines in potential nitric oxide donor drugs.

Dr. Joerg Schlingemann, DE | Director, Principal Expert Quality Control Systems | Merck Healthcare KGaA

Joerg Schlingemann is a director and principal expert for quality control systems within Merck KGaA's/EMD Serono's healthcare quality unit. He studied molecular biology in Uppsala and Heidelberg, where he completed a doctorate degree at the German Cancer Research Center in 2005. He has 14 years of experience in the pharmaceutical industry from various roles within quality control and quality assurance. Since late 2019, Joerg has been leading EMD Serono's analytical activities for N-nitrosamines. Joerg is married and has three children.

Marina Couva, CY | QPPV | Medochemie Ltd

Marina Couva has a lot of experience in the pharmaceutical industry in the fields of both quality and safety. She is a pharmacy graduate, a registered pharmacist in Cyprus, and also holds a master's degree in management. She has served in a number of positions in Medochemie Ltd, a generics pharmaceutical company with headquarters in Lemesos (Limassol), Cyprus. She is a qualified person and currently holds the role of the QPPV, as well as the position of group quality senior manager, responsible for GDP. Her experience spreads across many issues relating to GxP compliance, combining quality and safety.

Dr. Arianna Bassan, IT | Principal Consultant | Innovatune

Arianna Bassan is a chemist with long-term expertise in toxicology. She graduated from the University of Padova (Italy) and she earned her PhD in chemical physics at the department of physics of Stockholm University (Sweden). She had worked several years in international environments including Stockholm University, MSD/Merck&Co., and the European Commission. Her main interest lies in the use of computational toxicology for human health hazard assessment. She also led several different scientific projects with focus on data management (e.g., development of the EFSA's hazard database known now as OpenFoodTox, and management of pre-clinical data for pharma) and data curation. She is currently principal consultant in Innovatune, where she is also partner in the firm. She provides integrated toxicology services making the most of (Q)SAR and read-across methodologies for different applications including regulatory submissions (e.g. ICH M7) and product development. She is engaged in numerous activities aiming at standardising industrial and regulatory applications of computational toxicology. She is currently involved in different projects such as the update of the EFSA pesticides genotoxicity database and the EMA-funded research project MutaMind (led by Fraunhofer ITEM) that aims at shedding light on the mutagenicity of different classes of nitrosamines to distinguish highly potent from less potent carcinogens.