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

REGISTER NOW

Sheraton Milan Malpensa Airport Hotel & Conference Centre | Malpensa Terminal 1, S.S, 336 | 21010 Ferno VA, Italy

CONFERENCE & EXPO

7th IMPURITIES:
Genotoxic, Nitrosamine & Beyond Summit

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

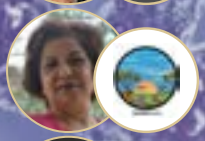
Dr. Arianna Bassan, IT
Principal Consultant
Innovatune

Dr. Michael Burns, UK
Principal Research Scientist – Mirabilis Lead
Lhasa Limited

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

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

SPONSORSHIP SPEAKING &
EXHIBITION OPPORTUNITIES AVAILABLE

Partners & Sponsors

INNOVATUNE Selvita Lhasa Limited

VONLANTHEN CONFERENCES

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

REGISTER NOW

7th IMPURITIES: Genotoxic, Nitrosamine & Beyond Summit

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

Introduction

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**.

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)

VONLANTHEN CONFERENCES

7th IMPURITIES: Genotoxic, Nitrosamine & Beyond Summit

Partners & Sponsors

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

Selvita is a preclinical Contract Research Organisation providing multidisciplinary support in resolving the unique challenges of research within the areas of drug discovery and drug development studies. Selvita was established in 2007 and currently employs over 1,000 professionals, of which over 40% hold a PhD degree. The company research sites are located in Krakow (HQ) and Poznan, Poland, as well as Zagreb, Croatia.

Selvita provides state-of-the-art analytical services supporting pharmaceutical and biopharmaceutical companies at various stages of drug development and CMC processes by providing contract laboratory services for testing. We have a diverse analytical instrumentation and expertise portfolio, allowing us to meet varied demands, including testing of starting materials, drug substances, intermediates, and final products of small and large molecules. Selvita complies with GMP and GLP requirements to meet the highest industry standards.

Selvita

Lhasa Limited is a Leeds-based not-for-profit organisation. At Lhasa, we are driven by our purpose: To enable informed decision-making on chemical safety. In line with this purpose, we create forward-thinking software solutions, which have been solving real-world chemical safety assessment problems for almost 40 years. Our technology is designed by scientists, for scientists, in collaboration with industry stakeholders and regulators. We are committed to enabling scientists to make better predictions on the safety of drugs, chemicals, and cosmetics by using existing data better and developing computer-aided reasoning and information systems for the advancement of science.

Lhasa Limited

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

09:00 Opening by Moderator

09:10

Recent updates on nitrosamines: Areas of uncertainty and misalignment

- Quality-related issues – Can we reduce levels of nitrosamines through CMC control alone?
- Safety issues – The relationship between safety challenges and what can and cannot be addressed from a CMC perspective; why 18ng is a disaster
- Regulatory issues – What is the current regulatory position? What is clear and, more importantly, what is not, and the impact of ambiguity

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

09:50 SPEED NETWORKING

10:20

Understanding the landscape of potential small and drug-substance-related nitrosamines in pharmaceuticals

- Using large datasets of existing drug substances, can we evaluate the true scale of challenges associated with NDSRIs?
- Examining the trends in potential formation, what lessons we can learn from them?
- Considering the risks posed by nitrosamines that could be formed, can future work be prioritised?

Dr. Michael Burns, UK | Principal Research Scientist – Mirabilis Lead | Lhasa Limited

10:50 NETWORKING/COFFEE/EXHIBITION BREAK

11:20

Risk assessment for pharma and biotech products

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

11:55

Analytical challenges

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

12:30

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

13:10 BUSINESS LUNCH

14:10 NETWORKING/COFFEE/EXHIBITION BREAK

14:30

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

15:10 OPEN SPONSORSHIP OPPORTUNITIES 15-20-30 MIN

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

15:30	**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
16:00	**NETWORKING/COFFEE/EXHIBITION BREAK**
16:30	 **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
17:10	 **End-to-end nitrosamine assessment and control** **Dr. Rodney Parsons, US** | Executive Director, Chemical Development | Bristol Myers Squibb
17:50	**Q&A/PANEL DISCUSSION (All Speakers of the Day Are Invited) & MODERATOR'S CLOSING REMARKS**
18:20	**NETWORKING/EXHIBITION BREAK** | 30min

Check Our

Upcoming Events

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

4th Extractables & Leachables Summit
May 10-11, 2023 | Vienna, Austria | #VLEnL

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

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:
emma.rosenberg@vonlanthen-conferences.com

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

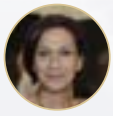
11:15 NETWORKING/COFFEE/EXHIBITION BREAK

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

7th IMPURITIES: Genotoxic, Nitrosamine & Beyond Summit

Registration Form

March **15-16**, 2023 | MILAN, ITALY & ONLINE (CET)

CHOOSE YOUR PACKAGE

Attendee packages	Register in February	Standard Price
☐ Standard - *Access to the full event, daily networking, refreshment breaks*	€1295* **per person*	€1495
☐ Virtual - *Access to the full live event and the live event recording*	€1295* **per person*	€1495
☐ Group Delegates: 3+ - *Access to the full event, daily networking, refreshment breaks*	€1195* **per person*	€1395

☐ **Promo materials distribution package** - *Distribution of your company's promotional materials to all conference attendees*	€999
☐ **Documentation package*** - *I cannot attend but would like to purchase the documentation package for this event* ** **Presentations** that are available for download will be subject to distribution rights by speaker*	€499

→ *Hotel accommodation & travel costs are not included in the registration fee*

To register for the Summit, please provide the details below. ** Required fields*

1

Name*: Surname*:

Position*:

E-mail*:

Special dietary requirements: ☐ *Vegetarian* ☐ *Gluten-free* ☐ *Other (please specify)* _____

2

Name*: Surname*:

Position*:

E-mail*:

Special dietary requirements: ☐ *Vegetarian* ☐ *Gluten-free* ☐ *Other (please specify)* _____

3

Name*: Surname*:

Position*:

E-mail*:

Special dietary requirements: ☐ *Vegetarian* ☐ *Gluten-free* ☐ *Other (please specify)* _____

4

Name*: Surname*:

Position*:

E-mail*:

Special dietary requirements: ☐ *Vegetarian* ☐ *Gluten-free* ☐ *Other (please specify)* _____

Company* (for corporate billing) / Name* (for individual billing)

Address

City / Country*

Phone Number*

VAT Number for Company* (only for EU)

Post code*

Date

Payment method
- ○ Wire transfer
- ○ Credit card

Invoice billing information*
- ○ Corporate
- ○ Individual

☐ By sending this form, I confirm that I have read and accepted the **Terms and Conditions**. To view the full Terms & Conditions and Privacy Policy terms, visit: vonlanthenevents.com/en/terms-conditions

To complete the registration process, fill out the form and send it to: register@vonlanthenevents.com

Upon receiving the registration form, you will receive an invoice by email.

Sponsorship packages	Presentation ☐ €4,999	Table Top ☐ €3,999	Bronze ☐ €5,999	Silver ☐ €6,999	Gold ☐ €8,999	Platinum ☐ €11,999
People attending	1	1	2	2	3	4
Logo on conference website, program, and pre/post-event communication activities	◆	◆	◆	◆	◆	◆
Discount on additional passes	10%	10%	15%	20%	30%	40%
Promotional material distribution (provided by sponsor)	◆	◆	◆	◆	◆	◆
Recognition on Vonlanthen Group's SM channels			◆	◆	◆	◆
Ad placed in final conference program			1/4 Page	1/4 Page	1/2 Page	Full Page
Recognition in chairman's opening address			◆	◆	◆	◆
Speaking slot	40 min			20 min	30 min	60 min
Table Top		◆	◆	◆	◆	
Host own seminar/workshop within the conference						40 min
Recognition in press release					◆	◆
Exhibition Stand with monitor for video presentations						◆

**For more information on the packages and to discuss your sponsorships requirements, please contact: emma.rosenberg@vonlanthen-conferences.com*