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Speakers

Carolien Buvé (PhD)
Nelson Labs, Belgium

Dr Gerd Jilge
Formerly Boehringer Ingelheim, Germany

Dr Cornelia Nopitsch-Mai
Bonn, Germany

Dr Ulrich Rose
Formerly EDQM, France

Dr Xaver Schratt
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Dr Reinhard Stidl
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Dr Andrew Teasdale
Formerly Astra Zeneca, UK

The Impurities Workshop

Practical Approaches for assessing the Risks of Impurities

Live Online Training from 18 - 20 November 2025

Part I - General Strategies for Identification and Control of Impurities
Live Online Training on 18 November 2025

Part II - Nitrosamine Impurities
Practical Approaches for Assessing the Risk of Nitrosamines and other Mutagenic Impurities in Drug Substances and Drug Products
Live Online Training on 19 November 2025

Part III - Elemental Impurities
Practical Approaches for Identification and Control
Live Online Training on 20 November 2025

Objectives

Part I of the Impurities Workshop will provide an opportunity to reinforce and expand your knowledge of the general area of impurities in chemical entities from initial development to the market with emphasis on

- Detection, profiling and control of impurities in drug substances, intermediates and drug products
- Practical aspects of method validation for impurities determination
- Analytical techniques used for detecting and qualifying impurities
- Extractables and Leachables as a source of impurities
- Approaches for investigation and determination of unexpected impurities

This Live Online Training is designed to provide a comprehensive review of impurities analysis and characterisation in drug substances and drug products and their recording and reporting.

Background

Setting specifications for impurities are one of the most critical topics in the development of new drug products. Impurities analysis in drug substances and drug products and their recording and reporting is quite often a challenge for the scientific experts in routine production and quality control. This challenge is even bigger when profiles of unknown impurities in complex matrices have to be established. The Sartan case made clear the importance of a thorough process understanding.

Target Audience

This Live Online Training is addressed to all personnel involved in development of drug substances and drug products from scientific staff to laboratory heads involved in R&D. The needs of Laboratory Managers, Supervisors and Analysts in pharmaceutical quality assurance and quality control departments will also be covered. This Live Online Training will also address regulatory requirements and hence is applicable to people working in the regulatory affairs area.

Programme

Analysis and Qualification of Impurities in Drug Substances and Drug Products – General Overview

- Impurity profiling in synthetic drug substances
- Qualification of impurities
- Degradation studies
- Identification of chiral impurities, polymorphic phases and new impurities
- Residual solvents
- Impurities in starting materials and intermediates
- Pharmacopoeial tests and acceptance criteria
- Drug product specifications and parametric release

Analytical Method Validation for Impurities Determination at various Development Stages

- Quantification of impurities
- How to define an impurity profile (stress tests)
- Reference substances
- Validation of methods at various development stages
- Statistical approaches to method validation (LOD & LOQ)

Presentation and Workshop: Selecting Analytical Procedures and Setting Acceptance Criteria of Impurities during Drug Substances Synthesis

- Purity analysis by HPLC, impurity profile
- Residual solvents by GC
- Inorganic impurities (heavy metals, sulphated ash)
- For chiral compounds in addition: enantiometric purity and proof of the absolute configuration

In the workshop the participants will learn which activities are necessary to characterize drug substances taking into account the following aspects:

- Analytical procedures are necessary for the characterization
- Experiments necessary to check the downstream impurities in order to justify acceptance criteria for the respective impurities
- Other impurities have to be taken into account
- Experiments to be performed in order to get a stability-indicating analytical procedure

Extractables and Leachables – What is expected from Packaging Materials for Drug Products?

- Why should Extractables & Leachables be assessed?
- Regulatory requirements and guidelines in the EU and US and pitfalls
- General flow and critical aspects of Extractables & Leachables studies
- Safety qualification of Extractables and Leachables

How to Avoid or Address Unexpected Impurities – Cleaning Procedures Pitfalls and Particulate Matter Contamination

- Is there such a thing as ‘unexpected impurities” or is there a lack of process understanding?
- Valsartan – overview of events
- Source of contamination
- Mechanistic understanding
- Examination of risk within other Sartans – overview of how to conduct a risk assessment and to identify key factors
- Are there other Mutagenic Impurities related risks?

Objectives

In Part II of the Impurities Workshop the relevant aspects of root cause analysis and risk assessment with respect to potential Nitrosamine contamination in drug substances and drug products will be discussed. You will hear what you need to know about the required risk assessments for medicinal products containing chemically synthesized APIs. In particular you will learn

- which root causes for Nitrosamine Impurities should be considered,
- which practical approaches can be applied to assess the risks related to potential Nitrosamine contamination,
- which safety aspects need to be considered regarding Nitrosamine Impurities in drug products,
- which regulatory actions are to be taken in case of Nitrosamine Impurities and what authorities expect in these cases.

You will get advice from industry experts on how to cope with the challenge of performing risk assessments. Furthermore, you will be informed about the European Pharmacopoeia activities (policy) on mutagenic impurities with focus on Nitrosamines.

Background

In June 2018 EU authorities were notified that a Chinese API manufacturer has detected the presence of N-nitrosodimethylamine, NDMA, in batches of Valsartan. NDMA is a genotoxic and carcinogenic agent in animals and is classified as a Class 2A carcinogen to humans. After a referral under Article 31 of Directive 2001/83/EC triggered by the European Commission the CHMP assessed the impact of the presence of this impurity on the benefit-risk balance of valsartan-containing drug products and issued a recommendation whether the concerning marketing authorisations can still be maintained or should be suspended.

Meanwhile, different Nitrosamines (NDMA, NDEA and others) were detected in almost every drug product which contains a Sartan derivative as an API. In an EMA Questions & Answers Document various potential sources of Nitrosamine contaminations are described. In September 2019 EMA published a press release where pharmaceutical companies were advised on steps to be taken to avoid nitrosamines in human medicines. In another document which appeared at about the same time Marketing Authorisation Holders are requested to evaluate the risk of the presence of Nitrosamine impurities in human medicinal products containing chemically synthesised APIs. As a consequence in case of contamination with Nitrosamines Marketing Authorisation Holders are requested to file a variation application.

Target Audience

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Programme

European Pharmacopoeia Activities on Nitrosamines and other Mutagenic Impurities

- Ph. Eur. General policy on DNA reactive impurities
- Control of Nitrosamines in Ph. Eur.
- Changes in individual and general monographs following the Sartan case
- New general chapter on control of nitrosamines

Root Causes for Nitrosamine Impurities and other Mutagenic Impurities – Practical Approaches to Assess the Risks

- Development of a systematic risk based approach
- Key factors and the development of a decision tree
  - API
  - Drug Product
  - Packaging

Safety Qualification of Impurities - current Principles and Methods

- General approaches and regulatory framework for impurity qualification by safety threshold derivation
- Generic and substance specific safety thresholds
- Threshold of Toxicological Concern (TTC) - different scenarios
- Derivation of Permitted Daily Exposure (PDE) limits
- Acceptable exposure calculations based on TD50 and their limitations
- Approaches for data poor substances: (Q)SARs and read-across
- Route-to-route considerations for safety thresholds
- Analytical methods used for quantification of N-nitrosylated APIs in drug products

Case Study: Conducting a Nitrosamine Risk Assessment - Evaluation through Case Studies

Several case studies will be presented and a risk assessment for different scenarios is shown taking into account e.g. manufacturing equipment, dosage form of the drug product, etc.

Nitrosamines and Other Genotoxic Impurities – Authorities' Expectations and Dossier Requirements

- The assessor’s approach: principles of toxicological assessment
- Structural alerts
- Limits and Permitted Daily Exposure
- The ALARP principle
- Examples of low daily dose drug substances
- Impurities derived from alkylating agents (mesilate, besilate, tosilate, diisothionate); examples
- Nitrosamines – the Valsartan case
- Potential mutagenicc residual solvents
- Impurities derived from metal catalysts

Objectives

In Part III of the Impurities Workshop the key principles of the ICH Q3D Guideline on elemental impurities will be highlighted. You will get to know the essential aspects and approaches of how to assess the risks and control elemental impurities in drug substances, drug products and excipients.

You will learn

- what has to be considered with respect to the drug substance monographs of the European Pharmacopoeia,
- how to perform a risk assessment in order to establish a control strategy for elemental impurities,
- how the route of administration and the duration of exposure affect the limits of elemental impurities

Background

In November 2014 the **ICH Q3D Guideline for Elemental Impurities** was published as Step 4 document. This document outlines

- the evaluation of the toxicity data for potential elemental impurities
- the PDEs for each element of toxicological concern
- the basis for an EI risk assessment and the key factors for evaluation.
- the development of controls designed to limit the inclusion of elemental impurities in drug products to levels at or below the PDE

Meanwhile ICH Q3D was revised twice, regarding Cadmium Inhalation PDE (ICH Q3D(R1); Step 2 document) and cutaneous and transdermal products (ICH Q3D(R2); Concept Paper).

Target Audience

This Live Online Training is addressed to all personnel involved in development of drug substances and drug products from scientific staff to laboratory heads involved in R&D. The needs of Laboratory Managers, Supervisors and Analysts in pharmaceutical quality assurance and quality control departments will also be covered.

Programme

European Pharmacopoeia Activities (Policy) on Elemental Impurities – an Update

- Implementation of Q3D in Ph. Eur.
- Changes in individual and general monographs
- Harmonisation of general chapter 2.4.20
- Second phase for revision of excipient monographs

Control Strategies for Elemental Impurities in Final Dosage Forms – Case Studies

- Utilisation of Data as part of an Integrated EI Risk Assessment Process
- Potential Sources of Elemental Impurities in the Finished Product
  - API
  - Equipment
  - Container-closure system
  - Excipients
- Conclusions

Workshop: Conducting a Risk Assessment

In this Workshop the participants will work on several case studies and perform a risk assessment for different scenarios taking into account e.g. manufacturing equipment, dosage form of the drug product etc.

Your Benefit


CERTIFICATE

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...".

This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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Speakers

Carolien Buvé (PhD)
Nelson Labs, Belgium

Dr Carolien Buvé is working as a scientific project manager at Nelson Labs (Belgium). She is the point of contact for pharmaceutical companies interested in extractables and leachables testing of packaging systems. She will be involved in different stages of such studies, going from study design, thereby taking into account sponsor's needs as well as practical constraints, to reporting of the results.

Dr Gerd Jilge
Formerly Boehringer Ingelheim, Germany

In 1991, Dr Gerd Jilge came to Boehringer Ingelheim working in drug product development, where he was responsible for method development and validation for the application of analytical procedures. In 2000, he took a position in Drug Regulatory Affairs of Boehringer Ingelheim GmbH with the focus on CMC documentation for the submission of new and registered drug products.

Dr Cornelia Nopitsch-Mai
Formerly Quality Assessor, Germany

Dr Cornelia Nopitsch-Mai was scientist at the Federal Institute for Drugs and Medical Devices in the assessment of the quality part of the dossier since 1991. Since 2000 she was assessor for the Certification Procedure (EDQM) in Strasbourg. She was member of the Technical Advisory Board (EDQM) from 2001 until 2010; in that time she was chairperson from 2005 until 2010. From 2007 until 2011 she was a member of the EMA Quality Working Party.

Dr Ulrich Rose
Former Deputy Head of the European Pharmacopoeia Department, EDQM, France

Dr Rose was Deputy Head of the European Pharmacopoeia Department at the EDQM in Strasbourg and in this context responsible for the preparation of monographs on chemical defined APIs, finished products, herbal drugs & preparations, and general chapters. He was also involved in the harmonization of international pharmacopoeias. Previously, he was responsible for the establishment and control of Ph. Eur. Reference Standards, and later served as coordinator and auditor for EDQM's Mutual Joint Audit Program, which audits Official Medicines Control Laboratories in Europe (OMCLs).

Dr Xaver Schratt
GBA Pharma GmbH, Germany

Dr Xaver Schratt is head of department R&D 2 and an expert for chromatography and mass spectrometry. In charge of national and international pharmaceutical companies he manages all analytical aspects of projects from preclinical stage up to phase III and post market approval with focus on method development, validation and qualification of reference standards.

Dr Reinhard Stidl
Safetree Consulting e.U., Austria

Dr Stidl has more than 15 years of experience as Toxicological Risk Assessor in the pharmaceutical context and is Senior Toxicologist at and founder of Safetree Consulting e.U. Dr. Stidl 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. He is specialized in chemical safety assessment, with focus on impurities (including extractables and leachables), active ingredients (carry-over PDEs, OELs) and excipients.

Dr Andrew Teasdale
Formerly Astra Zeneca, UK

Dr Andrew Teasdale PhD has over 20 years' experience in the pharmaceutical industry as an analytical chemist and within quality assurance and regulatory roles. He has led a number of industry expert 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). He is also currently the chairman of the Joint Pharmaceutical Analytical Group (JPAG) in the UK.

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P.O. Box 101764
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

The Impurities Workshop, Live Online Training from 18 - 20 November 2025

- ☐ *Part I: 18 November 2025*
- ☐ *Part II: 19 November 2025*
- ☐ *Part III: 20 November 2025*
- ☐ *Part I and II: 18 - 19 November 2025*
- ☐ *Part II and III: 19 - 20 November 2025*
- ☐ *Part I, II and III: 18 - 20 November 2025*

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

The Impurities Workshop Part I: General Strategies for Identification and Control of Impurities
18 November 2025, 08.30 – 17.15 h CET

The Impurities Workshop Part II: Nitrosamine Impurities
19 November 2025, 09.00 – 16.30 h CET

The Impurities Workshop Part III: Elemental Impurities
20 November 2025, 09.00 – 13.45 h CET

Technical Requirements

We use WebEx for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

The Impurities Workshop Part I
ECA Members € 990 | APIC Members € 1,090
Non-ECA Members € 1,190 | EU GMP Inspectorates € 595

The Impurities Workshop Part II
ECA Members € 990 | APIC Members € 1,090
Non-ECA Members € 1,190 | EU GMP Inspectorates € 595

The Impurities Workshop Part III
ECA Members € 690 | APIC Members € 740
Non-ECA Members 790 | EU GMP Inspectorates € 595

The Impurities Workshop Part I and II:
ECA Members € 1,690 | APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 1,190

The Impurities Workshop Part II and III:
ECA Members € 1,490 | APIC Members € 1,540
Non-ECA Members € 1,590
EU GMP Inspectorates € 1,190

The Impurities Workshop Part I – III:
ECA Members € 2,090 | APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,785

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under
number 21981 Part I
number 21983 Part II
number 21984 Part III
number 21980 Part I & II
number 21982 Part II & III
number 21979 Part I, II and III

Conference language

The official conference language will be English.