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Speakers

Dr Ward D'Autry
Nelson Labs, Belgium

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Dr Corina Nachtsheim
Quality Assessor, Germany

Dr Ulrich Rose
EDQM, France

Dr Xaver Schratt
GBA Pharma GmbH, Germany

Dr Andrew Teasdale
Astra Zeneca, UK

The Impurities Forum

Practical Approaches for Assessing the Risks of Impurities

Live Online Conference on 03/04 November 2021

Part I:

Identification and Control of Impurities in Drug Substances and Drug Products
Live Online on 03 November 2021

Part II:

Nitrosamines and other Mutagenic Impurities
Live Online on 04 November 2021

Objectives

Part I of the Impurities Forum 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
- Important monographs and chapters in Ph. Eur. for control of impurities
- 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 event 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 **Valsartan case** made clear the importance of a thorough process understanding.

Target Audience

This Live Online Conference addresses 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 event will also address regulatory requirements and hence is applicable to people working in the regulatory affairs area.

Programme

Impurities 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

Control of Impurities in Ph.Eur.

- Which impurities are controlled?
- General texts/monographs/ICH guidelines
- Organic impurities in Ph. Eur.
- Specification setting
- Validation
- Elemental impurities

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: Analytical Techniques for Determination and Qualification of Impurities in Starting Materials and Intermediates

Applying an example of an API synthesis the participants will learn in the Workshop 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

Unexpected Impurities: Approaches for Investigation and Determination

- 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 Forum 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 a **representative of the EDQM** will inform you about the European Pharmacopoeia activities (policy) on mutagenic impurities with focus on Nitrosamines.

Background

Mutagenic substances as impurities in drug substances or drug products are of big concern as they have the potential to alter or damage human DNA. Among these species Nitrosamines and elemental impurities have triggered various regulatory activities and initiatives. Since September 2019 Marketing Authorisation Holders are requested to evaluate the risk of the presence of Nitrosamine impurities in human medicinal products containing chemically synthesised APIs. In case of a contamination with Nitrosamines MAHs are requested to file a variation application. All regulatory activities with regard to such cases have to be completed within a 3 years period (end of March 2022). The ICH Q3D Guideline for Elemental Impurities was published as Step 4 document and has meanwhile been revised twice, regarding Cadmium Inhalation PDE and cutaneous and transdermal products.

Target Audience

The Live Online Conference addresses 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 event will also address regulatory requirements and hence is applicable to people working in the regulatory affairs area.

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

Mutagenic Impurities Introduced from Supply Chains Processes

- APIs, excipients, packaging materials impacting the purity profile
- Process mapping and evaluation of supply chain processes
- Risk measurement and evaluation of process steps according to ICHQ9
- Vendor audits, vendor complaint tracking and monitoring programs
- Risk-based approach for supplier quality evaluation
- Testing strategies

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.**

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 mutagenic residual solvents
- Impurities derived from metal catalysts

Dr Ward D'Autry
Nelson Labs, Belgium

Ward D'Autry is Study Director Extractables & Leachables at Nelson Labs. His key technical expertise is chromatography coupled to (high resolution) mass spectrometry, for the identification of small molecules. As study director he is on the interface between the sponsor's requests and the analytical laboratory.

Dr Gerd Jilge
Boehringer Ingelheim, Germany

Dr Gerd Jilge was responsible for method development and validation for the application of analytical procedures. After having taken a position in Drug Regulatory Affairs with the focus on CMC documentation for the submission of new and registered drug products he joined the Quality Management department where he is working on method development for new drug substances.

Jürgen Martin
Martin-Consulting, Germany

Mr Jürgen Martin has more than 25 years of experience in pharmaceutical industry and quality control. After his education at the university of Konstanz he has held different leading positions focusing on quality control topics at Byk Gulden, Altana Pharma and Nycomed. Between 2011 and 2019 he was building up and heading the quality control of the BIPSO GmbH. Since 2019 he is operating his own consultancy and software development office.

Dr Corina Nachtsheim
Quality Assessor, Germany

Dr Corina Nachtsheim is working as quality assessor at the German Federal Institute for Drugs and Medical Devices (BfArM) since Jan. 2001. Since Nov. 2007, she is an external expert in the framework of the certification procedure of the EDQM in Strasbourg. She became a member of the chemical Technical Advisory Board (EDQM) in Nov. 2011 and is currently chairperson.

Dr Ulrich Rose
EDQM, France

Dr Ulrich Rose works since 1991 at the EDQM in Strasbourg. Until 2011 he was responsible for establishment and monitoring of the Ph. Eur. reference standards and was involved in the elaboration and revision of monographs of the European Pharmacopoeia. After that he became coordinator and auditor for EDQM's Mutual Joint Audit Program where he had to audit the Official Medicines Control Laboratories (OMCLs) in Europe. Since 2014 he is head of division A and deputy head of the Ph. Eur. Department where he is overlooking the monograph work on chemicals, excipients, herbals and general chapters of Ph. Eur. and is involved in the international harmonisation of pharmacopoeias.

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 Andrew Teasdale
Astra Zeneca, United Kingdom

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.

Your Benefit

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.


CERTIFICATE

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Reservation Form (Please complete in full)

The Impurities Forum, Live Online Conference on 03/04 November 2021

☐ *Part I: 03 November 2021*
☐ ☐ *Part II: 04 November 2021*
☐ *Part I and Part II: 03/04 November 2021*

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:
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2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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.

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Date of the Live Online Conference

The Impurities Forum Part I:
Identification and Control of Impurities in Drug Substances and Drug Products
03 November 2021, 09.00 – 17.45 h CET

The Impurities Forum Part II:
Nitrosamines and other Mutagenic Impurities
04 November 2021, 09.00 – 16.30 h CET

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 Forum Part I
ECA Members € 890 | APIC Members € 990
Non-ECA Members € 1,090 | EU GMP Inspectorates € 545

The Impurities Forum Part II
ECA Members € 890 | APIC Members € 990
Non-ECA Members € 1,090 | EU GMP Inspectorates € 545

The Impurities Forum Part I and Part II
ECA Members € 1,590 | APIC Members € 1,690
Non-ECA Members € 1,790 | EU GMP Inspectorates € 895

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.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Conference language

The official conference language will be English.

Organisation and Contact

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

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