Nitrosamine Impurities GMP and Regulatory requirements

Amsterdam, The Netherlands
27 October 2020

Pre-Conference Session to the 23rd APIC/CEFIC GLOBAL GMP & REGULATORY API CONFERENCE

Highlights

- Nitrosamine Impurities – from where we stand
- Potential Nitrosamine Contamination and Supply Chain Quality Oversight
- Key Factors and Challenges of a Systematic Risk Evaluation
- Filing Variations/Changes as a Consequence of Nitrosamine Contamination

APIC active pharmaceutical ingredients committee (25 years of promoting patient safety)

a sector group of

cefic

ECA Academy Your GMP/GDP Information Source

Objectives

During this pre-Conference Session you will hear an update on how to deal with Nitrosamine Impurities from a GMP perspective and how to handle cases of Nitrosamine contamination in terms of filing changes/variations. You will get to know

- Which "lessons learned" future risk mitigation strategies can be based on
- How a comprehensive supply chain quality oversight should look like
- What has to be considered regarding the CEP procedure in case of Nitrosamine Impurities

You will receive first hand information from speakers representing the European QP Association and APIC.

This pre-conference session ideally complements the following 23rd APIC/CEFIC Global GMP & Regulatory API Conference.

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 known to be genotoxic and carcinogenic and is classified as a Class 2A carcinogen to humans. After a referral under Article 31 of Directive 2001/83/EC 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. Marketing Authorisation Holders have been requested to evaluate the risk of the presence of Nitrosamine impurities in human medicinal products containing chemically synthesised APIs.

Target Audience

This pre-conference session is of interest to all personnel involved in risk assessments of drug substances and drug products regarding potential Nitrosamine contamination. Scientific staff, Laboratory Managers, Supervisors and Analysts in pharmaceutical quality assurance and quality control departments as well as people working in the regulatory affairs area are addressed.

Important Information

You will receive a USB stick when you register in Amsterdam. Note: there will be no print-outs available during the conference. Additionally, the presentations will be available for download.

Programme

Nitrosamine Impurities – Lessons Learned

- Initial cause of Valsartan contamination and other causes
- Article 31 and its implications
- Where do we go from here?

How to evaluate Risks associated with Nitrosamine Impurities

- Key factors of a systematic risk based approach
- Challenges of assessing the risks of
  - Drug Products
  - APIs and Excipients
  - Packaging Materials
  - Implication of ICH M7

Nitrosamine Impurities and Supply Chain Quality Oversight

- How to deal with the challenge of complex supply chains
- What the QP has to consider
- Communication – which parties and key persons have to be involved?

Nitrosamine Impurities – handling Changes/Variations in a global Environment

- Variations/Changes as consequences to mitigate the risks
- Filing a variation/change
- Is a global approach workable?

Speakers

Marieke van Dalen, Aspen Oss B.V., The Netherlands

Ms Dalen is the global regulatory specialist in the regulatory group dedicated to API's, with almost 30 years of experience in the regulatory field. She is a board member of APIC, the European API Industry organization, and she participates in the Japan task force, Emerging markets task force and the Quality metrics task force. She frequently represents APIC in meetings and conferences organized by EMA, EDQM, ICH etc.

Dr Andrew Teasdale, Astra Zeneca, United Kingdom

Dr Teasdale is an analytical chemist and held several positions 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.

Dr Ulrich Kissel, European QP Association, KisselPharmaConsulting, Germany

Dr Kissel is Qualified Person and Member of the Board of Directors of the European Qualified Person Association (EQPA). He works as a GMP consultant and contract QP to the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

APIC Industry Best Practice documents

APIC developed a number of guidances on GMP and Regulatory Affairs, e.g.

- APIC Guidance on Nitrosamines Risk Assessment including Template for Report on Nitrosamines Risk Assessment, February 2020
- Q&A document - APIC 3rd party audit sub team for RSM suppliers, December 2019
- Data Integrity Best Practices Guide for APIs, version 1, March 2019

Learn about the implementation of these Guidelines at the 23rd Global GMP & Regulatory API Conference or at the Pre-Conference.

All APIC guidance documents are available for free download on the APIC/CEFIC website: www.apic.cefic.org/publications.html

Date
Tuesday, 27 October 2020, 09.00 h – 17.15 h
(Registration and coffee 08.30 h – 09.00 h)

Venue
Mövenpick Hotel Amsterdam City Centre
Piet Heinkade 11
1019 BR Amsterdam
Netherlands

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Fax +31 205191230
E-mail hotel.amsterdam@movenpick.com

Fee
EUR 990.- per delegate plus VAT.

A special fee of 890,- Euro is granted to participants who also register for the 23rd APIC/ CEFIC Global GMP & Regulatory API Conference.

The conference fee is payable in advance after receipt of invoice and includes lunch and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation link when you have registered for the event. Please use this link for your room reservation to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.api-conference.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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☐ **Pre-Conference Session "Nitrosamine Impurities - GMP and Regulatory requirements",** 27 October 2020, Amsterdam, The Netherlands

☐ **I also register for the 23rd Global GMP & Regulatory API Conference**, 28 - 30 October 2020, Amsterdam, The Netherlands

I want to take part in
☐ **All three conference days** (28-30 October 2020)
☐ **GMP part** (28-29 October 2020)
☐ **Regulatory Affairs part** (29-30 October 2020)

Please choose 3 out of 6 lectures (one out of each parallel session):

Parallel Session A
☐ Lecture 1: Quality culture
☐ Lecture 2: Specifics for Sterile APIs

Parallel Session B
☐ Lecture 3: ICH Q13 – Continuous Manufacturing of Drug Substances and Drug Products
☐ Lecture 4: API registration in Brazil: an overview

Parallel Session C
☐ Lecture 5: Cleaning in multipurpose facilities
☐ Lecture 6: APIC´s Experience with API Registrations in China

☐ Mr ☐ Ms Title _____

First name, surname

Company ☐ APIC Member ☐ ECA Member ☐ Inspectorate

Department

Important: Please indicate your company's VAT ID Number P.O. Number if applicable

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General Terms of Business
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 2 weeks prior to the conference 10 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice. German law shall apply. Court of jurisdiction is Heidelberg.

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. You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!

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