Nitrosamine Impurities GMP and Regulatory Requirements

Live Online Training
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 Nitrosamine Impurities and the Impact on the Ph. Eur.
- Nitrosamine Impurities and the CEP Procedure – an Update
- 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 EDQM, European QP Association and APIC.

This year is a special year and will be remembered for a long time. The Covid-19 pandemic is shaping our professional environment as well as our private lives. But life goes on and we need and want to educate ourselves.

Therefore we offer this year's pre-conference session of the 23rd APIC/CEFIC Global GMP & Regulatory API Conference as a Live Online Conference. All lectures will be held consecutively and can be attended by all participants live online.

This pre-conference session ideally complements the following 23rd APIC/CEFIC Global GMP & Regulatory API Conference – live online at your desk.

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

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 and the Impact on the Ph. Eur.
- Revisions of monographs and preparation of general texts

Nitrosamine Impurities and the CEP procedure – an update
- Actions taken on CEP applications
- GMP inspections
- Work to be done by CEP holders

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

Hélène Bruguera, EDQM, France
Ms Bruguera joined the European Directorate for the Quality of Medicines (EDQM) in 2000, as a scientific officer with the Certification Division. She is currently the Head of Division, dealing with the management of the evaluation of CEP applications as well as the EDQM inspection program for API manufacturers. She is a member of the IGDRP ASMF Working Group and a member of the EU team in the ICH Q11 IWG.

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.

Date
Tuesday, 27 October 2020, 09.00 h – 17.15 h

Technical Requirements
For our 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.

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.

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.
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Ms Anne Günster (Operations Director) at
+ 49 (0) 6221/84 44 50, or at
guenster@concept-heidelberg.de

For questions organisation etc.:
Ms Marion Grimm (Organisation Manager) at
+ 49 (0)6221/84 44 18, or at
grimm@concept-heidelberg.de

If the bill-to-address deviates from the specification to the right, please fill out here:

_____

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34
69007 Heidelberg
Germany

☐ **Pre-Conference Session "Nitrosamine Impurities - GMP and Regulatory Requirements",**
Live Online Training, 27 October 2020

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

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)

☐ 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

Street / P.O. Box

City Zip Code Country

Phone / Fax

E-mail (please fill in)

RI/21092020