ECA Academy
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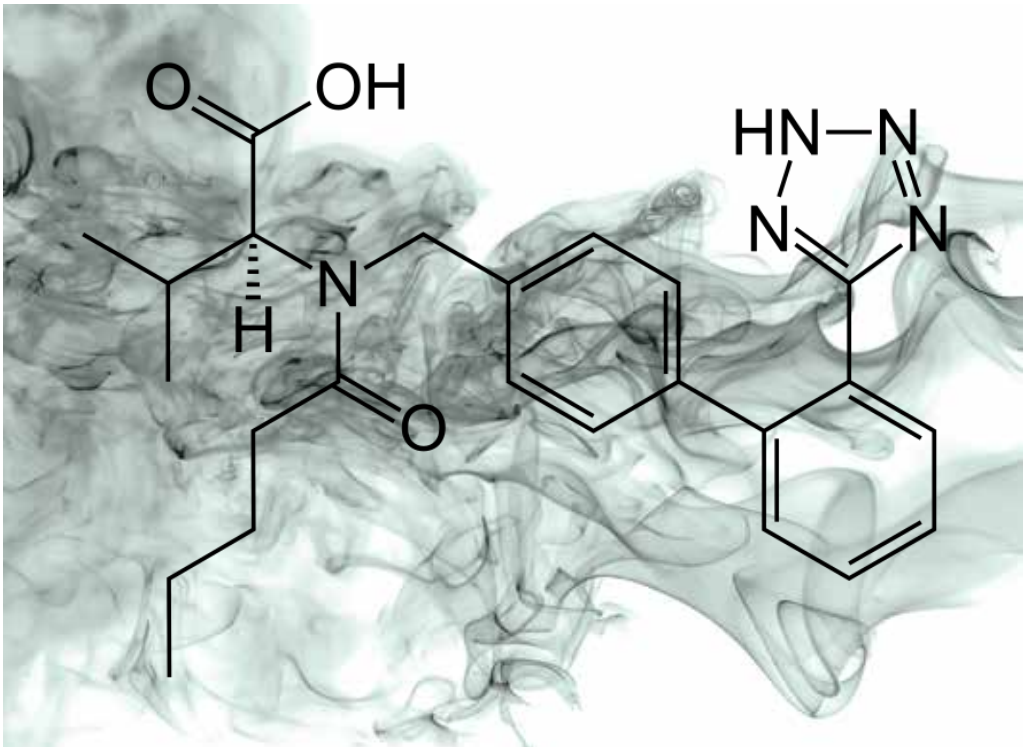
GMP Webinar Series on Impurities – Highlights and Updates

Impurities coming from Supply Chains

Date:
Tuesday, 12 January 2021, 14.00 – 15.30 h CET

Speaker:
Jürgen Martin, Martin Consulting, Germany



ECA has entrusted CONCEPT HEIDELBERG with the organisation of this webinar.

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Background

Pharmaceutical products are typically distributed within a network of global supply chains between API-, excipient- and packaging material suppliers and sites in pharmaceutical industry. It is one key part of GMP-activities to make sure impurities coming from the supply chain are managed adequately to avoid any product quality risk. Currently elemental impurities (covered by ICH Q3D Guideline) but also Nitrosamines (covered e.g. by EMA documents published in September 2019) are in the focus of the authorities. To manage these challenges risk management according to ICH Q9 guideline is a common and helpful tool to be in compliance for such topics in an efficient and ongoing way.

Educational Objectives

In this webinar you will get to know how the risks of contamination associated with supply chains can adequately be evaluated. The following aspects will be addressed:

- Process mapping to understand impact factors to product quality
- Risk measurement and evaluation of process steps according to ICHQ9
- Vendor audits as important activity for processes knowledge and to monitor the quality level
- Vendor complaint tracking as important source for quality level evaluation
- Definition of adequate in-house testing programs for impurities
- Risk based approach for supplier quality evaluation
- Defining mitigation activities (e.g. adjusted sampling and testing approach)
- Software support for information tracking

In order to illustrate the causal relations some case studies will be provided.

Target Audience

The webinar 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.

Speaker

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.

Fees (plus VAT)

Single participation: € 249.- for ECA Members
Single participation: € 299,- for non-ECA Members
(This fee does not include the ECA Membership. You will find more about the ECA Membership at https://www.gmp-compliance.org/about-the-academy).

Participation of a Group

You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC.

Group Participation (fee per person):

3-10 Persons EUR 254,15
11-20 Persons EUR 224,25
from 21 Persons EUR 194,35

Registration

By mail, fax, e-mail or online on the Internet at www.gmp-compliance.com. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

Technical Requirements

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Presentation/Certificate

The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Organisation/Contact

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Do you have any questions?

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Registration for the GMP Webinar "Impurities coming from Supply Chains"
on Tuesday, 12 January 2021, 14.00 – 15.30 h CET
Speaker: Jürgen Martin, Martin Consulting, Germany
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:
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  ☐ 11-20 Persons
  ☐ more than 20 Persons

Important:
Deadline is 12.00 h noon on 11 January 2021

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