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GMP Webinar
Ethylene and Diethylene Glycol Testing

- Pharmacopoeial Activities, Regulatory Developments and Analytical Testing -

Date:
Tuesday, 28 May 2024, 15.30 - 17.30 h CEST

Speakers:
Alexander Doppelreiter, CEO, Head QC bei Reference Analytics, Austria
Jenny Liu, Principal Scientist at United States Pharmacopoeia (USP), USA

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

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Background

Recent events have highlighted the serious risks posed by the contamination of medicines with diethylene glycol (DEG) and ethylene glycol (EG), particularly in children. A notable case occurred between June and September 2022 in Gambia, where children developed acute renal failure after being administered medicines that were later found to contain DEG and EG. This led to a rapid public health response, including the suspension of the use of all paracetamol and promethazine syrups and a recall of the contaminated products. The World Health Organisation (WHO) issued a global alert on the affected medicines from Maiden Pharmaceuticals Limited, India. Investigations directly linked the Acute Kidney Injury (AKI) cases to the contaminated syrups, emphasising the critical importance of strict quality management in the manufacture and regulation of medicines.

The WHO has called for urgent action following reports of over-the-counter cough syrups for children contaminated with high levels of DEG and EC in at least seven countries, resulting in more than 300 deaths. These incidents underscore the need for immediate and coordinated action by all stakeholders in the medical supply chain, including regulators, manufacturers, suppliers and distributors, to detect and eliminate substandard medical products, ensure the approval and safe sourcing of medical products, and improve surveillance and risk-based inspections.

In response to these concerns, the US Food and Drug Administration (FDA) has issued new guidance for the pharmaceutical industry on testing for EGs and DEGs in high-risk drug components. This guidance was prompted by WHO global health alerts about contaminated drugs in countries such as Indonesia, Gambia and Uzbekistan. EG and DEG are highly toxic substances used in industrial applications such as antifreeze and should never be included in medicines. Their contamination in liquid oral drugs has been linked to serious health consequences, including central nervous system (CNS), heart and kidney damage and even death. The FDA guidance aims to limit EG and DEG content in high-risk drug ingredients to no more than 0.10%, with a focus on glycerine, propylene glycol and certain sugar polyol solutions that have been contaminated in the past. This initiative emphasises the need for stringent testing and quality assurance measures in the manufacture and distribution of medicinal products.

The importance of this can also be seen in the number of warning letters issued by the FDA and the activities of other organisations such as the USP and WHO.

Educational Objectives / Programme

This webinar will give in two talks and a following Q&A session an overview of the impurities, possible sources and analytical strategies as well as USP's effort on EG/DEG testing.

Importance of Excipient Quality – USP's Effort on DEG/EG Testing of High-Risk Excipients

- USP mission and role; Importance of Excipient Quality
- History of DEG poisoning incidents and the Food, Drug & Cosmetic Act (Difference between Identification and Impurity tests)
- USP DEG/EG efforts: progress and challenges
- Next steps

Jenny Liu, Principal Scientist at USP

Analysis of the Current Warning Letters and Analytical Testing

- Content of current FDA warning letters
- Possible sources of contamination
- Laboratory Testing

Alexander Doppelreiter, CEO, Head QC bei Reference Analytics

Target Audience

This webinar addresses itself to all, which are involved in quality control of incoming goods, starting material or release of final drug product.

- It will be of significant value to analytical laboratory managers and their colleagues,
- Analytical scientists,
- QA, manufacturing and supply chain professionals.

Speakers

Alexander Doppelreiter studied at the University of Applied Sciences in Vienna. He has over 10 years of experience in different pharmaceutical companies and analytical laboratories like Baxter, VelaLabs, and Perkin Elmer. Since 2019 he is Head QC and CEO of Reference Analytics, a contract lab specialized in impurity analysis and consulting.

Jenny Liu holds a PhD in Chemistry from Boston University and has more than 20 years of experience in analytical method development and validation. She joined the United States Pharmacopoeia in 2013 after a period as a post-doctoral fellow and working at AustarPharma and Catalent. At USP, she is Responsible for the development, update, and harmonisation of excipient monographs and excipients-related general chapters under the Pharmacopeial Discussion Group (PDG) work plan.

Fees (plus VAT)

Single participation: € 349.- for ECA Members
Single participation: € 399,- 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 354,15
11-20 Persons EUR 324,25
more than 20 Persons EUR 294,35

Registration

By 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

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events 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.

Presentation/Certificate

The presentation will be made available to you prior to the Webinar as PDF files. 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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