ECA Academy
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Speaker

Emerich Grassinger
Takeda, Austria

GMP for Excipients

Live Online Training on 25 June 2025, 13:00 – 16:00 h (CEST)

Highlights

- Regulations and Guidelines for Excipients
- Formalized Risk Assessment for Excipients

Programme

Objectives

This Live Online Training provides regulatory requirements and recommendations (WHO, ICH, EU) for the handling and use of Excipients compared to Active Pharmaceutical Ingredients (APIs). The use, creation and implementation of a formalized Risk Assessment, which is common practice in the pharmaceutical industry nowadays, is a good tool to fulfil the GMP requirements. Therefore, the needed measurements and checks will be explained and the evaluation of the risks will be discussed.

Target Audience

This Live Online Training is prepared for personnel from Quality Control, Quality Assurance, and production who want to gain a better understanding of the requested regulatory requirements for Excipients, as well as having an efficient planning, execution, and evaluation of a formalized risk assessment.

Programme

Regulations and Guidelines for Excipients

- Regulations (European regulations, WHO, Pharmacopoeias)
- Requirements for Excipients (compared to APIs)
- Quality Risk Management (ICH Q9)
- Formalized Risk Assessment for ascertaining the appropriate GMP for Excipients

Formalized Risk Assessment for Excipients

- In which cases do you need a formalized Risk Assessment?
- Which risks need to be considered?
- How to do the evaluation?
- Which measurements could be useful?
- Which checks need to be performed?

Speaker

Emerich Grassinger
Takeda, Austria
Emerich Grassinger headed several labs within Boehringer Ingelheim where he also led several improvement projects throughout the supply chain involving the raw material releasing process. Thereafter he joined Haupt Pharma Wuelfing, where he was responsible for Quality Control, including the raw material laboratory and the sampling of incoming goods. Since 2019 he is head of Quality Control at Takeda in Vienna, Austria.

Date of the Live Online Training
Wednesday, 25 June 2025, 13.00 h – 16.00 h CEST

Technical Requirements
We use WebEx for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings 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.

Fees (per delegate, plus VAT)
ECA Members € 590
APIC Members € 640
Non-ECA Members € 690
EU GMP Inspectorates € 590
The fee is payable in advance after receipt of invoice.

Registration
Please register online at **www.gmp-compliance.org under the number 21801.**

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.

Conference language
The official conference language will be English.

Ordering Recordings
We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

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
Telefon +49(0) 62 21/84 44-0
Telefax 49(0) 62 21/84 44 34
E-Mail: info@concept-heidelberg.de
www.concept-heidelberg.com

For questions regarding content please contact:
Ms Anne Günster (Operations Director) at
+49(0) 62 21/84 44 50, or at
guenster@concept-heidelberg.de

For questions regarding organisation please contact:
Mr Ronny Strohwald (Organisation Manager) at
+49(0) 62 21/84 44 51 or at
strohwald@concept-heidelberg.de