

Speakers



Emerich Grassinger
Takeda, Austria



Dr Franz Schönfeld
German GMP and GDP Inspector at
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GMP for Excipients



Live Online Training 03 February 2026,
13:00 - 17:00 h (CET)



Highlights

- EU GMP Requirements for Excipients – View of an Inspector
- 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

EU GMP Requirements for Excipients – View of an Inspector

- Introduction and background
- Legal requirements: Supplier qualification and existing certification programmes
- Expectations of the authorities
- Observations and findings

Formalized Risk Assessment for Excipients

- Quality Risk Management (ICH Q9)
- Formalized risk assessment for ascertaining the appropriate GMP 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?
- Risk control, risk review, risk communication

Speakers



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.



Dr Franz Schönfeld, German GMP and GDP Inspector at the District Government of Upper Franconia

Dr Franz Schönfeld is a German GMP and GDP Inspector for active pharmaceutical ingredients and medicinal drug products at the District Government of Upper Franconia. He is head of the expert working group for APIs at the Central Authority of the Federal States for Health Protection in Germany and member of the GMDP Inspectors Working Group at EMA in Amsterdam.



Date of the Live Online Training

Tuesday, 03 February 2026, 13.00 h - 17.00 h CET

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 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 € 690
APIC Members € 740
Non-ECA Members € 790
EU GMP Inspectorates € 690

The fee is payable in advance after receipt of invoice.

Registration

Please register online at www.gmp-compliance.org under the number **22346**. To avoid incorrect information, please give us the exact address and full name of the participant.

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.

You cannot attend the Live Online Event?

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/recording.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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