



Self-Inspection

Compliant and Successful Self-Inspections and Internal Audits

 Live Online Session on 24 February 2026



Academy
Your GMP/GDP
Information Source

Objectives and Background

Self-inspections are a requirement in EU-GMP but also FDA:

- EU GMP Guideline Part 1, Chapter 9 Self Inspection: *"Self inspections should be conducted in order to monitor the implementation and compliance with Good Manufacturing Practice principles and to propose necessary corrective measures."*
- EU GMP Guideline Part 2, Chapter 2.5 Internal Audits: *"In order to verify compliance with the principles of GMP for APIs, regular internal audits should be performed in accordance with an approved schedule."*

The results and observations from self inspections provide evidence of the effectiveness of the existing quality assurance system. A self-inspection is a tool for evaluating and continuously improving the suitability and condition of systems, processes, equipment and premises.

However, self-inspections have their own character and require careful planning, implementation and follow-up.

Objectives

This Live Online Session will provide you with important information on the regulatory background and the successful implementation of self-inspections.

Target Audience

This Live Online Session is aimed at auditors and managers from the pharmaceutical and active pharmaceutical ingredients industry who plan, carry out and support self-inspections.

Programme

Regulatory Requirements

- Goal and purpose of the self-inspection
- Expectations regarding planning, implementation and follow-up
- GMP-compliant self-inspection reports

The Implementation of Self-Inspections

- Organisation, planning and preparation
- Audit team
- Topics and focal points
- Duration
- What needs to be considered during implementation?
- Follow-up

Speakers



Dr Rainer Gnibl

District Government of Upper Bavaria, Germany

Dr Rainer Gnibl is GMP Inspector and Head of the Inspectorate of the District Government and performs GMP-inspections worldwide. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.



Dr Felix Kern

Merck, Germany

Felix Kern is Associate Director and Head of Compliance Launch and Technology Center. Felix is a member of the new ECA Working Group for GMP-Auditors.

Details

Date of the Live Online Training

Tuesday, 24 February 2026, 13.00 – 16.30 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 events and you can check if your system meets the necessary requirements to participate.

Fees (per delegate plus VAT)

ECA Members EUR 590

APIC Members EUR 640

Non-ECA Members EUR 690

EU GMP Inspectorates EUR 590

The conference fee is payable in advance after receipt of invoice.

The Registration does not include ECA Membership.

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.

Organisation and Contact

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

CONCEPT HEIDELBERG

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All details and registration online:

www.gmp-compliance.org
under the number 22379

