Self-Inspection

Compliant and Successful Self-Inspections and Internal Audits

Live Online Session on 12 September 2024

ECA 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
Thursday, 12 September 2024,
13.00 – 16.45 h CEST

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.
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All details and registration online at:
www.gmp-compliance.org

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