ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Ciara Clarke
Sumac Works, Ireland

Irene Heiderich
Boehringer Ingelheim Pharma, Germay

Alexander Kammerlocher
GMP/GDP Inspectorate, Local Government, Germany

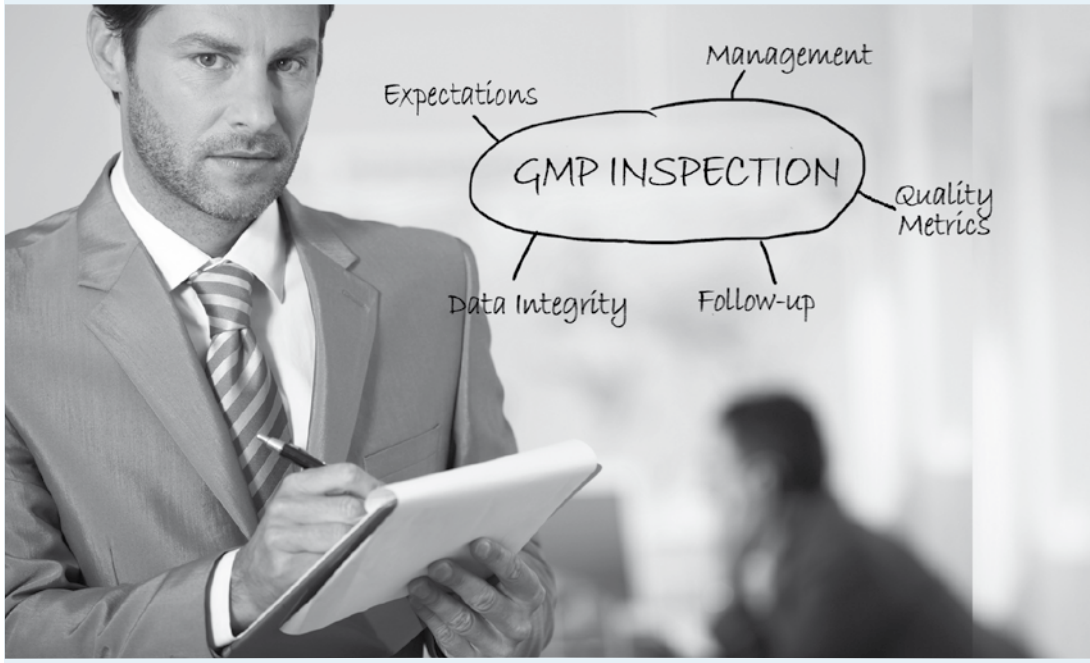
Katja Kotter
Vetter Pharma-Fertigung, Germany

Dr Ralf Schreiner
QProgress, Germany

Inspection Management

How to pass global GMP Inspections

Live Online Training on 18/19 October 2023



Highlights

- Inspection Management
  - How Inspectors are trained
  - Adequate Preparation
  - Mock Inspection
  - Successful Inspection Management
  - Efficient Follow-up
  - Distant Assessments
- Experience from global Inspections
  - FDA
  - Brazil (ANVISA)
  - Mexico (COFEPRIS)
  - Turkey (MOH)
  - Russia (FSI SID&GP)
  - Eurasian Economic Union (EAEU)
  - China (NMPA)
  - South Korea (MFDS)
  - Taiwan (TFDA)

All participants receive a Checklist for FDA Inspection Preparation

Objectives

You will understand the purpose and organisation of regulatory inspections and you will learn how to **prepare your company to pass an inspection or customer audit and how to assure the most positive outcome**.

Get practical knowledge of:

- What inspectors are looking for
- Successful preparation and management of inspections
- Performing a MOCK-Inspection
- Latest trends (with a view on virtual/remote inspections)

In addition, you will hear examples from global inspections to gain a **better understanding of what is expected**.

Background

GMP audits and inspections are **fundamental elements of managing quality** in the pharmaceutical industry. On the one hand, pharmaceutical companies have to perform supplier audits. And on the other hand, the pharmaceutical companies as well as the suppliers are frequently inspected by the authorities (both national and international inspectorates like the FDA) as a central element of supervision.

For the company, an inspection can have a decisive influence on the daily work and its economic future. A sound and thorough preparation is an essential key to successfully pass an inspection.

Target Audience

This GMP Education Course is designed for all persons involved in preparing, managing and escorting audits and inspections.

Moderator

Wolfgang Schmitt
CONCEPT Heidelberg (on behalf of ECA)

Programme

Approach and Expectations of the Agencies

- How inspectors are trained
- Skills needed
- Inspection preparation, strategy and tactics
- Information transfer between inspectorates
- What to expect, when being inspected in the near future
- Observations - some practical examples

Preparing for a Regulatory Inspection

- Team building
- Gap analysis and action plan
- Roles and responsibilities
- Training of the staff
- Function of moderator, escorts and experts

Case Study: Proactive Compliance and Inspection Management – it's more than Self Inspection

- How to increase inspection risk-awareness
- Risk categorisation and ranking
- Risk reduction prioritization
- Reporting of the results to senior management

The MOCK-Inspection: Auditing your Company to prepare for international Inspections

- Internal Audit and Mock-Inspection
- Audit strategy
- Roles and Responsibilities
- Communication and co-operation
- Sequence of preparation steps
- Co-operation with customers and external auditors

Expectations from Inspectorates worldwide

- Brazil (ANVISA)
- Mexico (COFEPRIS)
- Turkey (MOH)
- Russia (FSI SID&GP)
- Eurasian Economic Union (EAEU)
- China (NMPA)
- South Korea (MFDS)
- Taiwan (TFDA)

The FDA Approach

- The MRA between the U.S. and the EU and its consequences
- The FDA Inspection System
- What does FDA expect?

How to prepare for Distant Assessments/Hybrid Inspections (the Auditee's Perspective)

- Tools needed
- Which documents can be provided upfront – and how
- How to realise a safe document review
- How to support a virtual tour
- What problems can occur and possible solutions
- Resources and time requirements

Responding to Audit and Inspection Findings

- How to reply to report and observations
- Dissent and dispute
- Proof of CAPA effectiveness
- Ensuring that measures are implemented company-wide
- What to do if a target date can not be achieved?

GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.

This could be of interest for you as well

Would you like to train a larger group of participants in your company?
We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity

You will find a time schedule for each training course at www.gmp-compliance.org/training/gmp-gdp-in-house-trainings

Ciara Clarke
Sumac Works, Ireland

Ciara Clarke started her consultancy business 2021. In her last role she was Senior QA Executive, QP and Deputy RP at Viatris (formerly Mylan). She was also Assistant Lecturer in Science at the Technological University Dublin.

Irene Heiderich
Boehringer Ingelheim Pharma, Germany

Besides performing Self-Inspections, Irene Heiderich s also involved in the planning, performance and escort of customer audits and authority inspections.

Alexander Kammerlocher
GMP/GDP Inspectorate, Local Government, Germany

Alexander Kammerlocher is a GMP inspector at the local competent authority in the federal state of Baden-Württemberg.

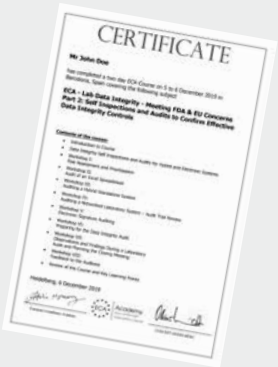
Katja Kotter
Vetter Pharma-Fertigung, Germany

Katja Kotter is Vice President Regulatory Affaires and Quality Compliance. She has broad experience in managing authority inspections and customer audits.

Dr Ralf Schreiner
QProgress, Germany

Dr Ralf Schreiner started his consultancy business in 2018. Prior to that, he spent 20 years in various management positions in the pharmaceutical industry, most recently as Executive Director Quality Systems at Actavis/Allergan.

Your Benefit:


CERTIFICATE

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires:

„... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...".

This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Inspection Management
Live Online Training on 18/19 October 2023

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Wednesday, 18 October 2023, 09.00h – 16.30h
Thursday, 19 October 2023, 09.00h – 15.30h
All times mentioned are 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. 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 € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

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

For questions regarding content:
Mr Wolfgang Schmitt (Operations Director) at
+49(0) 62 21/84 44 39, or per e-mail at
w.schmitt@concept-heidelberg.de

For questions regarding organisation please contact:
Mr Niklaus Thiel (Organisation Manager) at
+49(0) 62 21/84 44 43, or per e-mail at
thiel@concept-heidelberg.de