ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Katja Kotter
Vetter Pharma-Fertigung

Dr Jean-Denis Mallet
form. Head of the French Pharmaceutical Inspection Department (AFSSAPS, now ANSM)

Edel Ryan
Mylan

Dr Anke von Harpe
QProgress

Inspection Management

How to pass global GMP Inspections

Live Online Training on 17/18 November 2020

Highlights

- Inspection Management
  - Adequate Preparation
  - Successful Inspection Management
  - Efficient Follow-up
  - Virtual Audits
- 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)

Every Participant will get a detailed Checklist for 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
- Typical compliance issues and proactive compliance
- Performing a MOCK
- Latest trends (with a view on virtual/remote audits)

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)

Your Benefits

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.

Programme

The Challenges of GMP Audits and Inspections

- Regulatory Requirements
- Purposes and Reasons for GMP inspections
- Audit types

The View of a Former EU Inspector: Authority Expectations - Some Practical Examples

- Organisations, agencies and inspections worldwide and their differences
- Experiences from an ex-inspector's point of view
- What to expect, when being inspected in the near future

The FDA Approach

- The MRA between the U.S. and the EU and its consequences
- The FDA Inspection System
- What does FDA expect?
- Responding to FDA (483, Warning Letter)

Preparing for a Regulatory Inspection

- Team building
- Gap analysis and action plan
- Roles and responsibilities
- Staff Training
- Function of moderator, escorts and experts
- Virtual (remote) audits

Experiences with Various Inspectorates (What You Need to Know)

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

Typical Compliance Issues

- Quality System
- Laboratory control
- Production
- Material Management
- Facility & Equipment
- Packaging and labelling

The MOCK-Inspection: Auditing Your Company to prepare for 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

The Follow-up

- 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

Free tool for inspection preparation:

As a participant you will get a detailed checklist for inspection preparation (40 pages). This checklist can be adapted to prepare your pre-approval inspections, routine inspections or customer audits.

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

Speakers

Katja Kotter
Vetter Pharma-Fertigung GmbH & Co. KG, Germany

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

Jean-Denis Mallet, PhD
formerly Head of the French Pharmaceutical Inspection Department, France

Jean-Denis Mallet was the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (AFSSAPS). Currently he is working as a consultant for Pharmaplan.

Edel Ryan
Mylan, Ireland

Edel Ryan is Director, Complex Products Quality Operations. In this role she also supports CMOs in inspection readiness activities.

Dr Anke von Harpe
QProgress GmbH, Germany

Dr Anke von Harpe started her consultancy business in 2018. Prior to that, she held various senior QA positions in the pharmaceutical industry, including QP and Director Quality Systems.

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.

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 17/19 November 2020

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week 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 HEIDELBERGwill 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 January 2012).
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 https://www.gmp-compliance.org/privacy-policy). 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

Tuesday, 17 November 2020, 09.00 h – 17.00 h
Wednesday, 18 November 2020, 09.00 h – 17.00 h
All times mentioned are CET.

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
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.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

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:
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.

CF/06082020