ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

## Speakers

**Katja Kotter**
Vetter Pharma-Fertigung

**Savvas Koulouridas**
Fagron BV

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

**Markus Roemer**
comes compliance services

**Edel Ryan**
Mylan

**Thomas Noe Vestergaard Pedersen**
Danish Medicines Agency

**Dr Anke von Harpe**
QProgress

# Inspection Management

## How to pass global GMP Inspections

## 17 – 19 November 2020 | Hamburg, Germany


## Highlights

- Latest Developments
  - MRA between FDA and EU
  - How to prepare a Data Integrity Inspection
- Inspection Management
  - Adequate Preparation
  - Successful Inspection Management
  - Efficient Follow-up
- Experience from global Inspections
  - FDA
  - Brazil (ANVISA)
  - Mexico (COFEPRIS)
  - Turkey (MOH)
  - Russia (FSI SID&GP)
  - Saudi-Arabia (SFDA)
  - Taiwan (TFDA)
- Juristic Perspective
  - Support and Attendance
  - Replies and Response

- With inside Information from FDA and EU Inspectorates
- Every Participant will get a detailed Checklist for Inspection Preparation
- Workshop on Data Integrity Inspection

## 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-Inspection (also for Data Integrity)
- How legal department can support
- Latest trends

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

### 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

### What makes a good Inspector

- How inspectors are trained
- Skills needed
- Inspection preparation, strategy and tactics
- Information transfer between inspectorates

### The FDA Approach

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

### Experiences with various Inspectorates (what you need to know)

- Brazil (ANVISA)
- Mexico (COFEPRIS)
- Turkey (MOH)
- Russia (FSI SID&GP)
- Saudi-Arabia (SFDA)
- 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

### Workshop: Proactive Compliance and Inspection Management – it's more than Self Inspection

Case Study: An Inspection Management Risk Model

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

## Case Study: The juristic Perspective - how Legal can support QA

- Preparation
- Attendance
- Direct inspection support
- Replies and response to inspection reports

## 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

## Parallel Sessions:

You will be able to attend two of these parallel sessions. Please choose the two sessions you would like to attend when you register for the course.

**Session 1**
**Preparing for a Regulatory Inspection (with Inspection Simulation)**

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

The workshop includes a simulation of an inspection situation (role play).

**Session 2**
**What would you do if ... (Know your GMPs)**

An interactive review of different GMP scenarios which will take into account your knowledge of GMPs and enable detailed discussions on the implications of the actions taken.

**Session 3**
**Data Integrity**

- GMP process and laboratory data flow
- Preparing and presenting data sources and data governance for an inspection

**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.

# Social Event

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

# 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.

Savvas Koulouridas
Fagron BV, Netherlands

Savvas Koulouridas is Global Innovation Director of Fagron. He is a lawyer in profession and has also worked as a consultant on pharmaceutical law (GMP regulations and Pharmaceutical Contracts).

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.

Markus Roemer
comes compliance services, Germany

Markus Roemer is General Manager of comes compliance services, Germany. He was Senior Validation Consultant at Invensys Validation Technologies in Montreal, Canada and Director Compliance Services.at Systec & Services.

Edel Ryan
Mylan, Ireland

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

Thomas Noe Vestergaard Pedersen
Danish Medicines Agency, Denmark

Thomas Vestergaard Pedersen is a Medicines Inspector and Team Leader at the Danish Medicines Agency (GMP and GDP).

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.

## Date
Tuesday, 17 November 2020, 09.30 h – 17.30 h
(Registration and coffee 09.00 h -09.30 h)
Wednesday, 18 November 2020, 09.00 h – 17.30 h
Thursday, 19 November 2020, 08.30 h – 14.30 h

## Venue
Barceló Hotel Hamburg
Ferdinandstraße 15
20095 Hamburg, Germany
Phone +49(0)40 22 63 62 0
Email hamburg@barcelo.com

## Fees (per delegate, plus VAT)
ECA Members € 1,990
APIC Members € 2,090
Non-ECA Members € 2,190
EU GMP Inspectorates € 1,095
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all three days and all refreshments.
VAT is reclaimable

## Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

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

## 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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D-69007 Heidelberg
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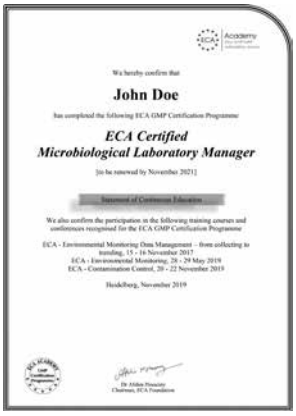
Telefax 49(0) 62 21/84 44 34
E-Mail: info@concept-heidelberg.de
www.concept-heidelberg.com

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

## 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.


We hereby confirm that
**John Doe**
has completed the following ECA GMP Certification Programme
***ECA Certified Microbiological Laboratory Manager***
[to be renewed by November 2021]
Statement of Continuous Education
We also confirm the participation in the following training courses and conferences recognised for the ECA GMP Certification Programme
ECA - Environmental Monitoring: Data Management – from collecting to trending, 15 - 16 November 2017
ECA - Environmental Monitoring, 28 - 29 May 2019
ECA - Contamination Control, 20 - 22 November 2019
Heidelberg, November 2019

## What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

## How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

## What Are the Benefits of ECA?

During the membership, you enjoy
- free access to the members' area where you always find the latest update of the "GMP Guideline Manager" online version – allowing you to access a GMP tree with guidelines sorted by topics or by authority. It lets you find relevant guidelines quick and easy. And as member you can also get to this detailed tree with the GMP WebApp on your smartphone or tablet PC.
- a 200,- Euro rebate for any ECA course and conference, plus the opportunity to complete the GMP Certification Programme with an internationally recognised certificate.

WA/17122019

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

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CONCEPT HEIDELBERG
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

## Inspection Management, 17 – 19 November 2020, Hamburg, Germany

Please choose TWO sessions:
☐ *Session 1: Preparing for a Regulatory Inspection*
☐ *Session 2: What would you do if … (Know your GMPs)*
☐ *Session 3: Data Integrity*

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.