



Academy
Your GMP/GDP
Information Source

Inspection Management

How to pass global GMP Inspections



SPEAKERS:



Katja Kotter
*Vetter Pharma-
Fertigung*



Savvas Koulouridas
Fagron Hellas



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



Thomas Noe Vestergaard Pedersen
*Danish Medicines
Agency*



Markus Roemer
*comes compliance
services*



Edel Ryan
Mylan



Mark Tucker, Ph.D
*form. US FDA
Investigator and
Compliance Officer*

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

6 - 8 November 2018, Barcelona, Spain

PROGRAMME:

- 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



This education course is recognised for the ECA GMP Certification Programme „Certified QA Manager“. Please find details at www.gmp-certification.eu

Inspection Management

6 - 8 November 2018, Barcelona, Spain

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.

Moderator

Wolfgang Schmitt

Target Audience

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

Note: The number of participants is limited.

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 View of a former FDA Inspector:

- The MRA between the U.S. and the EU
 - The future of FDA inspections
 - FDA inspections despite MRA
 - What FDA will expect from EU sites
- FDA's Quality Metrics Initiative
 - Current Status
- The FDA Inspection System
 - Classification of GMP deficiencies/Examples of critical deficiencies
 - What does the inspector expect?
 - PAI vs. system based inspection
 - What happens at FDA during and after the Inspection
 - Responding to FDA (483, Report, Warning Letter)
 - Hot topics and trends

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 international Inspections

- Internal audit expectations
- Audit hierarchy
- EU and FDA cGMP differences
- Quality System audit details
- Audit strategy and cycle
- Rolls and Responsibilities

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

Preparation and Management of Regulatory Inspections

- Tools to successfully manage regulatory inspections
- Features of on-line communication tools, e.g. NetMeeting, WebMeeting
- Layout of the Back Room
- Inspection workflow and definition of functions
- Docket system

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

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

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.

Parallel Sessions

You will be able to attend two of these parallel sessions. Please choose the 2 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

Risk Analysis related to the Inspection and Findings

- Conceptualisation of the "Risk"
- What is an inspection / audit finding
- Pre-existing classifications
- Quality Risk Management & GMP Findings

Session 3

Data Integrity

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

Social Event

In the evening of the first day, you are cordially invited to a social event (city tour and dinner). 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 Affairs and Quality Compliance. She studied Pharmaceutical Technology and Business Engineering and has broad experience in managing authority inspections and customer audits.



Savvas Koulouridas

Fagron Hellas, Greece
Savvas Koulouridas is Area Business Development Manager for South Europe and Latin America for Fagron. He is a lawyer in profession and has also worked as a consultant on pharmaceutical law (GMP regulations and Pharmaceutical Contracts).



Dr Jean-Denis Mallet

formerly Head of the French Pharmaceutical Inspection Department

Jean-Denis Mallet was the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (AFSSAPS). He has also been working in or with the pharmaceutical industry for many years. Currently he is working for NNE Pharmaplan.



Markus Roemer

comes compliance services

Markus Roemer is General Manager of comes compliance services, Germany. He started his professional career as a team member of the computer validation department at Vetter Pharma Fertigung in Ravensburg. Later he was (amongst others) 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. Before working for Mylan, Edel held various quality positions for example at Amgen and Pfizer.



Mark Tucker, Ph.D.,

former FDA Investigator and Compliance Officer

Mark Tucker was Director, Investigations Branch at the U.S. Food and Drug Administration (FDA). He also served as an Investigator and Compliance Officer with the FDA. Currently Mark Tucker is Vice President, CMC Quality at Ultragenyx Pharmaceutical Inc., USA.




Thomas Noe Vestergaard Pedersen

Danish Medicines Agency

Thomas Vestergaard Pedersen is a Medicines Inspector and Team Leader at the Danish Medicines Agency (GMP and GDP). Before that, he worked for 12 years as a manager/director at the Statens Serum Institute (now AJ Vaccines).

Easy Registration

 Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

 Reservation Form:
+ 49 6221 84 44 34

@ e-mail:
info@concept-heidelberg.de

 Internet:
www.gmp-compliance.org

Date

Tuesday, 06 November 2018, 09.30 h – 17.30 h
(Registration and coffee 09.00 h – 09.30 h)
Wednesday, 07 November 2018, 09.00 h – 18.00 h
Thursday, 08 November 2018, 08.30 h – 13.30 h

Venue

Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 93 503 53 00
Fax +34 93 4906045
sants@barcelo.com

Fees (per delegate plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
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 when you have registered for the event. Reservation should be made directly with the hotel. Early reservation is recommended.

Conference language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
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.de

For questions regarding content please contact:

Wolfgang Schmitt (Operations Director) at
+49-62 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)6221/84 44 43, or per e-mail at
thiel@concept-heidelberg.de

Use the GMP App at no costs!



The ECA Foundation has developed a GMP App which offers a comprehensive GMP Guideline database with more than 1,400 GMP Guidelines and ten thousands of pages. Check relevant Guidelines (full text versions) during internal audits, regulatory inspections or GMP compliance meetings – simply on your smartphone or tablet PC. In addition to this wealth of guideline information the GMP App also comprises features like GMP News, a comprehensive GMP Search Engine. To open the app just enter app.gmp-compliance.org in your browser and the WebApp opens immediately.

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.

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, 6 - 8 November 2018, Barcelona, Spain

Please choose the 2 sessions you would like to attend:

- Preparing for a Regulatory Inspection (with Inspection Simulation)
- Risk Analysis related to the Inspection and Findings
- Data Integrity

Mr. Ms.

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID number

P.O. Number if applicable

Street/P.O. Box

City

Zip Code

Country

Phone/Fax

E-Mail (please fill in)

General terms and conditions


1. You cannot attend the conference you have two options:
- 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 %
- within 1 week prior to the conference 50 %
- 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 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 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 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.

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