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

Inspection Management

How to Pass EU and FDA Inspections

23 – 25 September 2015, Barcelona, Spain

SPEAKERS:

Dr Martin M. Appel
Cilag AG/Johnson & Johnson

Richard M. Bonner
ECA, form. Eli Lilly

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

Frank Raisch
GSK

John Taylor
form. U.K. Medicines and Healthcare Products Regulatory Agency (MHRA)

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

PROGRAMME:

- Industry Perspective:
  - Adequate Preparation
  - Successful Inspection Management
  - Efficient Follow-up
- Regulatory Perspective:
  - Global Inspections
  - Enforcement
  - Expectations and Trends
- Juristic Perspective:
  - Support and Attendance
  - Replies and Response

ECA ACADEMY

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

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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
- The psychology of inspections
- How legal department can support

In addition you will hear trends from EU and FDA Inspections to gain a **better understanding of what is expected**.

Sufficient time for questions and answers is provided to discuss your issues.

Background

GMP audits and inspections are **fundamental elements of managing quality assurance** 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 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

Richard M. Bonner

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

Authority Expectations: some practical Examples from a former EU Inspector
- Organisations, agencies and inspections worlswide and their differences
- Experiences from an ex-inspector's point of view
- What to expect, when being inspected in the near future

The View of a former MHRA Inspector
- Quality management systems and their assessment
- Improvement through auditing and benchmarking

The View of a former FDA Inspector
- The FDA Inspection System
- Classification of GMP deficiencies/Examples of critical deficiencies
- FDA inspection findings
- What does the inspector expect when he arrives at your site
- What the FDA will look for
- PAI vs. System Inspection
- What happens at FDA during and after the Inspection
- Responding to FDA (483, Report, Warning Letter)
- Hot topics and trends in the agency that will result in future GMP guidance updates

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

How inspectors are trained
- What makes a good Inspector
- Skills needed
- Information transfer between inspectorates

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

Preparation and Management of Regulatory Inspections

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

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

The Psychology of Inspections

- Who is in charge?
- How to deal with conflicts
- What if you don't agree with an inspector?
- Body language of inspector and auditee
- Some "tricks of the trade"
- The Dos and Don'ts

Parallel Workshops

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.**

Workshop 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 workshops includes a simulation of an inspection situation (role play).

Workshop 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

Workshop 3
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.

Case Study: The juristic Perspective - how legal Department can support QA

- Preparation
- Attendance
- Direct Inspection Support
- Replies and Response to Inspection Reports

Free tools for inspection preparation:

1. 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.

2. In addition, you will get the GMP Navigator CD-ROM. This CD contains all relevant EU, FDA, ICH, and WHO guidelines. In the office or on the laptop during inspections, the CD-ROM is a useful tool for verifying, for example, whether a particular requirement is really laid down in the guidelines or not.

Speakers

Dr Martin M. Appel,
Cilag AG, Johnson & Johnson, Switzerland
Martin Appel is Director QA for the Global External Manufacturing of APIs at Johnson& Johnson. Before, he was Quality System Director at Cilag AG acting as liaison during official inspections from e.g. FDA, EU, SwissMedic as well as during customer audits and performed in-house audits and GMP Inspections at suppliers.

Richard M. Bonner,
ECA, formerly with Eli Lilly
Dick Bonner is Chairman of the ECA Foundation and of the European QP Association. He also works as a consultant to the Pharmaceutical Industry. Previous to his current role he was a Senior Quality Adviser for Eli Lilly and Company. He had 31 years experience within the pharmaceutical industry working in production, technical services and both Quality Control and Quality Assurance functions.

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. Jean-Denis is member of the Advisory Board of the ECA Foundation.

Frank Raisch,
GSK
Frank Raisch is Attorney-at-Law and Legal Counsel at GSK (GlaxoSmithKline). He studied at the University in Tübingen and Université Paris-Sorbonne. Besides working for GSK, he runs his own law firm.

John Taylor,
form. Medicines & Healthcare Products Regulatory Agency (MHRA), U.K.
Until July 2015, John Taylor was Quality and Standards Manager at MHRA. He also has a wide experience within the Inspection and Enforcement Division.

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 is Executive Director, QA and Compliance at Ultragenyx Pharmaceutical Inc.

Social Event

On 23 September 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.

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

Wednesday 23 September 2015, 10.30 h – 18.00 h
(Registration and coffee 10.00 h -10.30 h)
Thursday, 24 September 2015, 09.00 h - 18.00 h
Friday, 25 September 2015, 08.30 h – 14.00 h

Venue

Barceló Sants Hotel
Plaça dels Països Catalans, s/n
Estació de Sants
08014 Barcelona, Spain
Phone +34 (93) 503 53 00
Fax +34 (93) 490 60 45

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:
Wolfgang Schmitt (Operations Director) at
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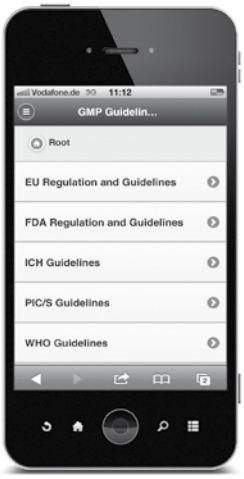
w.schmitt@concept-heidelberg.de
For questions regarding reservation, hotel, organisation etc.:
Ms Jessica Stürmer (Organisation Manager) at
+49-62 21 / 84 44 43, or per e-mail at
stuermer@concept-heidelberg.de.

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 a EUR 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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Please choose the 2 sessions you would like to attend:

☐ Workshop 1 Preparing for a Regulatory Inspection (with Inspection Simulation)
☐ Workshop 2 Risk Analysis related to the Inspection and Findings
☐ Workshop 3 Know your GMPs

☐ 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)**

CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

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 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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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)

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.