



- 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

5 – 7 November 2014, Berlin, Germany

SPEAKERS:

Dr Martin M. Appel
Cilag AG/Johnson & Johnson

Richard M. Bonner
ECA, form. Eli Lilly

Ian Holloway
*U.K. Medicines and Healthcare Products
Regulatory Agency (MHRA)*

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

Frank Raisch
GSK

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



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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 worldwide 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.

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.



Ian Holloway

Medicines & Healthcare Products Regulatory Agency (MHRA), U.K.

Ian Holloway is GMP/GDP inspector at the MHRA. Before that, he was Head of the Defective Medicines Report Centre at MHRA.



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.



Mark Tucker, Ph.D.

**former FDA Investigator and Compliance
Officer**

Mark Tucker was Senior Director, GMP Compliance at Genentech Inc., South San Francisco, USA, where he had the full strategic responsibility for GMP Compliance. Before joining Genentech in 2002, Mark was Director, Investigations Branch at U.S. Food and Drug Administration (FDA). He also served as an Investigator and Compliance Officer with the FDA.

Social Event

On 5 November you are cordially invited to a social event in Berlin. 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 05 November 2014, 10.30 h – 18.00 h
(Registration and coffee 10.00 h -10.30 h)
Thursday, 06 November 2014, 09.00 h - 18.00 h
Friday, 07 November 2014, 08.30 h – 14.15 h

Venue

InterCityHotel Berlin Hauptbahnhof
Katharina-Paulus-Straße 5
10557 Berlin, Germany
Phone +49 (0)30 288 755 0
Fax +49 (0)30 288 755 900

Fees

ECA Members: € 1.790,- per delegate + VAT.
APIC Members: € 1.890,- per delegate + VAT
Non-ECA Members: € 1.990,- per delegate + VAT.
EU GMP Inspectorates: € 995,- per delegate + VAT.
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.

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

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
+49-62 21/84 44 39, or per e-mail at
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.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG.
ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

What are The ECA Foundation and the ECA Academy?

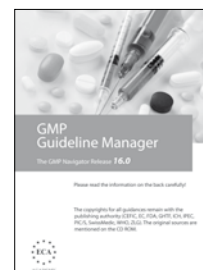
The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators 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:

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, 5 - 7 November 2014, Berlin, Germany
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)

General terms and conditions

- If you cannot attend the conference you have two options:
- We are happy to welcome a substitute colleague at any time.
 - 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 %.

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 2014)



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