ECA Certified QA Manager Course*

Every Participant will get:
- A detailed Checklist for Inspection Preparation (40 pages)
- The latest GMP Navigator CD-ROM (1.200 documents)

How to Pass EU & FDA Inspections and GMP Compliance Audits

25 – 27 May 2011, Prague, Czech Republic

SPEAKERS:

Dr Martin M. Appel
Johnson & Johnson, Switzerland

Richard M. Bonner
ECA, formerly Eli Lilly and Company Ltd, U.K.

Dr Jean-Denis Mallet
formerly Head of the French Pharmaceutical Inspection Department

John Taylor
Medicines and Healthcare Products Regulatory Agency, U.K.

Mark Tucker, Ph.D
Genentech Inc., USA
former FDA Investigator and Compliance Officer

PROGRAMME:

- Regulatory Overview:
  - What do Authorities expect
  - How Inspectors are trained
  - Regulatory Inspections
  - Typical Compliance Issues
- Preparing for a GMP Inspection:
  - Successful Preparation
  - Tools to manage an Inspection
  - The MOCK-Inspection
  - Dos and Don'ts
  - The Psychology of Inspections
- Inspections and Audits in third countries
- 4 Workshops

ECA
European Compliance 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**.

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

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

What do Authorities expect?
- What is a GMP inspection
- Differences in the Guidelines
- The quality system is the focus
- Preparation and Inspection
- Experiences from an ex-inspector's point of view

Regulatory Inspections: The View of an UK Inspector
- Introduction of MHRA GMP inspections
- Classification of GMP deficiencies/Examples of critical deficiencies
- MHRA inspection findings 2005/2006 for
- for API sites, tissue banks and blood centres
- Risk assessment in the audit process
- Inspection outcome measures
- EMEA compilation of community procedures on inspections and exchange of information
- The future

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

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. Net-Meeting, WebMeeting
- Lay-out of the Back Room
- Inspection workflow and definition of functions
- Docket system

Parallel Workshop

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 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

Outlook: Inspections and Audits in third Countries (Non-US & Non-MRA)

- Cultural issues and logistic issues outside of Europe
- How to assess sites in third countries
- Typical findings outside the EU

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.

Social Event

The European Compliance Academy (ECA) and CONCEPT HEIDELBERG cordially invite the conference participants to join them and the speakers for a social event on Wednesday evening in Prague. During an informal dinner you will have the opportunity to share your experiences and discuss the hot topics of the day with your colleagues.

Speakers

Dr Martin M. Appel, Cilag AG, Johnson & Johnson, Switzerland
Martin Appel has 20 years experience in several manager positions in the pharmaceutical industry. He was Quality System Director at Cilag AG and since 2008 he is Director QA for the Global External Manufacturing of APIs at Johnson&Johnson. He acted 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, U.K.
Dick Bonner is Regulatory Affairs Director at the ECA, member of the Advisory Board of the European QP Association and 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.

Jean-Denis Mallet, PhD, 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 at various positions including Quality Assurance, Production Management, Engineering and GMP Consulting. Jean-Denis is member of the Advisory Board of the ECA Foundation.

John Taylor, Medicines & Healthcare Products Regulatory Agency (MHRA), London, United Kingdom
John Taylor is Quality and Standards Manager Acting and Group Manager, Enforcement and Intelligence of the UK Medicines and Healthcare Products Regulatory Agency. He is currently responsible for all quality matters within the Inspection and Enforcement Division. John Taylor is a Chartered Chemist, a Fellow of the Royal Society of Chemistry, member of the British Institute of Regulatory Affairs and member of the Advisory Board of the European QP Association

Mark Tucker, Ph.D, Genentech Inc., USA
former FDA Investigator and Compliance Officer
Mark Tucker is Senior Director, GMP Compliance at Genentech Inc., South San Francisco, USA, where he has 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, where he represented the FDA at meetings with firm management and industry groups outlining and defending FDA positions. He started his career as Assistant Professor at the University of Southern California and Adjunct Assistant Professor at the Research and Education Institute, Harbor/UCLA Medical Center.

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, 25 May 2011, 10.30 h – 18.00 h
(Registration and coffee 10.00 h - 10.30 h)
Thursday, 26 May 2011, 09.00 h - 18.00 h
Friday, 27 May 2011, 08.30 h – 14.00 h

Venue

Dorint Hotel Don Giovanni Prague
Vinohradská 157A
130 20 Prague 3
Czech Republic
Phone +420 2 6703 1111
Fax +420 2 6703 6717

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. Please use this form for your room reservation or be sure to mention "VA 6863 ECA Course" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 25 April 2011. 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
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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.:
Detlef Benesch (Organisation Manager) at
+49-62 21 / 84 44 45, or per e-mail at
benesch@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 Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities.

The ECA will provide 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.

What Are the Benefits of ECA?
First benefit:
During the membership, you enjoy a € 200 discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?
By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website **http://www.gmp-compliance.or**

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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)

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 %.

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)!