ICH Q7 Auditor Training Course
11 – 13 March 2015, Vienna, Austria

Speakers
RICHARD M. BONNER
formerly Eli Lilly and Company Limited, UK
FRANCOIS VANDEWEYER
Janssen Pharmaceutica, Belgium
PETER C. ZIMMERMANN
Iskom, Germany

This course is recognised for the ECA GMP Certification Programme “Certified API (Production) Manager”. Please find details at www.gmp-certification.eu
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In compliance with the European Directives, Manufacturing Authorisation Holders of Medicinal Products Manufacturers must satisfy themselves that the APIs used as Starting Materials in the manufacture of Medicinal Products are compliant with the ICH Q7 GMP requirements that are included as Part II of The Rules Governing Medicinal Products in the European Union.

Audits are a powerful tool for senior management to meet these requirements and to determine whether a manufacturer is in compliance or not, i.e. to compare „what is in place“ with „what should be in place“.

This training course will inform the participant about the general advice on Good Auditing Practices included in the APIC “Auditing Guide” and the APIC Third Party Audit Programme (www.apic.cefic.org) which is based on the advice of the European Authorities on the Principles of Third Party Auditing. In addition to the training of the communication skills, the ICH Q7 Auditor Training Course will provide assistance on what to focus on during an API audit and on the current „state of the art“ from an industry perspective. The basic document for this part of the training will be the APIC/CEFIC’s „How-to-Do“ document, an interpretation of ICH Q7 requirements. For becoming a certified auditor within the „ICH Q7 Auditor Certification Scheme“, it is a prerequisite to have also participated in the ICH Q7 training courses for APIs manufactured either chemically or by cell culture/fermentation (2.5 days each). However, it is also possible to participate in this training course without the aim of certification.

Richard M. Bonner

CONDUCTING AN AUDIT – TOOLS AND TECHNICAL ASPECTS

The CEFIC / APIC Audit Programme – a Third Party Audit Option – Guidance on Auditing Practice

- CEFIC / APIC Quality Working Group
- EU Legislation and Advice on GMP Status of Active Substances
- Third Party Audit Principles
- The APIC Audit Programme
- Auditor Certification
- Phases of the APIC Audit Programme
- Contracts with Auditor and Auditee
- Audit Dos and Don’ts
- Advance preparations for successful audit
- Performing the Audit
- Closing Meeting
- Audit Report

How to prepare for an audit depending on the scope

How to write an audit report

- What makes a good “observation“?
- Elements of audit observations
- General rules on writing observations
- Types of observations
- Writing style
- Common pitfalls seen in writing observations

Interactive Session on ICH Q7

The participants will work on questions regarding GMP topics derived from ICH Q7. The questions and answers will be discussed in a plenary session. More questions will be discussed in working groups and the answers will then be presented in the plenary.

This interactive session is supposed to be a knowledge assessment. This assessment is only relevant for participants intending to obtain the APIC Auditor Certification.
CONDUCTING AN AUDIT – COMMUNICATION AND PSYCHOLOGICAL ASPECTS

Training Objectives
- Brush-up existing knowledge about communication and leading a conversation
- Analysis of the phenomenon of verbal and non-verbal communication
- Analysis of the art of questioning and conversation techniques
- Reflection on the auditor’s role
- Development of questioning and interview techniques
- Awareness of possible conflict situations
- Feedback and reflection on your own behaviour
- Exchange of experiences

COMMUNICATION PART I

General aspects of communication
- The meaning of communication in an audit
- Communication as a process
- Analysis of the process

Key issues of communication
- Verbal and non-verbal communication
- The first impression
- Determining important aspects in communication
- Exercise

COMMUNICATION PART II

Multicultural aspects
- Differences in body language
- Different rituals
- Different dos and taboos
- Workshop multicultural aspects: Experiences

Audit: A unique situation of communication
- The overall setting
- The participants
- The rules
- The topics

COMMUNICATION PART III

General aspects of opinions and observations
- Successful communication
- Skills of the listener
- Skills of the speaker
- Active listening
- Objective evidence of GMP Deficiencies directly related to ICH Q7
- Classification of Deficiencies

Questioning methods
- Open and closed ended questions
- Other questioning techniques
- Exercise
- Attitude and behaviour in front of the auditee
- Preparation for the role plays

Conducting an Audit – Role Plays
The participants will have the opportunity to manage an audit situation within a role play scenario.

During these role plays a trainer with academic education in psychology assesses the participants’ auditing skills and judges their aptitude for conducting audits.

This assessment is relevant only for participants intending to obtain the APIC Auditor Certification.

The Audit closing meeting and measuring success
- Lead auditor’s tasks and behaviour in the closing meeting
- Audit summary report
- Audit finding categories
- Audit response and follow-up audits
- Ways to measure the success of an audit

Written exam only for participants intending to obtain the APIC Auditor Certification:

The participants will have to answer some questions about GMP topics derived from ICH Q7 in a written exam. After having successfully passed this exam the participants are required to take another exam on current GMP topics as an internet-based multiple choice test approx. 2 weeks after the course has finished. The access code will be made available via email.

After having passed this test the participants will receive their APIC Auditor Certification via post.
Richard M. Bonner, formerly Eli Lilly and Company Limited, UK
Mr Bonner is currently located in the UK and 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. He has been involved in multiple inspections from the MHRA, FDA and other authorities. He has also been instrumental in obtaining ISO9000-2000 accreditation for manufacturing sites. He has audited extensively throughout the EU and in countries as far a field as Canada, USA, China, Pakistan, Egypt, Syria, Oman and Russia. Mr Bonner is a Qualified Person in Europe. He is also Chairman of the European Compliance Academy.

Francois Vandeweyer, Janssen Pharmaceutica, Belgium

Peter C. Zimmermann, Iskom, Germany
Mr Zimmermann is supervisor BDP and specialised in work- and organisational psychology. His responsibility includes among other things training of communication and conversation skills, rhetoric and presentation techniques, argumentation and negotiation as well as leadership and motivation. During the last years he has trained more than 500 auditors.

On Wednesday, 11 March 2015 the participants of the Auditor Training course are cordially invited to a social event. This event is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Prerequisites to become an APIC Certified ICH Q7 Auditor
In order to become an APIC Certified auditor the following prerequisites have to be fulfilled:

- You should have at least 5 years practical experience of GMP compliant manufacture in the pharmaceutical industry or API industry
- You should already have conducted at least 10 external audits in the last 3 years. At least 1 audit per year should have been related to APIs, Intermediates or Starting Materials with ICH Q7 as standard
- You have to complete one of the Compliance Courses before you take part in the Auditor Training Course.
- You have to pass a written exam directly after the Auditor Training Course
- You also have to pass an Internet-based exam appr. two weeks after the Auditor Training Course

This APIC certification is an option and not mandatory for the participation in these courses!
Date
Wednesday, 11 March 2015, 14:00 h – 18:00 h
(Registration 13:30 h – 14:00 h)
Thursday, 12 March 2015, 8:30 h – 18:15 h
Friday, 13 March 2015, 8:30 h – 14:00 h for participants intending to obtain the APIC Auditor Certification
Friday, 13 March 2015, 8:30 h – 12:45 h for participants not intending to obtain the APIC Auditor Certification

Venue
Austria Trend Hotel Park Royal
Palace Vienna
1140 Vienna, Austria
Phone +43 1 891 1 0
Fax +43 1 891 9 050

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 course. Reservation should be made directly with the hotel. Early reservation is recommended.

Conference language
The official conference language will be English.

Fees (per delegate plus VAT)
Non-ECA Members € 2,290
ECA Members € 2,090
APIC Members € 2,190
EU GMP Inspectorates € 1,145
Written Exam and Internet-based Test: € 250
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on second and third day and all refreshments. VAT is reclaimable.

Organisation and Contact
CONCEPT HEIDELBERG
P.O. Box 10 17 64
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 reservation, hotel, organisation etc.:
Ms Susanne Ludwig (Organisation Manager) at +49 (0) 62 21/84 44 44, or per e-mail at ludwig@concept-heidelberg.de.

For questions regarding content:
Dr Gerhard Becker (Operations Director) at +49 (0) 62 21/84 44 65, or per e-mail at Becker@concept-heidelberg.de.

Reservation Form (Please complete in full)
ICH Q7 Auditor Training Course
11 – 13 March 2015, Vienna, Austria

☐ Written Exam and Internet-based Test
(for those candidates only who want to apply for the auditor certification)

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company’s VAT ID Number

Purchase Order 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 %
   • within 1 week prior to the conference 25 %
   • 4 weeks prior to the conference 50 %
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 deduction 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 be confirmed)!

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.
Questionnaire for the APIC Auditor Certification

Important: This questionnaire has to be filled in by each participant of the ICH Q 7 Auditor Training Course.

For those candidates only who want to apply for the auditor certification: Please pay attention to the prerequisites on the reverse side of this page.

I would like to become an APIC Certified Auditor YES ☐ NO ☐

I would also like to conduct audits within the framework of the APIC Third Party Audit Programme YES ☐ NO ☐

Educational Background

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Work experience (minimum of 5 years experience in industry required)

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Practical experience as Auditor

Number of external Audits conducted in the last 3 years

How many of these audits have been related to APIs, Intermediates or Starting Materials?

Name (Please write in block letters)

Company

Date Signature

Please return the filled-in questionnaire to CONCEPT HEIDELBERG by Fax: +49(0)6221 - 84 44 34 or e-mail: info@concept-heidelberg.de