

APIC

Active Pharmaceutical
Ingredients Committee

Supported by

a sector group of



Speakers

RICHARD M. BONNER
formerly Eli Lilly and Company
Limited, UK

ANTHONY STOREY
Pfizer, United Kingdom

PETER C. ZIMMERMANN
Iskom, Germany

ICH Q7 Auditor Training Course

22 - 24 September 2010,
Vienna, Austria

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22-24 September 2010, Vienna, Austria

Objectives

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 now included as Part II of The Rules Governing Medicinal Products in the European Union. Manufacturers of Active Pharmaceutical Ingredients (APIs) also wish to assure themselves that they are complying with the GMP requirements. But how can it be verified whether a manufacturer is in compliance or not? The answer to this question is: performing audits. Audits are a powerful tool for senior management to determine the status of compliance, i.e. to compare „what is in place“ with „what should be in place“.

Auditing Requires Professionalism

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 that is being revised based on the advice of the European Authorities on the Principles of Third Party Auditing (www.apic.cefic.org). 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 participated in the ICH Q7 training courses for APIs manufactured either chemically or by cell culture/fermentation (2.5 days each) in **advance**. Nevertheless, it is also possible to participate in this training course without the aim of certification.

Moderator

Richard M. Bonner

Programme

The CEFIC / APIC Audit Programme – a Third Party Audit Option

- CEFIC / APIC Quality Working Group
- EU Legislation and Advice on GMP Status of Active Substances
- Third Party Audit Principles
- The APIC Audit Programme
- Conclusions

The APIC Audit Programme –Guidance on Auditing Practices

- Audit Dos and Don'ts
- Advance preparations for successful audit
- Appendices A and C of the APIC Audit Programme: Secrecy Agreement and Aide Mémoire
- Performing the Audit
- Closing Meeting

How to use a risk-based approach to produce an audit schedule

- Audit programme expectations
- The Quality System Focus
- Defining risk in audit program
- Audit program strategy
- Compliance risk assessment and compliance status tool

Why are audits so important?

Audits are used to determine the extent to which the management system requirements are matched. It is the auditors' duty to determine whether the audit criteria are fulfilled. This requires a good cooperation with the auditee. Cooperation is based on communication. For auditors communication means steering the conversation using questioning and interview techniques that enable a free exchange of information.

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 and review of the role plays

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

Speakers

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 now Associate Partner with Concept Heidelberg

Anthony Storey, Pfizer, United Kingdom

Tony Storey is currently located in Sandwich, UK. Tony is responsible for quality management of contract manufacturers including both API and Drug Product manufacturers. Prior to this Tony worked as an API QA manager at a Pfizer site with overall quality responsibility of the API plants at the facility. Tony is currently vice president of APIC (Active Pharmaceutical Ingredients Committee) and was previously chair of the APIC Quality Working Group.

Dipl.-Psych. 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.

Questionnaire for the APIC Auditor Certification

Important: This questionnaire has to be filled in by **those candidates only who want to apply for the auditor certification**. In this case please return the completed questionnaire with the registration for the ICH Q7 Auditor Training Course.

Examination: Back in your office, you will have to pass a multiple-choice Internet-based test on the content of the training course. The fee for this test is € 190,- + VAT and will be charged separately.

- I would like to become an APIC Certified Auditor**
- I would like to become an APIC Certified Auditor and would like to conduct audits on behalf of the APIC Third Party Audit Programme**

Educational Background

Degree or Diploma	Name/Location of Institution	Month/Year

Work experience (minimum of 2 years experience in industry or regulatory body required)

Company	Function	Time Period

Practical experience as Auditor

Number of Audits conducted so far	
How many of these audits have been internal company audits?	
How many of these audits have been external audits?	
Number of audits as lead auditor	
Number of authority inspections escorted	
When did you start auditing?	
When was the last audit?	

Certified by another organisation

If you have been certified as an auditor by another organisation, please identify the organisation, your certification number and the date of your original certification and the date the current certification will expire.

Certifying organisation	Certification number	Date of original certification	Expiry date of current certification

Name (Please write in block letters)

Company

Date

Signature

Date

Wednesday, 22 September 2010,
10.00 h – 17:30 h
(Registration/Coffee 9.30 - 10.00 h)
Thursday, 23 September 2010,
8:30 h – 18:15 h
Friday, 24 September 2010,
9.00 h – 12:00 h

Venue

Renaissance Wien Hotel
Linke Wienzeile/Ullmannstr. 71
1150 Wien
Phone +43 1 89 102
Fax +43 1 89 102 300

Fees

ECA Members
€ 2,061.- per delegate plus VAT
Non-ECA Members
€ 2,290.- per delegate plus VAT
EU GMP Inspectorates
€ 1,145.- per delegate plus VAT
APIC Members
€ 2,175,- per delegate plus VAT (does not include ECA membership)

The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and dinner on the first day, lunch on the second day 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 6343 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 10 August 2010. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.ichq7-week.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
info@concept-heidelberg.de
www.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.

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.

Social Event

On 22 September 2010, 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.



BECOME AN APIC CERTIFIED ICH Q7 AUDITOR!

If you have completed one of the ICH Q7 Training Courses (either the one on chemical synthesis or that on cell culture/fermentation) and the 'ICH Q7 Auditor Training Course' **you can become an APIC Certified ICH Q7 Auditor** (this certification is an option and not mandatory for the participation in these courses). The revised APIC Third Party Audit Programme will be presented during the course.

APIC AUDITOR CERTIFICATION

In order to become an APIC Certified Auditor, the 'qualified' auditor **must fill in the questionnaire and undergo an examination**. This examination exists of 2 parts.

Part 1: A trainer with academic education in psychology assesses the auditing skills of the participants during the Qualification Training Course and judges the participants' aptitude for conducting audits within the framework of the APIC Third Party Audit Programme.

Part 2: The participant has to take an **Internet-based exam** on the contents of the GMP-compliant manufacture of APIs in accordance with ICH Q7 and the training material presented during the course. This exam is created by APIC in co-operation with the API Compliance Institute.

Auditors who have successfully passed Part 1 and Part 2 will then become APIC Certified Auditors. The certificate is valid for three years.

Those auditors who would like to become active within the framework of the APIC Third Party Audit Programme have to indicate this together with their proof of qualification on the application form. The auditor's certification can be extended for another three years provided he/she has attended a recognised training course / conference on current GMP topics and has satisfactorily performed audits.

If either of these conditions are not met, the auditor's name will be withdrawn from the register of APIC Certified Auditors kept by the API Compliance Institute.

The API Compliance Institute keeps a register of all APIC Certified auditors. The API Compliance Institute as a Business Unit of Concept Heidelberg has been contracted by APIC to administer the APIC Third Party Audit Programme.

If you are not sure whether you should apply for this optional certification, please contact Dr Gerhard Becker, phone +49 (0)62 21 84 44 65, email: becker@concept-heidelberg.de.

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(In case you want to apply for the Auditor Certification please fill in the questionnaire and return it with your registration.)

PLEASE NOTE:
If you aim to obtain the APIC Auditor Certification you have to complete one of the compliance courses before the Auditor Training Course.

Mr Ms

Title, first name, surname

Company

IMPORTANT: Please fill in your company's VAT ID number!

P.O. Number if applicable

Department

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-mail (please fill in)

If the bill-to-address deviates from the specification above, please fill in here:

Please send this form to:

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 62 21 / 84 44 34
69007 Heidelberg
GERMANY

General Terms of Business

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 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT 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 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. **You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!**