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APIC

Active Pharmaceutical
Ingredients Committee

a sector group of



Speakers

Andy Bailey

Virusure, Austria

Richard M. Bonner

formerly Eli Lilly and
Company Limited, UK

Gemma Feenstra-Bielders

Abbott Healthcare
Products B.V.,
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Ralf Gengenbach

Gempex, Germany

Holger Kavermann

Roche Diagnostics,
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Reiner Kirrstetter

Sanofi-Aventis Deutsch-
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Karl Metzger

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ICH Q7 Training Courses 2012

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

18 - 20 June 2012, Berlin, Germany

ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation

18 - 20 June 2012, Berlin, Germany

ICH Q7 Auditor Training Course

20 - 22 June 2012, Berlin, Germany



ICH Q7 Training Courses

Objectives

These education courses have been developed to provide an **excellent knowledge of the requirements laid down in ICH Q7**. The contents of the guideline will be explained step by step and practical advices will be given on how to fulfil the requirements of ICH Q7. For example you will learn

- at which stage of production GMP compliance is to be applied
- how to comply with GMP hot topics like process validation, reprocessing/reworking, equipment qualification, change control, failure investigation etc,
- what has to be considered in order to be prepared for a GMP inspection.

Choose between two parallel GMP education courses according to your field of interest: **ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis or ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation**.

Combine the ICH Q7 Courses with the Auditor Training Course

Take advantage of combining your ICH Q7 Training Course on ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis or ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation with an ICH Q7 Auditor Training Course. In this course you will get to know the techniques and skills to be used during an audit.

As the number of participants for the Auditor Training Course is strictly limited early booking is recommended!

Become an APIC Certified ICH Q7 Auditor!

If you have completed one of the ICH Q7 Compliance Courses 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 APIC Auditor Certification – how does it work?

If you aim to become an APIC Certified Auditor **please fill in the attached questionnaire** and return it together with your registration for the ICH Q7 Auditor Training Course. During the Auditor Training Course a trainer with academic education in psychology assesses your auditing skills and judges your aptitude for conducting audits within the framework of the APIC Third Party Audit Programme.

Approx. 2 weeks after the course has finished you are required to take a written exam on the contents of the training material presented during one of the compliance courses and the Auditor Training Course. The exam is an internet-based multiple choice test and you will receive the access code via email. After having passed the test you will receive your **APIC Auditor Certification** via post.

The APIC Auditor Certification – when does it expire and how to recertify?

The auditor's certification is valid for **3 years**.

The certification can be extended for **another 3 years** provided

- you have attended a recognised training course / conference on current GMP topics and
- you have satisfactorily performed audits and
- you have taken another internet-based test at the time of your next re-certification.

If either of these conditions is not met, your 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.

What is the API Compliance Institute?

The API Compliance Institute as a Business Unit of Concept Heidelberg and 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.

Target Group

These education courses are designed for all persons involved in the manufacture of APIs (either chemically or by cell culture/fermentation) especially for persons from production, quality control, quality assurance and control, technical and regulatory affairs departments as well as for Qualified Persons and Auditors of the Manufacturing Authorisation Holders. We are also addressing interested parties from engineering companies, from the pharmaceutical industry and GMP inspectorates.

PLEASE NOTE: If you aim to obtain the APIC Auditor Certification you have to complete one of the Compliance Courses and the Auditor Training Course!

The Course Week at a Glance

Monday	Tuesday	Wednesday	Thursday	Friday	
Joint Session	Parallel Sessions		Joint Session		
ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation	ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis	ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation	ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation	ICH Q7 Auditor Training Course	ICH Q7 Auditor Training Course
Parallel Sessions		ICH Q7 Auditor Training Course			
ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis	ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation				

Basic requirements of GMP compliant manufacture of APIs – The ICH Q7 Compliance Courses

The courses ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis and ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation focus on general and special aspects of the provisions laid down in ICH Q7.

The GMP regulations in Europe and the US and their relevance for API manufacturers and for Qualified Persons and Auditors of the Manufacturing Authorisation Holders will be discussed. General aspects of quality issues will be presented, e.g. the role of the quality unit, requirements for the documentation, aspects of materials management and GMP in the laboratory areas.

Selected chapters of ICH Q7 with regard to APIs manufactured by cell culture/fermentation and chemically manufactured APIs respectively will be discussed in detail. Practical advice will be given on how to fulfil these requirements, e.g. in engineering and design, equipment qualification and calibration, process and cleaning validation, re-use of materials, etc.

The courses will deal with **GMP compliance issues** like handling deviations and changes, implementing and maintaining a change control system and preparing for GMP inspections. Each participant has the opportunity to choose **2 out of 3 interactive specific training sessions** where specific aspects will be discussed in detail.

Auditing Requires Professionalism – The ICH Q7 Auditor Training Course

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. In addition to the training of the communication skills, the 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/CEPIC’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).** Nevertheless, it is also possible to participate in this training course without the aim of certification.

Joint Programme

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation

Regulations and Quality Issues

APIC support on GMP Compliance and Supply Chain Integrity assurance

- Information on APIC
- Contribution to GMP Compliance and Supply Chain Integrity
 - How to do Document
 - Quality Agreements
 - Supplier qualification
 - EU Variations Regulation
- Next steps

GMP Regulations in Europe and the US

- General overview of Regulations (EU, US and others)
- Introduction of ICH
- ICH Q7 in general
- ICH Q7 for chemical APIs / for biotech APIs

Input of ICH Q8, Q9, Q10 and Q11

- Purpose & Scope
- Quality System Principles
- Quality Risk Management System
- Internal Audits
- Product Quality Reviews

Written, documented, recorded – The Management of GMP Documentation

- General aspects and requirements
- Types of GMP Documentation
- Purposes of GMP Documentation
- The structure of Document Management
- Evaluation of your Documentation System
- The Document Management Cycle

Product Quality Review – What needs to be done

- Regulatory requirements and expectations
- Responsibilities on site
- How to compile the PQR efficiently
- PQR and GMP inspections
- Observations on this topic

Parallel Programme

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

Special issues for chemically synthesised APIs

Equipment qualification and calibration

- Regulatory requirements – guidelines
- Validation project: Validation Master Plan – risk analysis, DQ, IQ, OQ, PQ
- Practical approaches to equipment qualification and calibration
- How to handle “old equipment”
- Documentation (validation plans and protocols, validation report, revalidation)

Batch release process and re-use of materials

- Regulatory requirements
- Responsibilities of the Quality Unit
- Batch Record Review and the Decision
- Rejection and re-use of materials
- Reprocessing, reworking, recovery

(Maintenance of) Traceability

- Flow of Materials within the Supply Chain
- Batch Numbering Systems
- Traceability of Starting Materials
- Traceability from Dispensing to Distribution
- How to Deal with Exceptions

Cleaning Validation

- Cleaning requirements and cleaning methods
- Cleaning verification versus validation
- Acceptance levels
- Cleaning validation approaches in mono vs multipurpose environments
- Monitoring of cleaning effectiveness after validation

Engineering and Design

- Good Engineering Practices
- Buildings, equipment
- Flow of materials
- Requirements for utilities
- Water quality in API manufacture
- Containment

Practical Approaches to Process Validation

- Purpose of process validation
- Prospective, concurrent and retrospective validation approaches
- Process validation protocol design
- Dos and don'ts in process validation
- Revalidation of processes
- Change control and process validation

Stability Package for APIs

- Stability Specification
- Stability Studies
- Stability test methods
- Stress tests
- Packaging
- Guidance on API stability testing

Specific Interactive Training Sessions

A: Defining API Starting Materials (Case Studies)

B: Cleaning Validation

C: How to identify and control critical quality attributes in API synthesis

Please choose two sessions

Parallel Programme

ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation

Special issues for biotech APIs

GMP Inspections at Biotech Companies

- General Inspection Principles
- Cell Banks Facility
- Biological Materials and Culture Media
- Fermentation
- Viral removal/inactivation
- Laboratories
- Recent regulatory findings
- Most common FDA audit observations

cGMP and Biotechnology Buildings and Equipment

- Specific requirements for Biotech Facilities
- Aseptic and non-aseptic processing
- Environmental requirements
- Design standards for process equipment
- Cleaning and sterilization of equipment
- Cleaning Validation

Cleaning and Cleaning Validation in Biotech Manufacturing Processes

- Identification of cleaning mechanisms and selection of cleaning agents
- Selection of analytical methods for the detection of residues
- Establishment of limits in fermentation and downstream processing
- Grouping strategies
- Final rinse versus swab testing

Lessons learned from GMP failures involving virus contamination

- Virus contamination in GMP manufactured products (examples)
- How to implement continued vigilance with regard to potential virus contamination
- Virus contamination and root cause analysis
- Application of appropriate risk control measures
- Approaches to minimise the risk of contamination

Change Control and Comparability

- When is something considered as a change?
- Consequences of changes in bio(techno)logical production
- Minor and major changes
- Comparability protocol
- What if you see differences?

Cellbanking –Master Cell Banks (MCB) and Working Cell Banks (WCB)

- Establishment of MCB and WCB
- Definition of 'API starting material'
- Cell Bank qualification and testing
- Cell Bank maintenance and record keeping

Specific Interactive Training Sessions

A: Process validation for biotech manufacturing processes

B: Cleaning Validation

C: Risk management and risk assessment

Please choose two sessions

Joint Programme

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation

Compliance Issues

Supply chain life cycle: Reduced testing and supplier qualification

- ICH Q7 requirements
- Supplier qualification covering the full supply chain
- One strategy for supplier qualification from non-critical raw material to API
- Requirements and strategy for reduced testing (CoA release) of materials

Internal Change Control Management

- Changes: Good or bad? Forced or voluntary?
- The Importance of Change Control
- Scope and Responsibilities
- General requirements
- Detailed requirements for Specific Changes
- Implementation of Changes

Deviation Handling and Failure Investigations

- Definitions and Basic Requirements
- Scope and Responsibilities
- Detailed Requirements
- Principles of Justification for Deviations
- A quick look on Root Cause Analysis
- The Role of the Quality Unit for Handling Deviations and Justification

Preparing for GMP Inspections, Critical Observations

- Experience with GMP inspections of API manufacturers
- Major findings/observations during inspections
- Survey on frequently asked questions – discussion of their relevance



Social Event

On Monday, 18 June 2012 the participants of the ICH Q7 Compliance Courses 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.

ICH Q7 Auditor Training Course

Programme on Day 1

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

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

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

Programme on Day 2 and 3

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 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



Social Event

On 20 June 2012, the participants of the ICH Q7 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.

Speakers

Dr Andy Bailey, ViruSure GmbH, Vienna, Austria

Dr Bailey has been actively involved in the pathogen safety of biopharmaceuticals for over 11 years. Originally a Biochemist, Dr Bailey served for nine years at the MRC Virology Unit in Glasgow, Scotland. In 1995, he moved as Director of Virus Validation services to Q-One Biotech Ltd, and in 2001 to the Pathogen Safety group of Baxter Healthcare in Vienna, Austria. He was the main founder of ViruSure GmbH, a specialist virus safety testing company in Vienna, Austria, in 2005. Over the last 10 years, Dr. Bailey has presented at numerous regulatory agencies on virus and prion safety, either in support of products or as an invited speaker at expert workshops, including the UK MHRA, German PEI, French AFFSAPS, US FDA, EMA and JMHLW (Japan).

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.

Gemma Feenstra-Bielders Abbott Healthcare Products B.V., The Netherlands

Ralf Gengenbach, gempex, Germany

Mr Gengenbach is founder and managing director of gempex Co. Ltd., Germany. He is member of different organisations, among others DIN UA2 (Board for standards 'biotechnology'), of DECHEMA and ISPE. He is approved Quality Auditor according to DIN ISO 9000ff.

Dr Holger Kavermann, Roche Diagnostics, Germany

Dr Kavermann studied microbiology at the University of Göttingen and obtained his PhD in medical microbiology at the University of Munich. In 2003 he joined Roche Diagnostics GmbH, as Manager QC. He is responsible for the microbiological and cell biological analytics of QC- and In-Process-Control-samples in the production of biotechnological derived active pharmaceutical ingredients.

Dr Reiner Kirrstetter, Sanofi-Aventis, Germany

Currently working in the Global Quality Organisation. Educational Background: Chemistry, Ph.D. at the University of Heidelberg in 1976. Worked for more than 30 years in pharmaceutical industry (Research, PD, Production, Quality Operations). Since 22 years experienced in GMP and Regulatory Compliance (4 years as Site Quality Head of API Frankfurt). Performed GMP audits in Europe, US, China, India, Japan. Involved in several Regulatory Inspections from FDA and German Authorities. Published 20 articles related to GMP and QM Requirements.

Karl Metzger, gmPlan GmbH, Germany

Mr Metzger is Managing Partner of gmPlan GmbH. He is APIC certified ICH Q7 Auditor and has more than 15 years experience in global auditing of chemical, biotechnological and pharmaceutical manufacturers. Previous to his current position he held appointments with BASF Pharma, Concept Heidelberg, Euroengineering and finally with Welding as Management responsible for the company's integrated Management System and deputy QP for APIs. Furthermore Karl was vice chairman of FECC's 'Good Trade and Distribution Committee'.

Peter Mungenast, Merck KGaA, Germany

Mr Mungenast studied Biology and Chemistry at the University in Karlsruhe. Then he worked in different functions for Merck KGaA. Since 1996 he is responsible for cleaning validation, training and different projects in the Quality Assurance department.

Dr Jordi Ruiz-Combalia, Bioiberica S.A., Spain

Dr Ruiz Combalia has 35 years experience in API Industry, where he has had different responsibilities, from R&D Director to Quality Control Director. Head of the Organic Chemistry Expert Group of the Real Farmacopea Española, Head of the CRB Working Party of The European Pharmacopoeia, and collaborates with the APIC (Active Pharmaceutical Ingredients Committee) in the GMP Working Group.

Jolande Schoemaker,

Schoemaker Consultancy, The Netherlands

Ms Schoemaker is currently located in The Netherlands and works as a consultant to the pharmaceutical industry. Previous to her current role she was the Director Quality Affairs at Crucell. Jolande gained a wide field of experience in many aspects of the pharmaceutical and biotechnology industry, including formulation of drugs, manufacturing of sterile pharmaceutical products, hospital care and clinical trials, Regulatory Affairs, Quality Control and Quality Assurance. Furthermore, she was involved in many regulatory inspections, including some conducted by the US FDA, the Canadian and the British Inspectorate.

Dr Rob Slobbe, Philips Corporate Technologies, The Netherlands

Dr Slobbe was employed as Compliance Manager of DSM Pharma Chemicals in Venlo, The Netherlands, Rob is responsible for quality assurance, quality control, regulatory affairs and safety, health and environment in multipurpose API/ pharmaceutical intermediate manufacturing facility. Next to the quality and regulatory affairs experiences gained in this position, Rob has performed several API audits in the light of the APIC Audit Programme as certified ICH Q7 Auditor. In 2008 Rob joined Philips Corporate Technologies.

Francois Vandeweyer, Janssen Pharmaceutica, Belgium

Graduated in 1979 as Bachelor in Chemistry. He joined Janssen Pharmaceutica (part of Johnson & Johnson) in 1981 in chemical development. Until 1995 increasing responsibilities within the organisation mainly in the Quality Control Unit (Manager QC Lab 1994). Starting from 1995 he joined the QA department. Several Senior Manager responsibilities (sGMP Auditor – Release – Quality Systems). 2005 Sr Manager GMP Compliance Chemical Operations Belgium (sites Geel – Olen – Beerse). 2009 Director Global Compliance EMEA/AP for Johnson & Johnson.

Elmar Wenzel, Freelance Consultant, Germany

Mr Wenzel was formerly head of API production at the Plank-stadt site of AstraZeneca, now Corden Pharma. He is now freelance consultant.

Dr Frank Ziemke-Kägeler, Roche Diagnostics, Germany

Dr Ziemke-Kägeler studied Biology at the Technical University in Braunschweig. He did his PhD at the National Research Centre for Biotechnology (GBF) in Braunschweig. Since 1997 he worked in Microbiological Quality Control with Roche Diagnostics in several positions, being responsible for environmental monitoring, microbiological in process- and release testing and for the characterisation and safety testing of cell banks for biotech manufacturing. As Director Quality Control he is now responsible for environmental monitoring and cleaning validation for the Penzberg biotech facility.

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.

Organisational Details

ICH Q7 Course Week in June 2012

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

ICH Q7 Compliance for APIs Manufactured by Cell Culture/ Fermentation

Date of both courses:

Monday, 18 June 2012, 09:30-18:00 h

(Registration 9:00-09:30 h)

Tuesday, 19 June 2012, 8:30-17:30 h

Wednesday, 20 June 2012, 9:00-13:00 h

ICH Q7 Auditor Training Course

Date:

Wednesday, 20 June 2012, 14:00-18:00 h

(Registration 13:30-14.00 h)

Thursday, 21 June 2012, 8:30-18:15 h

Friday, 22 June 2012, 8:30-12:15 h

Venue

Steigenberger Hotel Berlin

Los-Angeles-Platz 1

10789 Berlin, Germany

Phone: +49 (0)30 212 7 - 0

Fax +49 (0)30 212 7-117

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 "ECA 7220" to receive the specially negotiated rate (single room € 125,- per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 17 May 2012. Early reservation is recommended.

Fees

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

Non-ECA Members € 1.990.- per delegate plus VAT

ECA Members € 1.790.- per delegate plus VAT

APIC Members € 1.890.- per delegate plus VAT

(does not include ECA Membership)

EU GMP Inspectorates € 995.- per delegate plus VAT

ICH Q7 Compliance for APIs Manufactured by Cell Culture/ Fermentation

Non-ECA Members € 1.990.- per delegate plus VAT

ECA Members € 1.790.- per delegate plus VAT

APIC Members € 1.890.- per delegate plus VAT

(does not include ECA Membership)

EU GMP Inspectorates € 995.- per delegate plus VAT

In both cases, the conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all 3 days and all refreshments. VAT is reclaimable.

ICH Q7 Auditor Training Course

Non-ECA Members € 2.290.- per delegate plus VAT

ECA Members € 2.090.- per delegate plus VAT

APIC Members € 2.190.- per delegate plus VAT

(does not include ECA Membership)

EU GMP Inspectorates € 1.145.- per delegate plus VAT

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on 2 days and all refreshments. VAT is reclaimable.

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

E-mail: 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.

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 YES NO

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

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

Reservation Form (Please complete in full)

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

18 – 20 June 2012, Berlin, Germany

Please choose two interactive training sessions:

A: Defining API starting materials

B: Cleaning Validation

C: How to identify and control critical quality attributes in API synthesis

ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation

18 – 20 June 2012, Berlin, Germany

Please choose two interactive training sessions:

A: Process validation for biotech manufacturing processes

B: Cleaning validation

C: Risk management and risk assessment

ICH Q7 Auditor Training Course

20 – 22 June 2012, Berlin, Germany

In case you want to apply for the Auditor Certification please fill in the inserted 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.

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)!**