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ECA ACADEMY

ICH Q7 Training Courses

How to apply ICH Q9, Q10 and Q11 in modern API Manufacturing

SPEAKERS:

ANDY BAILEY
ViruSure, Austria

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

RALF GENGENBACH
Gempex, Germany

HOLGER KAVERMANN
Roche Diagnostics, Germany

KARL METZGER
GmPlan, Germany

PETER MUNGENAST
Merck KGaA, Germany

ROB SLOBBE
Sapiens Steering Brain Stimulation, The Netherlands

PAUL STOCKBRIDGE
Stockbridge Biopharm Consulting, UK

FRANCOIS VANDEWEYER
Janssen Pharmaceutica, Belgium

FRANK ZIEMKE-KÄGELER
Roche Diagnostics, Germany

PETER C. ZIMMERMANN
Iskom, Germany

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis
1 – 3 December 2014, Berlin , Germany

ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation
1 – 3 December 2014, Berlin , Germany

ICH Q7 Audi[illegible]ng Course
Fully booked*
3 – 5 Dece[illegible] 2014, Berlin, Germany

NEW Date and Venue OF THE ICH Q7 AUDITOR TRAINING COURSE
11 – 13 March 2015, Vienna, Austria

These courses are recognised for the ECA GMP Certification Programme „Certified API Production Manager". Please find details at www.gmp-certification.eu

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. **You will also get to know the key principles of risk management, quality systems and development and manufacture of APIs as they are laid down in ICH Q9, Q10 and Q11.** 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,
- how to use a risk-based approach within the concept of supplier qualification,
- How to link material attributes and process parameters to drug substances CQAs,
- 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.

The ICH Q7 Auditor Training Course will inform you 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. Moreover you will learn about the key principles of writing a professional audit report.

Combine the ICH Q7 Courses with the Auditor Training Course

Take advantage of combining your ICH Q7 Training Course on ICH Q7 Compliance for Chemical APIs or ICH Q7 Compliance for Biotech APIs 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!

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.
This certification is an option and not mandatory for the participation in these courses.

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 standard.

ICH Q7 Training Courses

The APIC Auditor Certification – how does it work?

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.

Approx. 2 weeks after the Auditor Training Course has finished you are required to take an 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 that

- you have attended at least two training course/conference on current GMP topics during the current period of certification and
- you have satisfactorily performed at least three audits during the current period of certification 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 is 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.

REGULATORY SESSION

Regulatory Introduction – How to combine ICH Q7 with ICH Q 9, Q10 and Q11
- General overview of Regulations (EU, US and others)
- Introduction of ICH
- ICH Q7 in general
- ICH Q7 for chemical APIs / for biotech APIs
- Interrelationship between ICH Q7 and ICH Q9, Q10 and Q11

APIC's How to do Guide and further APIC activities
- Information on APIC
- Contribution to GMP Compliance and Supply Chain Integrity
  - How to do Document
  - Quality Agreements
  - Supplier qualification
  - EU Variations Regulation
  - Further activities

COMPLIANCE SESSION PART 1 – MANAGEMENT PROCESS

Major Compliance Issues at API Manufacturers
- Common pitfalls and typical audit findings
- Top observations from inspections by European authorities
- Experiences made by FDA
- Recent statistics from FDA Warning Letters to API manufacturers

The set-up of an efficient Quality System – How to apply ICH Q10
- The Quality Unit – roles and responsibilities
- 21 CFR 211.22 requirements
- Key principles and elements of ICH Q10
- Recommendations and examples

How to use ICH Q9 and ICH Q11 in API Development, Manufacturing and Quality Assurance
- General quality risk management process
- Potential applications for quality risk management
- Risk management tools suitable for manufacture of APIs
- Manufacturing process development
- Starting materials: selection sourcing and control
- Life cycle management

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)

Storage, Transport and Distribution of APIs
- Flow of materials within the supply chain
- Batch numbering systems
- Traceability of starting materials
- Traceability from dispensing to distribution
- How to deal with exceptions

Parallel Programme

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

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

Stability Testing of APIs
- Stability specification
- Stability studies
- Stability test methods
- Stress tests
- Packaging
- Guidance on API stability testing

Process Validation in API manufacturing
- Regulatory requirements in the EU and US
- Key principles of the FDA Guidance on Process Validation
- Validation approaches and how to apply the principles of ICH Q8, Q9, Q10 and Q11
- Continuous process verification and life-cycle approach

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

Specific Interactive Training Sessions
A: Defining API Starting Materials (Case Studies)
B: Cleaning Validation
C: Practical implementation of ICH Q11 – How to identify and control CQAs in API synthesis
Please choose two sessions

Parallel Programme

ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation

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

Instances of Virus Contamination in GMP manufactured Products – what can we learn?
- 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

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

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: Principles of risk assessment from Cell Banks to viral safety
Please choose two sessions

COMPLIANCE SESSION PART 3 – LIFECYCLE MANAGEMENT AND CONTINUOUS IMPROVEMENT

Joint Programme

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis
ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation

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 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, 1 December 2014 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 in March 2015

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 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".

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 (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.

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

ICH Q7 Auditor Training Course in March 2015

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.

<u>This assessment is relevant only for participants intending to obtain the APIC Auditor Certification.</u>

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.

Social Event
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.

Speakers

Dr Andy Bailey, ViruSure GmbH, 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, EMEA and JMHLW (Japan).

Richard M. Bonner, formerly Eli Lilly, 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.

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.

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 Rob Slobbe, Sapiens Steering Brain Stimulation, The Netherlands
Before joining Sapiens, Rob was responsible as Senior Director for Quality & Regulatory Affairs at Philips Corporate Technologies, responsible for defining and implementing suitable quality management systems in a number of Philips sub-organizations to obtain ISO13485-certification. Moreover, he managed the CE-marking of several medical device and non-medical device products. Prior to Philips, Rob acquired in-depth Quality Assurance and Quality Control knowledge and experience in the pharmaceutical industry as Compliance manager at DSM Pharma Chemicals and Quality and Regulatory Director at DSM Biomedical, adding to a profound regulatory background acquired previously as Manager Regulatory Affairs at Organon Teknika, where he was responsible for world-wide registration of high-risk in vitro diagnostics and medical devices. Rob holds a PhD degree in Biochemistry from the University of Nijmegen.

Dr Paul Stockbridge, Stockbridge Biopharm Consulting, UK
Dr Stockbridge spent 23 years with Eli Lilly, initially in fermentation development and then in quality assurance where he became a Q.P. and Q.A. Advisor for biotechnology projects for which he travelled globally. He then moved to a Head of Quality Operations role with Aventis Pharma before being appointed to the role of Corporate Quality Director for Cobra Biomanufacturing Plc. After over 7 years with Cobra he is now providing independent consulting and training services for the steriles, aseptic and biotechnology industries. Paul has a degree in biology, a PhD in fermentation, is an EU Qualified Person and is a Fellow of the U.K. Society of Biology.

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.

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

Dates

ICH Q7 Compliance for APIs manufactured by Chemical Synthesis and
ICH Q7 Compliance for APIs manufactured by Cell Culture/Fermentation
Monday, 1 December 2014, 09:30 h – 17:45 h
(Registration 9:00 h – 09:30 h)
Tuesday, 2 December 2014, 8:30 h – 17.30 h
Wednesday, 3 December 2014, 8:30 h – 13:00 h

ICH Q7 Auditor Training Course
Wednesday, 3 Dece[**Fully booked***]:00 h – 18:00 h
(Registrat[illegible])
Thursday, 4 December 2014 , 8:30 h – 18:15 h
Friday, 5 December 2014 , 8:30 h – 12:30 h

Venue

Steigenberger Hotel am Kanzleramt
Ella-Trebe-Straße 5
10557 Berlin, Germany
Phone +49 (0)30 92102570
Fax +49 (0)30 921025799

NEW Date and Venue for the ICH Q7 Auditor Training Course

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
Schlossallee 8
1140 Vienna, Austria
Phone +43 1 8911 0
Fax +43 1 8911 9050

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.

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.

Fees (per delegate plus VAT)

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis
or
ICH Q7 Compliance for APIs Manufactured by Cell Culture/ Fermentation
Non-ECA Members € 1.990.-
ECA Members € 1.790.-
APIC Members € 1.890.-
EU GMP Inspectorates € 995.-
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.-
ECA Members € 2.090.-
APIC Members € 2.190.-
EU GMP Inspectorates € 1.145.-
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.

Internet-based Test: € 250,-

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

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 **each participant of the ICH Q 7 Auditor Training Course.**
For those candidates only who want to apply for the auditor certification: Back in your office, you will have to pass a multiple-choice Internet-based test. The fee for this test is € 250,- + VAT and will be charged separately.

Please note the following prerequisites which have to be fulfilled in order to become an APIC Certified Auditor:
- At least 5 years practical experience of GMP compliant manufacture in the pharmaceutical industry or API industry
- Having 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.

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 5 years experience in industry required)

Company	Function	Time Period

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

Reservation Form (Please complete in full)

☐ ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

1 - 3 December 2014, Berlin, Germany

Please choose TWO interactive training sessions:

A: Defining API starting materials (case studies) ☐
B: Cleaning Validation ☐
C: Practical implementation of ICH Q11 – How to identify and control CQAs in API synthesis ☐

☐ ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation

1 - 3 December 2014, Berlin, Germany

Please choose TWO interactive training sessions:

A: Process validation for biotech manufacturing processes ☐
B: Cleaning validation ☐
C: Principles of risk assessment from cell banks to viral safety ☐

☐ ICH Q7 Auditor Training Course

11 – 13 March 2015, Vienna, Austria

If you register for the Auditor Training Course you have to fill in the questionnaire on page 11 and return it with your registration.

☐ Internet-based Test **(For those candidates only who want to apply for the auditor certification)**

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.**

☐ Mr ☐ Ms

Title, first name, surname

Company Department

IMPORTANT: Please fill in 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)

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)!**

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