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APIC
Active Pharmaceutical Ingredients Committee
a sector group of cefic

ECA Academy
Your GMP/GDP Information Source

SPEAKERS:

RALF GENGENBACH
Gempex, Germany

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Roche Diagnostics, Germany

PAUL LOPOLITO
STERIS Corporation, USA

PETER MUNGENAST
Merck KGaA, Germany

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Roche Diagnostics, Germany

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Philips Image Guided Therapies, The Netherlands

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Biopharm Consulting, UK

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Janssen Pharmaceutica, Belgium

JOS VAN DER VEN
Aspen Oss B.V.

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Iskom, Germany

ICH Q7 Training Courses

ICH Q7 in modern API Manufacturing – what to do and how to do

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis
12 – 14 November 2018, Barcelona, Spain

ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation
12 – 14 November 2018, Barcelona, Spain

ICH Q7 Auditor Training Course
14 – 16 November 2018, Barcelona, Spain

All participants will receive APIC's Side by Side comparison of „ICH Q7" and the „How to do Document - APIC's interpretation of ICH Q7".

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, Q11 and the ICH Q7 Q&A Document.** 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!

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.

The Course Week at a Glance

<table>
<tr><th>Monday</th><th colspan="2">Tuesday</th><th>Wednesday</th><th>Thursday</th><th>Friday</th></tr>
<tr><td>Joint Session</td><td colspan="2">Parallel Sessions</td><td>Joint Session</td><td rowspan="3">ICH Q7 Auditor Training Course</td><td rowspan="2">ICH Q7 Auditor Training Course</td></tr>
<tr><td rowspan="2">ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

and

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

and

ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation</td></tr>
<tr><td colspan="2"></td><td>ICH Q7 Auditor Training Course</td><td></td></tr>
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Certificates - Certification

Certificate of Attendance

A Certificate of Attendance will be provided in any case for all participants for each course.

Additional options

ECA certified QA Manager and Auditor for APIs

Pre-requisites:

- First you have to take part in one of the **ICH Q7 Compliance Courses** (either „ICH Q7 Compliance for APIs manufactured by Chemical Synthesis“ or „ICH Q7 Compliance for APIs manufactured by Cell Culture/Fermentation“),
- Thereafter you have to take part in the **ICH Q7 Auditor Training Course**.

If you have completed both the ICH Q7 Compliance Course and the ICH Q7 Auditor Training Course you will receive the ECA Certificate **„QA Manager and Auditor for APIs“**

APIC Auditor Certification

Pre-requisites:

- 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 take part in one of the **ICH Q7 Compliance Courses** (either „ICH Q7 Compliance for APIs manufactured by Chemical Synthesis“ or „ICH Q7 Compliance for APIs manufactured by Cell Culture/Fermentation“) **before** attending the ICH Q7 Auditor Training Course
- You have to take part in the **ICH Q7 Auditor Training Course after** having attended one of the ICH Q7 Compliance Courses
- 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

Thereafter you will receive the APIC Auditor Certificate.
➔ **Please return the filled in Questionnaire* on page 11!**

*(*The questionnaire is needed to verify the pre-requisite to apply for the APIC Auditor Certification and to better plan the auditor Workshop)*

COMPLIANCE SESSION PART 1 – MANAGEMENT PROCESS

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
  - ASMF Guideline
  - FMD and GDP for APIs
- ICH Q7 Q&A How to do Document
- Further activities

Roles and Responsibilities of the Quality Unit – How to apply ICH Q10
- The Pharmaceutical Quality System
- How to Apply ICH Q10 in the API area
- The Set-up of a Good Quality System
- Some Recommendations for the Quality Unit

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

ICH Q7 Q&A – What to do and how do do
- Overview about the ICH Q7 Questions and Answers Document
- Some Highlights from the Q&A Document and their interpretation
  - Distribution procedures, intercontinental shipments
  - Risk assessment and validation
  - Complaints and recalls
- Interactive Session

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

Parallel Programme

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

COMPLIANCE SESSION PART 2 – PRODUCTION AND QC ISSUES

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

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)

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

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

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

Joint Programme

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

COMPLIANCE SESSION PART 3 – LIFECYCLE MANAGEMENT AND CONTINUOUS IMPROVEMENT

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

Dinner

On Monday, 12 November 2018, the participants of the ICH Q7 Compliance Courses are cordially invited to a dinner. This event is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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 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

Applying Quality Risk Management to prepare for an Audit

- Expectations for the content of reports of audits of active substance manufacturers
- Supplier Qualification, supplier classification
- GMP Risk Factors
- Regulatory Expectations of Auditing

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.

- Risk based Audit Model for Suppliers

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

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 the Internet-based exam successfully the participants will receive their **APIC Auditor Certification** via post.

Dinner
On Wednesday, 14 November 2018, the participants of the Auditor Training course are cordially invited to a dinner. This event is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers

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.

Paul Lopolito, STERIS Corporation, USA
Paul Lopolito is a Technical Services Manager for the Life Sciences Division of STERIS Corporation (Mentor, Ohio). He currently provides global technical support related to process research cleaners, stainless steel maintenance, and contamination control, which includes field support, site audits, training presentations and educational seminars. He has over 15 years of industry experience and has held positions as a technical services manager, manufacturing manager and laboratory manager. He is a frequent speaker at industry events including INTERPHEX, PDA, ISPE, ACHEMA, AALAS, and IVT. He has published several articles and book-chapters related to cleaning validation and contamination control. He earned a BA in Biological Sciences from Goucher College in Towson, MD.

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.

Sabine Schachtschneider, Roche Diagnostics, Germany
Sabine was trained as medical-technical analyst and biotechnician, started at Roche Diagnostics GmbH in 2000 and throughout the last 14 years within the Roche Pharma QC she filled roles as specialist for cleaning validation as well as method validation for biochemical and microbiological laboratories. Currently Sabine is acting as expert for cell bank releases.

Dr Rob Slobbe, Philips Image Guided Therapies The Netherlands
Dr. Rob Slobbe is Head of Quality & Regulatory with Philips Image Guided Therapies – Business Incubation. He steers the Philips organization as responsible Q&R executive towards regulatory and quality compliance with medical device and pharmaceutical regulations, particularly through the design and implementation of quality management systems meeting appropriate cGMP standards. Moreover, Dr Slobbe is specifically responsible for supplier qualification and evaluation and redesigning Philips internal processes to foster innovation. Dr Slobbe is an experienced cGMP auditor, covering good industry practices and compliance of systems, facilities and operations and since 2001 has carried out numerous audits as lead auditor on behalf of the independent third party auditing program of APIC.

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 Jos van der Ven, Aspen Oss B.V., The Netherlands
Jos van der Ven studied Chemistry at Utrecht University (the Netherlands) where he obtained his PhD in Bio-organic Chemistry in 1993. After a postdoc, he joined Quest International (currently Givaudan) as project manager R&D.. He then moved to Diosynth Oss and held different positions in API Manufacturing with increasing responsibilities for 8 years. After a period as plant manager, he joined the Quality department as a QA manager for (bio)chemical APIs for 8 years. During this period he contributed to the subsequent transitions as a result of the takeovers by Schering-Plough, MSD and latest Aspen Pharmacare. His activities in API manufacturing covered subjects such as cleaning in (bio)chemical production, deviation and change control, release, 'QA-on-the-floor', inspections by e.g. IGZ and FDA, and a SAP implementation. Currently he is Business Process Manager Quality at Aspen Oss B.V..

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, 12 November 2018, 09:30 h – 17:20 h
(Registration 9:00 h – 09:30 h)

Tuesday, 13 November 2018, 8:30 h – 17:30 h
Wednesday, 14 November 2018, 8:30 h – 12:45 h

ICH Q7 Auditor Training Course

Wednesday, 14 November 2018, 14:00 h – 17:35 h
(Registration 13:30 h – 14:00 h)

Thursday, 15 November 2018, 8:30 h – 18:00 h

Friday, 16 November 2018, 8:30 h – 12:45 h
for participants **not** intending to obtain the APIC Auditor Certification

Friday, 16 November 2018, 8:30 h – 14:00 h
for participants intending to obtain the APIC Auditor Certification

Venue

Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 93 503 53 00
email sants@barcelo.com

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.

Written exam and Internet-based Test: € 250,-

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 6221/84 44-0
Fax +49 (0) 6221/84 44 34

For questions regarding content:
Dr Gerhard Becker (Operations Director) at +49(0) 6221/84 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) 6221/84 44 44, or per e-mail at ludwig@concept-heidelberg.de.

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

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

***) Please fill in the following tables and mind the prerequisites mentioned below!**

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

***) Please note: the pre-requisites for obtaining the APIC Auditor Certification are the following:**

- having conducted already 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

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

12 – 14 November 2018, Barcelona, Spain

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 ☐

Do you wish to attend the **Social Event on 12 November, 2018**? ☐ Yes ☐ No

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

12 – 14 November 2018, Barcelona, Spain

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 ☐

Do you wish to attend the **Social Event on 12 November, 2018**? ☐ Yes ☐ No

☐ ICH Q7 Auditor Training Course

14 – 16 November 2018, Barcelona, Spain

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

Do you wish to attend the **Social Event on 14 November, 2018**? ☐ Yes ☐ No

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

☐ 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 and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.

If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.

In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

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.

RI/11062018