ICH Q7 Training Courses 2022

ICH Q7 in modern API Manufacturing – what to do and how to do
21-25 November 2022, Heidelberg, Germany

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis | 21-23 Nov 2022

ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation | 21-23 Nov 2022

ICH Q7 Auditor Training Course | 23-25 Nov 2022

Speakers

Andy Bailey
ViruSure, Austria

Markus Dathe
F. Hoffmann-La Roche, Switzerland

Ralf Gengenbach
gempex, Germany

Paul Lopolito
Steris Corporation, USA

Peter Mungenast
Merck KGaA, Germany

Danny De Scheemaecker
Janssen Pharmaceutica NV, Belgium

Frank Sielaff
GMP Inspector, Regional Authority, Darmstadt, Germany

Paul Stockbridge
Stockbridge BioPharm Consulting, UK

Francois Vandeweyer
VDWcGMP Consultancy, Belgium

Peter C. Zimmermann
Iskom, Germany

Supported by APIC 30 YEARS ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE a sector group of cefic ECA Academy Your GMP/GDP Information Source

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**

Take advantage of combining one of the ICH Q7 Courses with the Auditor Training Course and receive the ECA Certifcate "QA Manager and Auditor for APIs".

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, you will be provided with 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.

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

Certificates | Certification

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

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 **pass a written exam** directly after the Auditor Training Course.
- You also have to **pass an Internet-based exam** approximately two weeks after the Auditor Training Course.

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

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

Target Group

These training 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, technical and regulatory affairs departments as well as for Qualified Persons and Auditors. 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 Programme
Part 1</td><td colspan="2">Parallel Sessions
Part 2</td><td>Joint Programme
Part 3</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 rowspan="2">ICH Q7
Compliance
for APIs
Manufactured
by
Chemical
Synthesis</td><td rowspan="2">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>ICH Q7
Auditor Training
Course</td><td></td></tr>
</table>

Monday - Joint Programme

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

ICH – A General Introduction

- What is ICH ?
- API related ICH Guidelines
- ICH Quality Guidelines
- ICH Q7 – Hot topics and requirements
- Overview of guidance documents (Q8 to Q14)

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

Regulatory Framework - an Inspector's View

- Overview: relevant guidelines
- Inspections in drug product facilities - relevant topics for API manufacturers
- Recent findings in inspections

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

Preparing for GMP Inspections

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

Tuesday - Parallel Sessions

Compliance Session Part 2 – Production and QC Issues

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

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

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 reports, revalidation)

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

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

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

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

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

Wednesday Morning - Joint Programme

Compliance Session Part 3 – Life Cycle 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

How to implement ICH Q3D

- Regulatory requirements
- „Five steps implementation strategy“
- How to handle CEP updates and new registrations from the perspective of the Marketing Authorisation Holder

Data Integrity in the light of ICH Q7

- Which requirements are applicable to APIs under ICH Q7?
- Specific Requirements and Interpretations
- Consideration for specific risks
- The hubris of hybrid records
- Case study: how to achieve Data Integrity on a risk-based approach

Stability Testing of APIs

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

After the Training Courses took place, all participants will receive APIC's Side-by-Side Comparison Booklet of "ICH Q7 GMP for Active Pharmaceutical Ingredients" and the "How to do Document" - APIC's Interpretation of ICH Q7.

Wednesday Afternoon - Auditor Training Course

Conducting an Audit – Tools and Technical Aspects

CEFIC/APIC's Activities and Working Groups – APIC's Third Party Audit Programme

- 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 between Auditor and Auditee
- Audit Dos and Don'ts
- Advance preparations for a successful audit
- Performing the audit
- Closing meeting
- Audit report

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
- Risk based Audit Model for Suppliers

Audit Sessions

1. How to prepare for specific audit situations
2. How to write an audit report
3. How to classify observations

You will work on questions and case studies concerning these topics.

Thursday

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

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

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.

Communication Part II

Multicultural Aspects

- Differences in body language
- Different rituals
- Different Dos and Don'ts
- 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-ended and closed-ended questions
- Other questioning techniques
- Exercise
- Attitude and behaviour in front of the auditee

Preparation for the Role Plays

Friday

The Audit Closing Meeting and Measuring Success

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

Conducting an Audit - Remote Audits

During these sessions the speakers will explain the differences and commonalities of onsite and remote audits and will point out the advantages and disadvantages of each kind of audit set up.

Written Exam only for participants intending to obtain the APIC Auditor Certification

You will have to answer questions about GMP topics derived from ICH Q7 in a written exam. After having passed successfully this exam, you will be required to take another exam on current GMP topics as an internet-based multiple choice test, approximately 2 weeks after the course.

The access code will be made available via email.

After having passed this test successfully, you will receive the **APIC Auditor Certification**.

Testimonials of participants attending one of the previous ICH Q7 Weeks

"Thank you for great talks and excellent organisation! "
Dr. Michel Van Overschelde | Johnson & Johnson Pharmaceutical RD Division Janssen Pharmaceutica N.V.

" Excellent presentations today. Really enjoyable day watching the roleplays well done. I have obtained great ideas and taken lots of great notes for my training."
Joanne Johnston | Zoetis Rathdrum

"Good opportunity at the role plays to see audit situations, good to have interactive communication."
Farina Neuwirth | CU Chemie Uetikon GmbH

„It's really good experience by interacting with experienced faculty and learned a lot during training sessions. It's really good about time management during sessions and the host of the Live Online Training supported a lot to get the answers from trainers for all my questions."
Parasuramu Kamma

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.

Dr Markus Dathe
F. Hoffmann-La Roche AG, Switzerland

Analytical and Process Chemist with more than 20 years of practical experience in laboratory, quality and informatics functions. Dr Dathe held several positions in life sciences and pharma operations of Novartis since 1997, joined Siegfried in 2006 and is GMP Systems Coordinator in the Synthetic Small Molecules Technical Development of Roche since 2011. He had been successfully leading global projects in the area of CDS, LIMS and QMS.

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.

Paul Lopolito
STERIS Corporation, USA

Mr 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.

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.

Danny De Scheemaecker
Janssen Pharmaceutica NV, Belgium

Danny joined the Janssen Pharmaceutica organization in 1991 as a bachelor in Chemistry in the chemical control lab of the Janssen SM API production site in Geel. Afterwards he led different key projects. Early 2000 Danny became GMP auditor of the chemical production site in Geel, including the responsibility for supplier qualification. He was active as senior manager within the Asia Pacific group of Supplier Quality, until he became quality director of the global SM API team for external manufacturing of the Janssen supply chain in 2014. Since June 2022 he is director external manufacturing Pharmaceutical Regulatory Compliance for Johnson and Johnson.

Dr Frank Sielaff
GMP Inspector, Regional Authority, Darmstadt, Germany

GMP-Inspector at the Regierungspräsidium Darmstadt with the focus on inspection of drug manufacturers and laboratories in Germany and countries outside of the EU. Before joining the GMP-inspectorate Dr Sielaff was several years employed in the pharmaceutical industry as Head of Quality Control and as Qualified Person.

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
VDWcGMP Consultancy, Belgium

Mr Vandeweyer 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. Starting from 1995 he joined the QA department. Several Senior Manager responsibilities. 2005 Sr Manager GMP Compliance Chemical Operations Belgium (sites Geel – Olen – Beerse). 2009 Director Global Compliance EMEA/AP for Johnson & Johnson. Since May 2019 he is a freelance consultant.

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.

About the organisers

The APIC "the Active Pharmaceutical Ingredients Committee" is a Sector Group within Cefic (the European Chemical Industry Council).

Objectives of the APIC

Mission:

- To represent the interests of pharmaceutical and chemical companies producing APIs and intermediates globally by being recognized experts who advance and influence the global GMP and Regulatory environment.
- To promote the use of compliant APIs in medicinal products to ensure patient safety.

Major Strategic Objectives, such as:

- To strongly advocate regulatory compliance in all global markets and its enforcement through inspection.
- To support global harmonisation in the fields of quality and regulatory affairs.
- To be the forum where API manufacturers discuss GMP, RA and other technical issues that affect their business.

Cooperation and Contacts:

In order to achieve its mission APIC is in regular contact with national and intergovernmental bodies, such as:

- European Commission (EC)
- European Medicines Agency (EMA)
- European Directorate for the Quality of Medicines & Healthcare (EDQM)
- European Parliament (EP)
- US Food and Drug Administration (FDA)
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- World Health Organization (WHO)
- Council of Europe (CoE)
- Pharmaceutical Inspection Cooperation Scheme (PIC/S)

The ECA Academy is the educational organisation of the ECA Foundation (please see www.eca-foundation.org for more information). It develops and organises a wealth of international education courses, conferences (also as part of a GMP Certification Programme) and webinars around GMP and regulatory compliance, picking up emerging GMP challenges and currently discussed subjects. While courses and webinars are designed to provide continuous education for GMP professionals in production, quality control, quality assurance etc., European conferences are organised as discussion forums on new trends and developments.

The Academy is supported by the ECA Foundation Advisory Board. This Board acts as conceptual sponsor in the development of new courses and conferences and ensures best quality and participant satisfaction by evaluating all events. As the Foundation does not employ own staff all services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg, a leading professional European training and information services provider in the pharmaceutical industry environment (please see www.concept-heidelberg.com for further information).

As Europe's leading advanced training and information services provider in this area CONCEPT HEIDELBERG develops and organises more than 350 seminars and conferences in 11 European countries.

CONCEPT HEIDELBERG has been entrusted by APIC/CEFIC to organise the ICH Q7 Week. This event is co-sponsored by the ECA Academy (www.gmp-compliance.org).

For more information about CONCEPT HEIDELBERG, please visit: www.concept-heidelberg.com.

Organisational details

Dates

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

Date of both courses:
Monday, 21 November 2022, 09.00 - 18.00 h (CET)
(Registration 08.30 - 09.00 h)
Tuesday, 22 November 2022, 08.30 - 17.30 h (CET)
Wednesday, 23 November 2022, 08.30 - 13.00 h (CET)

ICH Q7 Auditor Training Course

Wednesday, 23 November 2022, 14.00 - 18.15 h (CET)
(Registration 13.30 - 14.00 h)
Thursday, 24 November 2022, 08.30 - 18.00 h (CET)
Friday, 25 November 2022, 08.30 - 12.45 h (CET) for participants **not** intending to obtain the APIC Auditor Certification

Friday, 25 November 2022, 08.30 - 14.45 h (CET) for participants intending to obtain the APIC Auditor Certification

Venue

Hotel NH Heidelberg
Bergheimer Straße 91
69115 Heidelberg
Germany

Phone: +49 (0) 6221/13 27 0
Fax: +49 (0) 6221/13 27 100
E-Mail: nhheidelberg@nh-hotels.com

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Presentations/Certificate

The presentations will be made available to you prior to the training course as PDF files. After the event, you will automatically receive your certificate of participation.

Registration

Via the attached reservation form, by e-mail or by fax.
You may also 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.

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.

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

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Ms Anne Günster (Operations Director) at
+49 (0) 6221/84 44 50, or per e-mail at
guenster@concept-heidelberg.de

For questions regarding organisation:
Mr Niklaus Thiel (Organisation Manager) at
+49 (0) 6221/84 44 43, or per e-mail at
thiel@concept-heidelberg.de

ECA GMP Certification Programme „Certified API Production Manager“

These courses are recognised for the ECA GMP Certification Programme „Certified API Production Manager“.

Please find details at www.gmp-certification.eu.

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 pre-requisites 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 via
Fax: +49(0)6221 - 84 44 34 or e-mail: thiel@concept-heidelberg.de

Registration Form (Please complete in full)

☐ **ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis**

21- 23 November 2022, Heidelberg, Germany

Please choose TWO out of three 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**

21 - 23 November 2022, Heidelberg, Germany

Please choose TWO out of three 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**

23 - 25 November 2022, Heidelberg, Germany

☐ **Written Exam and Internet-based Test**

(For those candidates only who apply for the auditor certification)

! If you register for the Auditor Training Course, please fill in the questionnaire on the previous page and return it with your registration.

☐ 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.