

# ICH Q7 Training Courses 2021

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

21 - 25 June 2021

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis | 21 - 23 June 2021

ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation | 21 - 23 June 2021

ICH Q7 Auditor Training Course | 23 - 25 June 2021



Live Online

## Speakers

Jens Brillault  
*CU Chemie Uetikon GmbH, Germany*

Markus Dathe  
*F. Hoffmann-La Roche, Switzerland*

Ralf Gengenbach  
*gempex, Germany*

Paul Lopolito  
*Steris Corporation, USA*

Stephan Löw  
*CSL Behring, Germany*

Peter Mungenast  
*Merck KGaA, Germany*

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

Paul Stockbridge  
*Stockbridge BioPharm Consulting, UK*

Walter Tabotta  
*Virusure GmbH, Austria*

Francois Vandeweyer  
*VDWcGMP Consultancy, Belgium*

Peter C. Zimmermann  
*Iskom, Germany*



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## 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, re-processing/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 Certificate "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!**

## Target Group

These Live Online 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.



## 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.)

# The Course Week at a Glance

Monday	Tuesday	Wednesday		Thursday	Friday
<b>Joint Programme Part 1</b>	<b>Joint Programme Part 2</b>	<b>Parallel Sessions Part 3</b>		<b>ICH Q7 Auditor Training Course</b>	<b>ICH Q7 Auditor Training Course</b>
ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis  and  ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation	ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis  and  ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation	ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis	ICH Q7 Compliance for APIs Manufactured by cell Culture/Fermentation		
		<b>ICH Q7 Auditor Training Course</b>			

## 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

#### Preparing for GMP Inspections, Critical Observations

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

### Compliance Session Part 2 – Life cycle management and continuous improvement

#### API in IMP - a Risk Based Approach

- IMP Regulations in ICH Q7: Chapter 19, new WHO drafts on IMPs
- What is different from Commercial Products?
- What is the necessary Degree of Formality?
- What does appropriate means practically?
- Phase-appropriateness: a practical approach to systematic Risk Management in development

#### 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

#### 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

#### 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



## 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

### 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

### 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

## 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



After the Live Online Training, all participants will receive by mail APIC's Side-by-Side Comparison of “ICH Q7 GMP for Active Pharmaceutical Ingredients” and the “How to do Document” - APIC's Interpretation of ICH Q7.



## Conducting an audit – tools and technical aspects

### CEFIC / APIC's activities and working groups – QP demands for an API audit – 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.

**These audit sessions are supposed to be a knowledge assessment. This assessment is only relevant for participants intending to obtain the APIC Auditor Certification.**



### Testimonials of the last ICH Q7 Week

*"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

## 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

#### 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



### 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

### 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 or Onsite

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, approx. 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**.



**Dr Jens Brillault**  
**CU Chemie Uetikon GmbH, Germany**

Dr Brillault is Quality Director at CU Chemie Uetikon (a member of the SEQENS group) in Lahr, Germany. He holds a PhD in Chemistry from the University of Freiburg, Germany. Since 2009, he is working in the field of Quality Assurance and Regulatory Affairs in the API industry. Dr Brillault represents his company in APIC since 5 years, since 1 year he is vice-chair of the quality working party of APIC and a member of APIC Executive Committee. Since 09/2020, he is the leader of APIC 3rd party audit task force.



**Dr Markus Dathe**  
**F. Hoffmann-La Roche AG, Basel, 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 Coordinator in the 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.



**Stephan Löw**  
**CSL Behring GmbH, Germany**

Mr Löw studied Engineering and Biotechnology and works for CSL Behring GmbH as Manager Technical Support Laboratories. Before he has worked as Aseptic Expert, Project-Manager and Operation Manager Vaccine Formulation & Filling at GSK Vaccines. In a former position he was head of QA Microbiology at Sandoz Industrial Products and in the Quality Control Laboratory for Microbiology.



**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 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.



**Dr Walter Tabotta**  
**Virusure GmbH, Vienna, Austria**

Dr Tabotta is a veterinarian by training and thereafter completed his doctorate at the Institute of Virology, University of Vienna, Austria. He continued his post-doctoral activities at the Institute of Virology and worked eventually for a company specialising in the development of encapsulated cell based therapies for the treatment of cancers. In 2008, he moved as manager of the in vitro laboratories to Virusure and serves there now as Qualified Person.



**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](http://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](http://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](http://www.gmp-compliance.org)).

If you have any questions related to this event, please send an e-mail to [info@concept-heidelberg.de](mailto:info@concept-heidelberg.de). For more information about CONCEPT HEIDELBERG, please visit: [www.concept-heidelberg.com](http://www.concept-heidelberg.com)



## Dates of the Live Online Training

### 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 June 2021, 09:30 h – 17:15 h

Tuesday, 22 June 2021, 09:00 h – 17:15 h

Wednesday, 23 June 2021, 08:30 – 12:30 h

### ICH Q7 Auditor Training Course

Wednesday, 23 June 2021, 13:30 h – 16:15 h

Thursday, 24 June 2021, 08:30 h – 16:30 h

Friday, 25 June 2021, 08:30 h – 13:15 h for participants not intending to obtain the APIC Auditor Certification

Friday, 25 June 2021, 08:30 h – 14:30 h for participants intending to obtain the APIC Auditor Certification

## Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.

At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Participants intending to obtain the APIC Auditor Certification: For the Role Plays, please make sure that you will have a webcam, microphone (preferably headset), a constant internet connection (preferably via LAN) and join the Webex session via the Webex Application (not via the temporarily browser application).

## Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training 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. Or, you register online at [www.ichq7-week.org](http://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

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[www.concept-heidelberg.de](http://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](mailto:guenster@concept-heidelberg.de)

### For questions organisation:

Mr Niklaus Thiel (Organisation Manager) at +49 (0) 6221/84 44 43, or per e-mail at [thiel@concept-heidelberg.de](mailto: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](http://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*) <input type="checkbox"/> NO <input type="checkbox"/>
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**\*) 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

## Registration Form (Please complete in full)



- ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis**  
Live Online Training on 21 - 23 June 2021



- ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation**  
Live Online Training on 21 - 23 June 2021



- ICH Q7 Auditor Training Course**  
Live Online Training on 23 - 25 June 2021

- 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 HEIDELBERG 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. 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.

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