

Reservation Form (Please complete in full)

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

22-24 June 2009, Prague, Czech Republic

Please choose two interactive training sessions:

- A: Defining API starting materials
B: Stability Programmes – Current practices and pitfalls
C: Cleaning Validation
D: Change control – Regulatory aspects

ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation

22-24 June 2009, Prague, Czech Republic

Please choose two interactive training sessions:

- A: Process validation for biotech manufacturing processes
B: Evaluation and characterisation of viral clearance procedures
C: Cleaning validation
D: Dealing with OOS results

ICH Q7 Auditor Training Course

24-26 June 2009, Prague, Czech Republic

(In case you want to apply for the Auditor Certification please fill in the questionnaire on page 10 and return it with your registration.)

Mr Ms

Title, first name, surname

Company

IMPORTANT: Please fill in your company's VAT ID number!

P.O. Number if applicable

Department

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-mail (please fill in)

If the bill-to-address deviates from the specification above, please fill in here:

Please send this form to:

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 62 21 / 84 44 34
69007 Heidelberg
GERMANY

General Terms of Business

If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely, we must charge the following processing fees:

Cancellation

- until 2 weeks prior to the conference 10 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid.

CONCEPT will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee even if you have not made the payment yet. **You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!**

Supported by

APIC

Active Pharmaceutical
Ingredients Committee

a sector group of



EUROPEAN COMPLIANCE
ACADEMY

Speakers

Dr Andy Bailey
Virusure, Austria

Mr Richard M. Bonner
formerly Eli Lilly, UK

Mr Ralf Gengenbach
Gempex, Germany

Dr Holger Kavermann
*Roche Diagnostics,
Germany*

Dr Reiner Kirrstetter
*Sanofi-Aventis Deutsch-
land, Germany*

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

Ms Jolande Schoemaker
*Schoemaker Consultancy,
The Netherlands*

Dr Rob Slobbe
*Philips Corporate
Technologies,
The Netherlands*

Dr Jan Smeets
*DSM Anti-Infectives,
The Netherlands*

Mr Anthony Storey
Pfizer, United Kingdom

Dr Hans-Peter Volkland
GMP Experts, Germany

Mr Elmar Wenzel
*Freelance Consultant,
Germany*

Dr Frank Ziemke-Kägeler
*Roche Diagnostics,
Germany*

Dipl.Psych.
Peter C. Zimmermann
Iskom, Germany



ICH Q7 Training Courses

**ICH Q7 Compliance for APIs Manufactured by
Chemical Synthesis**
22-24 June 2009, Prague, Czech Republic

**ICH Q7 Compliance for APIs Manufactured by
Cell Culture/Fermentation**
22-24 June 2009, Prague, Czech Republic

ICH Q7 Auditor Training Course
24-26 June 2009, Prague, Czech Republic

Objectives

The education courses have been developed to **provide an excellent knowledge of the requirements laid down in ICH Q7.**

Choose between two 3-day 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.

These courses will explain the contents of ICH Q7 step by step and give practical advice on how to fulfil these requirements. For example:

- At which stage of production will GMP compliance be necessary and how can it be verified?
- How to comply with GMP hot topics like process validation, reprocessing/reworking, equipment qualification, failure investigation, etc.?
- What are necessary features; what is nice to have? Which procedures are available for regulatory submission of information on APIs and on post approval changes to their manufacture?

The number of participants is strictly limited.

Combine the ICH Q7 Courses with the Auditor Training Course

With this programme, you have the unique opportunity to combine your ICH Q7 Training Course on Chemical Synthesis or Cell Culture/ Fermentation with an ICH Q7 Auditor Training Course. This training course will inform you about the techniques and skills to be used during an audit.

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

Become an APIC Certified ICH Q7 Auditor!

If you have completed one of the ICH Q7 Training Courses held from 22-24 June 2009 (either the one on chemical synthesis or that on cell culture/ fermentation) and the 'ICH Q7 Auditor Training Course' from 24-26 June 2009 **you can become an APIC Certified ICH Q7 Auditor** (this certification is an option and not mandatory for the participation in these courses). The revised APIC Third Party Audit Programme will be presented during the course.

APIC Auditor Certification

In order to become an APIC Certified Auditor, the 'qualified' auditor **must fill in the questionnaire on page 10 and undergo an examination.** This examination exists of 2 parts.

Part 1: A trainer with academic education in psychology assesses the auditing skills of the participants during the Qualification Training Course and judges the participants' aptitude for conducting audits within the framework of the APIC Third Party Audit Programme.

Part 2: The participant has to take a an **Internet-based exam** on the contents of the GMP-compliant manufacture of APIs in accordance with ICH Q7 and the training material presented during the course. This exam is created by APIC in co-operation with the API Compliance Institute.

Auditors who have successfully passed Part 1 and Part 2 will then become APIC Certified Auditors. The certificate is valid for three years.

Those auditors who would like to become active within the framework of the APIC Third Party Audit Programme have to indicate this together with their proof of qualification on the application form. The auditor's certification can be extended for another three years provided he/she has attended a recognised training course / conference on current GMP topics and has satisfactorily performed audits.

If either of these conditions are not met, the auditor's name will be withdrawn from the register of APIC Certified Auditors kept by the API Compliance Institute.

The API Compliance Institute keeps a register of all APIC Certified auditors. The API Compliance Institute as a Business Unit of Concept Heidelberg has been contracted by APIC to administer the APIC Third Party Audit Programme. If you are not sure whether you should apply for this optional certification, please contact Dr Gerhard Becker, phone +49 (0)62 21 84 44 65, email: becker@concept-heidelberg.de.



ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

ICH Q7 Compliance for APIs Manufactured by Cell Culture/ Fermentation

Date of both courses:

Monday, 22 June 2009, 10:00 h – 18:00 h

(Registration and coffee on Monday, 22 June 2009, 9:00 h – 10:00 h)

Tuesday, 23 June 2009, 8:30 h – 18:00 h

Wednesday, 24 June 2009, 8:00 h – 14:00 h

ICH Q7 Auditor Training Course

Date:

Wednesday, 24 June 2009, 14:00 h – 18:00 h

(Registration and coffee on Wednesday, 24 June 2009, 13:30 h – 14:00 h)

Thursday, 25 June 2009, 8:30 h – 18:15 h

Friday, 26 June 2009, 8:30 h – 12:15 h

Venue of the 3 courses

Dorint Hotel Don Giovanni Prague

Vinohradská 157a

130 20 Prague 3

Czech Republic

Phone +420 267 03 1111

Fax +420 267 03 6704



Fees

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

22-24 June 2009, Prague, Czech Republic

ECA Members € 1,791.- per delegate plus VAT

Non-ECA Members € 1,990.- per delegate plus VAT

EU GMP Inspectorates € 995.- per delegate plus VAT

APIC Members (does not include ECA Membership) € 1,890.- per delegate plus VAT.

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

ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation

22-24 June 2009, Prague, Czech Republic

ECA Members € 1,791.- per delegate plus VAT

Non-ECA Members € 1,990.- per delegate plus VAT

EU GMP Inspectorates € 995.- per delegate plus VAT

APIC Members (does not include ECA Membership) € 1,890.- per delegate plus VAT.

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

ICH Q7 Auditor Training Course

24-26 June 2009, Prague, Czech Republic

ECA Members € 2,061.- per delegate plus VAT

Non-ECA Members € 2,290.- per delegate plus VAT

EU GMP Inspectorates € 1,145.- per delegate plus VAT

APIC Members (does not include ECA Membership) € 2,175.- per delegate plus VAT.

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

Registration

Via the attached reservation form, by e-mail or by fax message.

Or you register online at www.ichq7-week.org.

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 conference. Please use this form for your room reservation or be sure to mention code "VA 5928 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 29 May 2009.

Early reservation is recommended.

Conference Language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG

P.O. Box 10 17 64

D-69007 Heidelberg, Germany

Phone +49 (0) 62 21/84 44-0

Fax +49 (0) 62 21/84 44 34

info@concept-heidelberg.de

www.concept-heidelberg.de

For questions regarding content:

Dr Gerhard Becker (Operations Director) at

+49(0)62 21/84 44 65,

or per e-mail at becker@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Susanne Ludwig (Organisation Manager) at

+49(0)62 21 / 84 44 44, or per e-mail at

ludwig@concept-heidelberg.de.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?

First benefit:

During the membership, you enjoy a 10 % discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:

The GMP Guidelines Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.



How Do You Become a Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years - free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website <http://www.gmp-compliance.org>

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

Communication Part I

- **General aspects of communication**
 - The meaning of communication in an audit
 - Communication as a process
 - Analysis of the process
- **Key issues of communication**
 - Verbal and non-verbal communication
 - The first impression
 - Determining important aspects in communication
 - Exercise

Communication Part II

- **Multicultural aspects**
 - Differences in body language
 - Different rituals
 - Different dos and taboos
 - Workshop multicultural aspects: Experiences
- **Audit: A unique situation of communication**
 - The overall setting
 - The participants
 - The rules
 - The topics

Communication Part III

- **General aspects of opinions and observations**
 - Successful communication
 - Skills of the listener
 - Skills of the speaker
 - Active listening
 - Objective evidence of GMP deficiencies directly related to ICH Q7
 - Classification of Deficiencies
- **Questioning methods**
 - Open and closed ended questions
 - Other questioning techniques
 - Exercise
- **Attitude and behaviour in front of the auditee**
- **Preparation for the role plays**

Conducting an Audit

- **Role plays and review of the role plays**

Audit closing meeting and measuring success

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

Questionnaire for the APIC Auditor Certification

Important: This questionnaire has to be filled in by **those candidates only who want to apply for the auditor certification**. In this case please return the completed questionnaire with the registration for the ICH Q7 Auditor Training Course.

Examination: Back in your office, you will have to pass a multiple-choice Internet-based test on the content of the training course. The fee for this test is € 90,- + VAT and will be charged separately.

- I would like to become an APIC Certified Auditor
- I would like to become an APIC Certified Auditor and would like to conduct audits on behalf of the APIC Third Party Audit Programme

Educational Background

| Degree or Diploma | Name/Location of Institution | Month/Year |
|-------------------|------------------------------|------------|
| | | |
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Work experience (minimum of 2 years experience in industry or regulatory body required)

| Company | Function | Time Period |
|---------|----------|-------------|
| | | |
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Practical experience as Auditor

| | |
|---|--|
| Number of Audits conducted so far | |
| How many of these audits have been internal company audits? | |
| How many of these audits have been external audits? | |
| Number of audits as lead auditor | |
| Number of authority inspections escorted | |
| When did you start auditing? | |
| When was the last audit? | |

Certified by another organisation

If you have been certified as an auditor by another organisation, please identify the organisation, your certification number and the date of your original certification and the date the current certification will expire.

| Certifying organisation | Certification number | Date of original certification | Expiry date of current certification |
|-------------------------|----------------------|--------------------------------|--------------------------------------|
| | | | |
| | | | |
| | | | |

Name (Please write in block letters)

Date

Signature

Speakers

Dr Andy Bailey

Virusure, Austria

Mr Richard M. Bonner

formerly Eli Lilly and Company Limited, UK

Mr Ralf Gengenbach

Gempex, Germany

Dr Holger Kavermann

Roche Diagnostics, Germany

Dr Reiner Kirrstetter

Sanofi-Aventis Deutschland GmbH, Germany

Dr Jordi Ruiz-Combalia

BIOIBERICA S.A., Spain

Ms Jolande Schoemaker

Schoemaker Consultancy, The Netherlands

Dr Rob Slobbe

Philips Corporate Technologies, The Netherlands

Dr Jan Smeets

DSM Anti-Infectives, The Netherlands

Mr Anthony Storey

Pfizer, United Kingdom

Dr Hans-Peter Volkland

GMP Experts, Germany

Mr Elmar Wenzel

Germany

Dr Frank Ziemke-Kägeler

Roche Diagnostics, Germany

Dipl.Psych. Peter C. Zimmermann

Iskom, Germany)

About APIC and CEFIC

The Active Pharmaceutical Ingredients Committee (APIC) is a sector group of CEFIC. CEFIC, the European Chemical Industry Council, is the Brussels-based organisation representing national chemical federations and chemical companies all over Europe. In total, CEFIC represents, directly or indirectly, more than 40,000 large, medium and small chemical companies in Europe, which employ about 2 million people and account for more than 30 % of world chemical production. The aims of APIC are:

- To represent the interests of that part of the industry engaged in the manufacture of pharmacologically active ingredients and intermediates.
- To be the recognised forum for the industry to address issues of relevance. To be the recognised voice of this sector for the competent authorities.

The Programme

| Monday, 22 June 2009 | Tuesday, 23 June 2009 | Wednesday, 24 June 2009 | Thursday, 25 June 2009 | Friday, 26 June 2009 |
|---|---|--|---|---------------------------------------|
| Joint Programme | Parallel Sessions | | Joint Programme | ICH Q7 Auditor Training Course |
| ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation | ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis | ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation | ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation | ICH Q7 Auditor Training Course |
| Parallel Sessions | | | | |
| ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation | ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis | ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation | ICH Q7 Auditor Training Course | |

Dr Andy Bailey, ViruSure GmbH, Vienna, Austria

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

Mr Richard M. Bonner, formerly Eli Lilly and Company Limited, UK

Mr Bonner is currently located in the UK and works as a consultant to the Pharmaceutical Industry. Previous to his current role he was a Senior Quality Adviser for Eli Lilly and Company. He had 31 years experience within the pharmaceutical industry working in production, technical services and both Quality Control and Quality Assurance functions. He has been involved in multiple inspections from the MHRA, FDA and other authorities. He has also been instrumental in obtaining ISO9000-2000 accreditation for manufacturing sites. He has audited extensively throughout the EU and in countries as far a field as Canada, USA, China, Pakistan, Egypt, Syria, Oman and Russia. Mr Bonner is a Qualified Person in Europe. He is now Associate Partner with Concept Heidelberg.

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

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

Dr Reiner Kirrstetter, Sanofi-Aventis, Germany

Dr Kirrstetter is currently working in the corporate group Technical Quality & Compliance Expertise. He is chemist and gained his PhD at the University of Heidelberg. Dr. Kirrstetter has been working for sanofi-aventis and former Hoechst AG/Hoechst Marion Roussel/Aventis Pharma since 1980 in research, development, production and quality operations. He is experienced in GMP and regulatory compliance since 1988 and has been involved in 8 FDA inspections as a team leader or deputy.

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

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

Ms Jolande Schoemaker, Schoemaker Consultancy, The Netherlands

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

Dr Rob Slobbe, Philips Corporate Technologies, The Netherlands

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

Dr Jan Smeets, DSM Anti-Infectives, The Netherlands

Dr Smeets has been working for 12 years with DSM (formerly Gist-brocades) with different positions in research & development and regulatory affairs for APIs and intermediates. He is international regulatory affairs manager in the International Safety, Health and Compliance Department of DSM Anti-Infectives, where he is responsible for the world-wide submissions and approvals of registration dossiers of several manufacturing sites within the company.

Dr Hans-Peter Volkland, GMP Experts, Germany

Dr Volkland worked for several years in R&D and in various quality positions (QA, QC, Validation, Qualification). In 2001 he joined PCS (Pharmaceutical Consultancy Services) as Senior Consultant and Senior Auditor. In 2006 he set up his own consultancy company, Pharma and API Consulting (PAAC). In 2009 he founded GMP Experts which provides GMP consulting, auditing and training for the pharma and API business.

Mr Elmar Wenzel, Freelance Consultant, Germany

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

Dr Frank Ziemke-Kägeler

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

Dipl.-Psych. 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.

ICH Q7 Auditor Training Course

24-26 June 2009

Objectives

In compliance with the European Directives, Manufacturing Authorisation Holders of Medicinal Products Manufacturers must satisfy themselves that the APIs used as Starting Materials in the manufacture of Medicinal Products are compliant with the ICH Q7 GMP requirements that are now included as Part II of The Rules Governing Medicinal Products in the European Union. Manufacturers of Active Pharmaceutical Ingredients (APIs) also wish to assure themselves that they are complying with the GMP requirements. But how can it be verified whether a manufacturer is in compliance or not? The answer to this question is: performing audits. Audits are a powerful tool for senior management to determine the status of compliance, i.e. to compare „what is in place“ with „what should be in place“.

Auditing Requires Professionalism

This training course will inform the participant about the general advice on Good Auditing Practices included in the APIC „Auditing Guide“ and the APIC Third Party Audit Programme that is being revised based on the advice of the European Authorities on the Principles of Third Party Auditing (www.apic.cefic.org). In addition to the training of the communication skills, the ICH Q7 Auditor Training Course will provide assistance on what to focus on during an API audit and on the current „state of the art“ from an industry perspective. The basic document for this part of the training will be the APIC/CEFIC's „How-to-Do“ document, an interpretation of ICH Q7 requirements. For becoming a certified auditor within the „ICH Q7 Auditor Certification Scheme“, it is a prerequisite to have participated in the ICH Q7 training courses for APIs manufactured either chemically or by cell culture/fermentation (2.5 days each). Nevertheless, it is also possible to participate in this training course without the aim of certification.

Programme Day 1

The CEFIC / APIC Audit Programme – a Third Party Audit Option

- CEFIC / APIC Quality Working Group
- EU Legislation and Advice on GMP Status of Active Substances
- Third Party Audit Principles
- The APIC Audit Programme
- Conclusions

The APIC Audit Programme – Guidance on auditing practices

- Audit Dos and Don'ts
- Advance preparations for successful audit
- Appendices A and C of the APIC Audit Programme: Secrecy Agreement and Aide Mémoire
- Performing the Audit
- Closing Meeting

How to use a risk-based approach to produce an audit schedule

- Audit programme expectations
- The Quality System Focus
- Defining risk in audit program
- Audit program strategy
- Compliance risk assessment and compliance status tool

Programme Day 2

Why are audits so important?

Audits are used to determine the extent to which the management system requirements are matched. It is the auditors' duty to determine whether the audit criteria are fulfilled. This requires a good cooperation with the auditee. Cooperation is based on communication. For auditors communication means steering the conversation using questioning and interview techniques that enable a free exchange of information.

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

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

Equipment qualification and calibration

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

Batch release process and re-use of materials

- Regulatory requirements
- Responsibilities of the quality unit
- Batch Record Review and the decision
- Rejection and re-use of materials
- Reprocessing, reworking, recovery

Cleaning Validation

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

Engineering and Design

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

Practical Approaches to Process Validation

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

Specific Interactive Training Sessions

| | | |
|----|---|--------------------|
| A: | Defining API starting materials (Case Studies) | (R. Slobbe) |
| B: | Stability Programmes – Current practices and pitfalls | (J. Ruiz Combalia) |
| C: | Cleaning Validation | (H.-P. Volkland) |
| D: | Change control – Regulatory aspects | (J. Smeets) |

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

cGMP and Biotechnology Buildings and Equipment

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

Cleaning and Cleaning Validation in Biotech Manufacturing Processes

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

Process Controls in Biotech Manufacturing Processes

- Proper inoculation, expansion of culture
- Control of critical operating parameters (e.g. temperature, pH, agitation rates, addition of gases, pressure)
- Monitoring of the process for cell growth, viability (where appropriate), productivity
- Monitoring of bioburden

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 | (R. Bonner) |
| B: | Evaluation and characterisation of viral clearance procedures | (A. Bailey) |
| C: | Cleaning validation | (F. Ziemke-Kägeler) |
| D: | Dealing with OOS results | (J. Schoemaker) |

Please choose two sessions

Joint Programme

Regulatory Affairs Aspects for APIs

Handling regulatory Changes and Variations

- Common Technical Document (CTD)
- Certificate of Suitability (CEP) and Active Substance Master File (DMF)
- Variations in the EU – new approach
- Changes in the US
- Handling variations and changes
- Differences in the EU and FDA perspective
- How to ensure regulatory compliance

Compliance Issues

Product Quality Review – What needs to be done

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

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 eviations
- A quick look on Root Cause Analysis
- The role of the quality unit for handling deviations and justification

Preparing for GMP Inspections, Critical Observations

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

Social Events in Prague

On Monday, 22 June the participants of the ICH Q7 Compliance Courses are cordially invited to a social event in the heart of Prague.



On Wednesday, 24 June a social event for the participants of the Auditor Training course will be organised.

These events are excellent opportunities to share your experiences with colleagues from other companies in a relaxed atmosphere.



ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis

22-24 June 2009

ICH Q7 Compliance for APIs Manufactured by Cell Culture/ Fermentation

22-24 June 2009

Each course is divided into four parts:

In the **general part** special aspects of the new European Directive 2004/27/EC and their relevance for API manufacturers and for **Qualified Persons and Auditors of the Manufacturing Authorisation Holders** will be discussed. General aspects of quality issues will be presented, e.g. the role of the quality unit, requirements for the documentation, aspects of materials management and GMP in the laboratory areas.

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

In the third part **regulatory aspects for APIs** with regard to the internationally harmonised format of the dossier, the Common Technical Document (CTD) and other feasible ways to submit the required information about the quality of the drug substance, the CEP (Certificate of Suitability) and the ASMF (Active Substance Master File), will be presented.

The **fourth and last part** of the course will deal with **compliance issues** like handling deviations and changes, implementing a change control system and ways of compiling the Product Quality Review. Each participant has the opportunity to choose 2 out of 4 **interactive specific training sessions** where specific aspects will be discussed in detail.

Joint Programme

General Part - Regulations and Quality Issues

GMP Regulations in Europe and the US

- The "New" EU Pharmaceutical Legislation and the Relevance for API manufacturers
- GMP Regulations for APIs in the US
- ICH Q7 - The most important GMP Guide for APIs
- Keywords in ICH Q7: What do they mean?
- Part II of the EC GMP Guide
- Consequences for contract manufacturers, agents, brokers and distributors
- Current regulatory trends

Quality Management and Quality Systems

- Roles and responsibilities of the quality unit
- The quality system is the focus
- How ICH Q10 can contribute
- The Set-up of a good quality system
- Some recommendations for the quality unit

Written, documented, recorded - The Management of GMP Documentation

- General aspects and requirements
- Types of GMP documentation
- Purposes of GMP documentation
- The structure of document management
- Evaluation of your documentation system
- The Document Management Cycle

Plenary Workshop