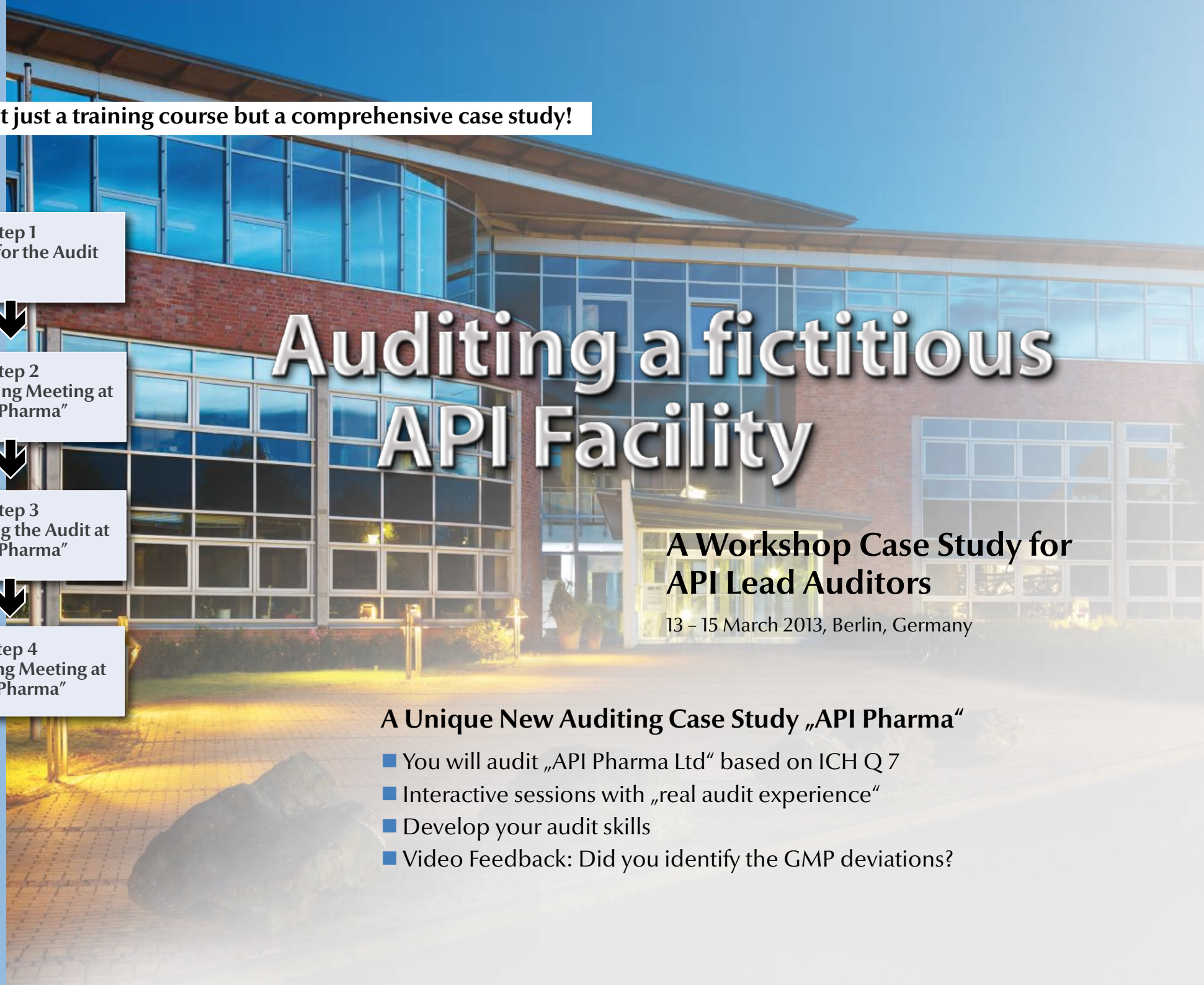


This is not just a training course but a comprehensive case study!

Step 1
Prepare for the Audit

Step 2
The Opening Meeting at "API Pharma"

Step 3
Performing the Audit at "API Pharma"

Step 4
The Closing Meeting at "API Pharma"

Auditing a fictitious API Facility

A Workshop Case Study for API Lead Auditors

13 – 15 March 2013, Berlin, Germany

A Unique New Auditing Case Study „API Pharma"

- You will audit „API Pharma Ltd" based on ICH Q 7
- Interactive sessions with „real audit experience"
- Develop your audit skills
- Video Feedback: Did you identify the GMP deviations?

ECA
European Compliance Academy

Auditing a fictitious API Facility

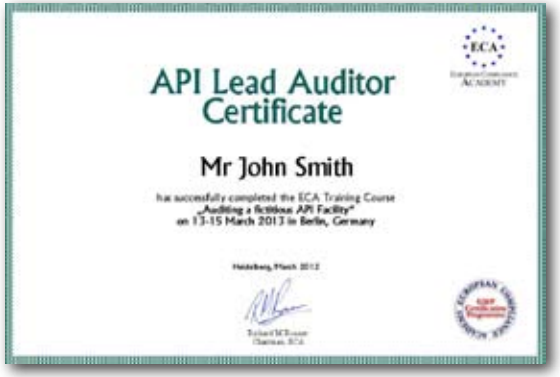
13 – 15 March 2013, Berlin, Germany

Objectives

In this training course you will have the opportunity to **prepare and conduct an audit at different departments of a fictitious API Manufacturing plant**. According to a case study you are confronted with specific situations in that company where you have to act as auditors in an appropriate way. You will learn

- how to apply your technical and communication skills
- how to focus on specific API related aspects
- how to deal with possible fraud, cultural and language differences e.g. in overseas audits

The illustration of communication aspects will be supported by video feedback.
The basic documents for this training course will be the ICH Q7 Guideline and APIC/CEFIC's „How-to-Do" document, an interpretation of the ICH Q7 requirements.



Target Audience

This training course is designed for experienced auditors being in charge of performing audits at API manufacturing sites all over the world. The course is recommended for Auditors who have already received the APIC Auditor Certification within the framework of the APIC Audit Programme, although auditors who are experienced through other means are welcome to attend. **All participants receive the ECA "API Lead Auditor Certificate" after having successfully completed the training course. The number of participants is limited to 20.**

Speakers

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 has 35 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 and Chairman of the European Compliance Academy.

Dr Tom Buggy, DSM Sinochem Pharmaceuticals, The Netherlands
Dr Buggy is the International GMP Compliance Adviser for DSM Sinochem Pharmaceuticals (former DSM Anti-Infectives) based in Delft. He is responsible for the international Quality procedures, Internal Auditing of the manufacturing sites and generally supporting the DSM sites on Quality related topics. He has 27 years experience of working in the Pharmaceutical Industry specialising on the Research, Development, Manufacture and Quality Assurance of APIs. He represents DSM in the CEFIC/APIC Quality Working Group.

Anthony Storey, Pfizer, UK
Tony Storey is currently located in Sandwich, UK. Tony is responsible for quality management of contract manufacturers including both API and Drug Product manufacturers. Prior to this Tony worked as an API QA manager at a Pfizer site with overall quality responsibility of the API plants at the facility. Tony is currently vice president of APIC (Active Pharmaceutical Ingredients Committee) and was previously chair of the APIC Quality Working Group.

Francois Vandeweyer, Janssen Pharmaceutica, Belgium
Graduated in 1979 as Bachelor in Chemistry. He joined Janssen Pharmaceutica (part of Johnson & Johnson) in 1981 in chemical development. Until 1995 increasing responsibilities within the organisation mainly in the Quality Control Unit (Manager QC Lab 1994). Starting from 1995 he joined the QA department. Several Senior Manager responsibilities (sGMP Auditor – Release – Quality Systems). 2005 Sr Manager GMP Compliance Chemical Operations Belgium (sites Geel – Olen – Beerse). 2009 Director Global Compliance EMA/AP for Johnson & Johnson.

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.

The Case Study
„API Pharma Ltd“
(a fictitious company)

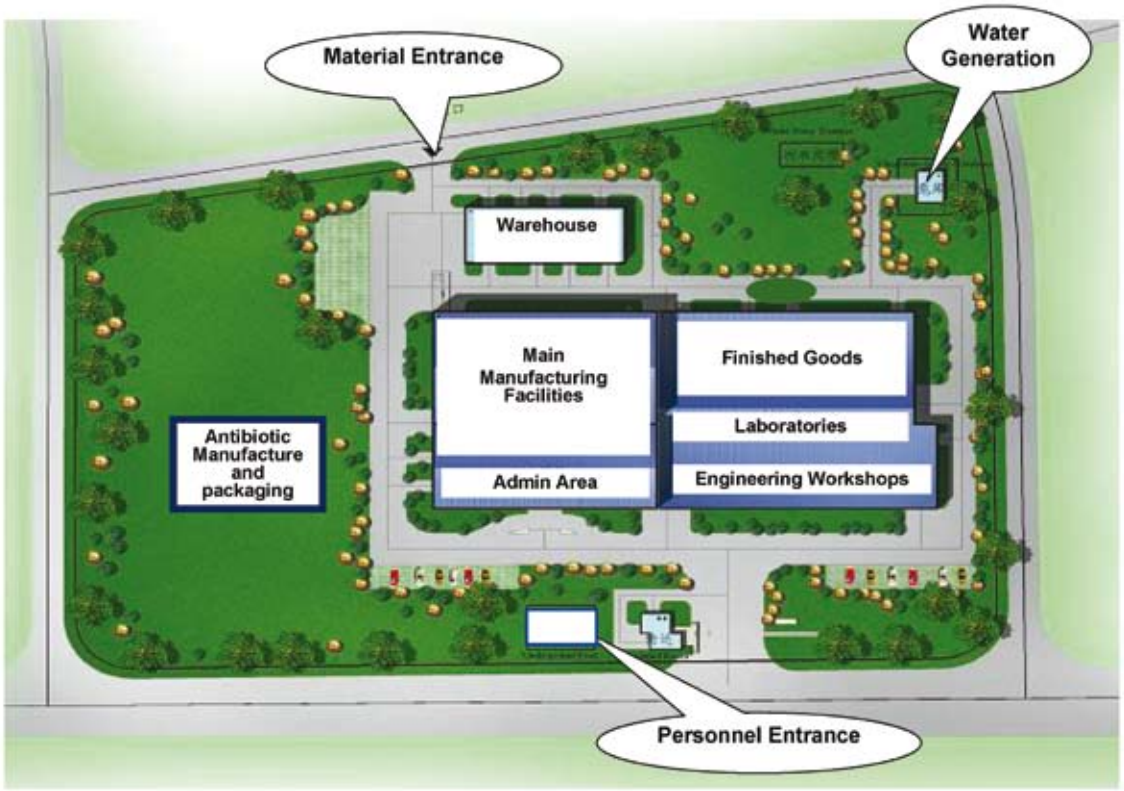
API Pharma was established in the 1990's and is a contract manufacturing organisation that produces API's for a number of clients. API Pharma has been producing two different APIs under licence for a company called Pharmtech Ltd. The first material is called Fantasium, which is an analgesic and has been produced for about 2 years the other material is called Delerium, an antidepressant, which has been made for over 5 years. Pharmtech receives these APIs in bulk and both produces final formulated capsule products themselves and also supplies them to various other Drug Product manufacturers for final formulation. Both products are administered to patients in an oral capsule form.

Pharmtech Ltd have recently been receiving some complaints from its customers that capsules made from the Fantasium API appear to have lost some of their efficacy and are hence not as effective as they used to be in the control of headaches. To date, Pharmtech Ltd has not had any customer complaints against their other own formulated products. There are no such complaints against Delerium.

Pharmtech have asked their QA group to arrange an audit of API Pharma to see if there is anything occurring at API Pharma that could be causing this apparent reduction in efficacy before replying to these complaints.

The participants of the training course are that audit group, and have now arrived at API Pharma to carry out this audit.

API Pharma plc, UK.
Plant Layout



Day 1

STEP 1 Prepare for the Audit

In this first phase of the case study the participants will prepare an audit scope document outlining their approach to the forthcoming audit of API Pharma Ltd based on ICH Q7.

- The participants will be divided in groups. Each group will be provided with an information package containing documents relevant for the audit.
- The audit groups have the task to define their role and the general audit strategy.

Additional Presentation:
How to efficiently prepare and conduct an audit - Soft skills and cultural aspects

↺ **Feedback from the Trainer**

Day 1

STEP 2 The Opening Meeting

The management of "API Pharma Ltd" will give a brief overview about the company, the Quality Management System and the facilities. This information complements the information package the participants have already received.

- The audit groups will then modify their audit scope document to identify their specific audit strategy with focus on the possible critical areas.

↺ **Feedback from the Trainer**

Day 2

STEP 3 Performing the Audit

Each audit group will perform an audit at the following departments:

- Production
- Validation Support
- Quality Control Laboratory
- Quality Assurance

In addition a reading room is available for the purpose of reviewing some of the company's GMP documents.
The audit interviews of the groups will be video taped. In a subsequent feedback session each group will present their findings.

Day 3

Video Feedback: How did you perform the audit

The video taped audit interviews will be evaluated and discussed with respect to psychological aspects like attitude, behaviour, body language, questioning techniques etc.

Day 3

STEP 4 The Closing Meeting

The groups will prepare an audit Closing Meeting and present their findings and overall assessment about the GMP status of „API Pharma Ltd" in that Closing Meeting.
A GMP feedback and a soft skills feedback from the speakers will round off the Audit Workshop

Additional Presentation on how to deal with possible fraud, cultural and language differences in overseas audits

↺ **Feedback from the Trainer**

Social Event

On 13 March 2013, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

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 200 € 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**.

Special offer with Lufthansa - up to 20% discounted travel for all ECA Events Attendees

Lufthansa Mobility Partner

As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability).

And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.
And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Wednesday, 13 March 2013, 9.00 h – 17.00 h
(Registration and Coffee 8.30 h - 9.00 h)
Thursday, 14 March 2013, 8.30 h – 17.15 h
Friday, 15 March 2013, 8.30 h – 12:15 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone: +49 (0)30 212 7 - 0
Fax +49 (0)30 212 7-117

Registration
Via attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Fees
ECA Members € 2.090.-*
APIC Members € 2.190.- *
(does not include ECA Membership)
Non-ECA Members € 2.290.-*
EU GMP Inspectorates € 1.145.-*
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on the first and second day, snack on the third day and all refreshments.

* per delegate plus VAT. VAT is reclaimable.

Conference language
The official conference language will be English.

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.
Reservation should be made directly with the hotel. Early reservation is recommended.

Organisation and Contact
CONCEPT HEIDELBERG
P.O. Box 10 17 64
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 +49-62 21/84 44 65, or per e-mail at becker@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Susanne Ludwig (Organisation Manager) at +49-62 21/84 44 44, or per e-mail at ludwig@concept-heidelberg.de

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If the bill-to-address deviates from the specification to the right, please fill out here:

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CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg, Germany

Registration form (please complete in full)

Auditing a fictitious API Facility, 13 – 15 March 2013, Berlin, Germany

☐ Mr ☐ Ms Title _____

First name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order No. (if applicable)**

Street / P.O. Box

City Zip Code Country

Phone / Fax E-mail (please fill in)

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)!
(As of January 2012)

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