

**Speakers:**

**Richard M. Bonner**  
*Formerly with Eli Lilly,  
United Kingdom*

**Dr Heinrich Prinz**  
*CellMed AG, Germany*

**Dr Stephan Rosenberger**  
*Lonza AG, Belgium*

**Daniel Scheidegger**  
*Genzyme Pharmaceuticals,  
Switzerland*

**Dr Thomas Schneppe**  
*Bayer HealthCare AG,  
Germany*

**Dr Helene Zuurmond**  
*Pfizer, Belgium*



# ICH Q9 / ICH Q10 Training Courses

## ICH Q 9 Training Course

21 -22 April 2010, Budapest, Hungary

## ICH Q 10 Training Course

22 - 23 April 2010, Budapest, Hungary

Quality Manual of a fictitious  
company with GMP and ISO 9000  
elements **free of charge**  
for all participants of the  
ICH Q10 Course!



EUROPEAN COMPLIANCE  
ACADEMY

**Save money and book both courses for € 990,- each!**

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# ICH Q9 Training Course

21-22 April 2010, Budapest, Hungary

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|--|---|
| <b>Objectives</b>  | <p>The Guideline ICH Q9 „Quality Risk Management“ was finalised in November 2005 (Step 5). Consequently, this guideline has to be implemented in the EU, the US (FDA) and in Japan.</p> <p>The ICH Q9 training course in hand deals with the <b>practical implementation of the requirements</b>. Individual examples help to show the application in the following GMP areas:</p> <ul style="list-style-type: none"><li>■ Validation</li><li>■ Change Control/Change Management</li><li>■ Auditing/Inspections</li><li>■ Quality Systems</li></ul> <p>As a complement to the lectures, the closing <b>workshop</b> offers the opportunity to practise Quality Risk Management techniques <b>with a case study</b>.</p> |
| <b>Target Group</b>  | <p>This event has been designed for quality assurance personnel. It also addresses staff from other departments, like e.g. production, engineering, quality control, and regulatory affairs in so far as they are subject to EU and FDA GMP compliance.</p>   |
| <b>Moderator</b>   | <p>This conference will be moderated by Richard M. Bonner</p>   |
| <b>ICH Q 9 Quality Risk Management</b>   | <ul style="list-style-type: none"><li>■ Basic requirements</li><li>■ Comparison to ISO 14971</li></ul>  |
| <b>How to Realise Quality Risk Management in a GMP Environment</b>                                       | <ul style="list-style-type: none"><li>■ An overview of the diverse techniques (HACCP, FTA etc.)</li><li>■ Access benefit of some tools</li><li>■ Examples from the production of drug (medicinal) products and APIs</li></ul>   |
| <b>How to Apply Quality Risk Management in Validation</b>  | <ul style="list-style-type: none"><li>■ Understand why the use of risk management in process validation is now expected</li><li>■ What does the FDA expect for batch conformance prior to, and post, product approval</li><li>■ What is the benefit of using the risk management approach versus the traditional 3 batch validation approach?</li><li>■ What does ICH Q9 mean with respect to quality risk management in validation</li><li>■ Learn why the quality risk management approach to validation will result in less ongoing process support during production</li></ul>  |
| <b>Design of an Event Handling System based on a Quality System and Quality Risk Management Approach</b> | <ul style="list-style-type: none"><li>■ The quality system</li><li>■ Risk management principles</li><li>■ Events (e. g. deviations, complaints etc.)</li><li>■ Risk Management Application</li><li>■ Outputs</li></ul>  |
| <b>How to implement Quality Risk Management in a Pharmaceutical Company</b>                              | <ul style="list-style-type: none"><li>■ The risk-based approach and his impact on key GMP processes (GAMP®5, Draft FDA Guidance on Process Validation, etc)</li><li>■ ICH Q9 in the context of ICH Q8 and ICH Q10</li><li>■ The implementation of „quality risk management thinking and doing“ on management and shop floor level (tools and experiences)</li></ul>   |
| <b>How to Make a Risk-based Audit Schedule</b>   | <ul style="list-style-type: none"><li>■ Understand how to assess risk between different operations</li><li>■ Identify priorities for the audit</li><li>■ Learn how to use a point system to assign audit priorities based on risk</li><li>■ How to use a template to make a risk based audit schedule</li></ul>   |

## Workshop Quality Risk Management in Practice

Learn how to **create an audit schedule by looking at the various risk categories** associated with the various operational activities within the differing units. This workshop will help you look across the different units from production operations, vendors, third-parties and laboratories, rank them by risk and then apply this to a template to create an audit schedule covering the next 3 years.

**After the workshop you will be able to use or adapt the template to conduct a similar risk profile for your own facilities and third-party operations**



## Speakers



### **Richard M. Bonner, formerly with Eli Lilly, United Kingdom**

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. Mr Bonner is a Qualified Person in Europe. He is now Associate Partner with Concept Heidelberg.



### **Dr Helene Zuurmond, Pfizer, Belgium**

Dr Helene Zuurmond studied Chemistry at Leiden University in the Netherlands. After working at a Pfizer site in Italy in the registration compliance and quality systems area, she is now working in the Global Quality Organisation within the same company, where she is responsible for design and implementation of compliant and efficient quality systems at the Pfizer manufacturing sites



### **Dr Heinrich Prinz, CellMed AG, Germany**

Dr Prinz worked with Boehringer Mannheim before he joined Biotest. Until recently he was Head of Quality Assurance, responsible for both the pharmaceutical and the medical device division of Biotest AG. Since 2003 he works as a freelance consultant and part of his time he is head of Quality Control and Quality Assurance of CellMed AG.



### **Dr Thomas Schneppe, Bayer HealthCare AG, Berlin, Germany**

Dr Thomas Schneppe worked for Klöckner Pentapack Contract Manufacturing, Asche AG and Schering AG. Since 2006 he is Head of the Department Integrated Quality Management Training at Bayer HealthCare AG.

# ICH Q 10 Training Course

22-23 April 2010, Budapest, Hungary

## Objectives

FDA's Final Report „Pharmaceutical cGMPs for the 21st Century – A Risk-based Approach“ brings about a great number of changes. One key document is the FDA Guidance for Industry: Quality System Approach to Pharmaceutical cGMP.

In parallel, the International Conference on Harmonisation has published the Guidance ICH Q10 Pharmaceutical Quality Systems.

The course in hand will provide you with information on the content and consequences of these documents.

The following topics will be covered:

- Modern management concepts, like CAPA
- Risk management in quality systems
- Continuous improvement
- ISO 9001 in the GMP environment

In addition the topics will be further discussed in **interactive workshops**.

## Target Group

This event has been designed for quality assurance personnel. It also addresses staff from other departments, like e.g. production, engineering, quality control, and regulatory affairs in so far as they are subject to EU and FDA GMP compliance.

## Moderator

This conference will be moderated by Daniel Scheidegger, Managing Director, Genzyme Pharmaceuticals, Switzerland. He is also Chairman of the European Compliance Academy (ECA).

## ICH Q 10 and FDA's Guidance on Pharmaceutical Quality Systems

- What is the content of the new guidance?
- The impact of the Draft Guidance on cGMP for Combination Products
- How to comply with the Guidelines

## Pharmaceutical Quality System: What is needed to complement the existing system in the company?

- ICH Q10 in the context of ICH Q8 and ICH Q9
- Managing quality in a systematic manner and with adequate system support (GxP, QC, QA, QM, Continuous Improvement...)
- Balancing compliance activities to foster best practice and to manage costs of compliance

## The Corrective and Preventive Action System (CAPA)

- Where does CAPA come from?
- How to establish a CAPA system in a company
- CAPA benefits from a business perspective

## How to Incorporate ISO 9000 into a GMP System

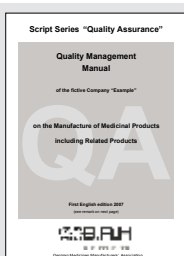
- ISO 9001 the standard for Quality System
- What are the differences between GMP and ISO 9001?
- Product quality versus system quality

## Annual Reviews as a Tool to Improve Quality

- What kind of data and information should be reviewed?
- How to establish a useful quality review

## APIC's Quality Management Guidance – Content and practical Examples of implementation

- Introduction to QMS for API manufacturers
- Quality Manual, the basic document of QMS
- System approaches in Q7
- Implementation of QMS - some milestones



## Quality Management Manual of a fictive Company – free of charge for all participants

The Quality Management Manual of the fictive company "Example" does not only take into consideration the quality assurance system (QA System) as required by the GMP regulation but also the requirements of the international standards EN ISO 9001: 2000 on Quality Management Systems and EN ISO 13485: 2003 "Quality Management Systems – Medical Devices – Requirements for Regulatory Purposes". The Quality Manual was developed by a task force of the German Medicines Manufacturers Association. The content is structured according to ISO 9001. In the appendix of the publication you will find exemplary job descriptions, e.g. for the Qualified Person, Head of Production and Head of Quality Control. Further examples include forms for the review by the management and a process flow chart.

## Workshops

We offer three parallel workshops in the afternoon



### Workshop 1

#### How to Involve Management in a Quality System That Meets EU and FDA Inspections

During the workshop you will learn how to integrate the management representative into the new responsibility and to comply with FDA's new Quality System Guidance, European GMP and ISO 9001. As a result of this workshop, the key topics for an SOP will be defined

### Workshop 2

#### How to Establish a CAPA System in a Company

Today, Corrective Action and Preventive Action (CAPA) should be an integral part of a modern quality system. The requirement, originally developed in FDA's CDRH office for the field of medical device, is increasingly mandatory for the field of drug products and APIs. In the workshop you will learn to understand the CAPA system and to implement CAPA in a practice-oriented way in the individual fields.

### Workshop 3

#### How to monitor process performance and Quality System effectiveness?

Continuous improvement is one of the key processes in a modern, robust Quality Management System to enhance the organisation's effectiveness and to increase the efficiency of the Quality Systems and related processes continuously. Using a risk based approach in monitoring established Compliance/ Quality Key Performance Indicators enables Management to concentrate resources on critical compliance issues and to keep focus of site inspection readiness. You will practice this technique in a Workshop

## Speakers



### Dr Heinrich Prinz, CellMed AG, Germany

Dr Prinz worked with Boehringer Mannheim before he joined Biotest. Until recently he was Head of Quality Assurance, responsible for both the pharmaceutical and the medical device division of Biotest AG. Since 2003 he works as a freelance consultant and part of his time he is head of Quality Control and Quality Assurance of CellMed AG.



### Dr Stephan Rosenberger, Lonza Peptides, Belgium

After several years in the R&D department in Switzerland and the US, Stephan Rosenberger worked at Siegfried Switzerland in Zofingen in charge of Outsourcing of regulated intermediates and Active Pharmaceutical Ingredients before he took over the responsibility of QA function for Drug product and Drug Substance, following the position of global Director Quality Management Systems. In 2007 he moved to Corporate Quality of Lonza AG in Switzerland and works currently as Senior VP Quality Intelligence for Lonza Peptides in Brussels



### Daniel Scheidegger, Genzyme Pharmaceuticals, Switzerland

Daniel Scheidegger worked for F. Hoffmann-La Roche AG in Basel, Switzerland, in R&D and as manager of chemical production. From 1987 to 1993 he was Head of drug production at CIMEX AG in Switzerland, following 4 years with F. Hoffmann-La Roche AG, Basel, as QA manager responsible for quality assurance of APIs. Since 1997 Managing Director and Vice President Operations at Genzyme Pharmaceuticals, Sygena Facility Liestal, Switzerland.



### Dr Thomas Schneppe, Bayer HealthCare AG, Berlin, Germany

Dr Thomas Schneppe worked for Klöckner Pentapack Contract Manufacturing, Asche AG and Schering AG. Since 2006 he is Head of the Department Integrated Quality Management Training at Bayer HealthCare AG.

## Social Event

On Wednesday evening **you are cordially invited to a social event**. This is an excellent opportunity to share your own views and experiences with colleagues from other companies in a relaxed and casual 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 certification modules:

- Certified Quality Assurance Manager – Pharmaceutical Production (ECA)
- Certified Quality Assurance Manager – API Production (ECA)
- Certified Quality Control Manager (ECA)
- Certified Pharmaceutical Engineering Manager (ECA)
- Certified Computer Validation Manager (ECA)
- Certified Regulatory Affairs Manager (ECA)
- Certified Validation Manager (ECA)

On the internet at [www.gmp-compliance.org](http://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](mailto: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 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>.

**ICH Q9 Training Course** Wednesday, 21 April 2010, 10:00 – 17:30 h  
(Registration and coffee 09.30 – 10.00 h)  
Thursday, 22 April 2010, 09.00 – 12.15 h

**Conference fees** Non-ECA Members € 1,290.- per delegate plus VAT  
ECA Members € 1,161.- per delegate plus VAT  
APIC Members € 1,225.- per delegate plus VAT  
(does not include ECA membership)  
EU GMP Inspectorates € 645.- per delegate plus VAT  
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and dinner (Social Event) on the first day, and all refreshments. VAT is reclaimable.

**ICH Q10 Training Course** Thursday, 22 April 2010, 13:30 – 17:00 h  
(Registration and coffee 13.00 – 13.30 h)  
Friday, 23 April 2010, 09.00 – 16.00 h

**Conference fees** Non-ECA Members € 1,290.- per delegate plus VAT  
ECA Members € 1,161.- per delegate plus VAT  
APIC Members € 1,225.- per delegate plus VAT  
(does not include ECA membership)  
EU GMP Inspectorates € 645.- per delegate plus VAT  
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch on the second day and all refreshments. VAT is reclaimable.

**Venue of both courses** Hilton Budapest WestEnd  
Váci út 1-3  
1062 Budapest, Hungary  
Phone +36 1 288 5500  
Fax +36 1 288 5588



**Accommodation** CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. Please make your reservation via the Personalised Online Group Page POG [www.hilton.com/ECA](http://www.hilton.com/ECA) where you also can modify/cancel your reservation until 23 March 2010 without any penalty. Early reservation is recommended.

**Save money and book both courses for € 990,- each!**

If you book the “ICH Q9 Training Course” AND the „ICH Q10 Training Course“ simultaneously, the fee for each conference reduces as follows:  
Non-ECA Members € 990.- per delegate plus VAT  
APIC Members € 940.- per delegate plus VAT  
(does not include ECA membership)  
ECA Members € 891.- per delegate plus VAT  
EU GMP Inspectorates € 495.- per delegate plus VAT

**Registration** Via attached reservation form, by e-mail or by fax message.  
Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

**Conference language** The official conference language will be English.

## 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:

Mr Oliver Schmidt (Operations Manager) at +49-62 21 / 84 44 23,  
or per e-mail at schmidt@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.

## 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)!**

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*Registration form (please complete in full)*

- ICH Q 9 Training Course**, 21-22 April 2010, Budapest, Hungary
- ICH Q 10 Training Course**, 22-23 April 2010, Budapest, Hungary
- Workshop 1 How to Involve Management in a Quality System
- Workshop 2 How to Establish a CAPA System in a Company
- Workshop 3 How to monitor process performance and Quality System effectiveness?
- (Please choose ONE workshop)

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## Easy Registration



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info@concept-heidelberg.de



**Internet:**  
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