ECA
ACADEMY

Speakers:

Richard M. Bonner
Formerly with Eli Lilly, United Kingdom

Dr Heinrich Prinz
Apceth GmbH, Germany

Dr Bernd Renger
Immediate Past Chair of the European QP Association; Renger Consulting, Germany

Dr Thomas Schneppe
Bayer Pharma AG, Germany

Dr Helene Zuurmond
Pfizer, Belgium

ICH Q9 / ICH Q10 Training Courses

ICH Q 9 Training Course
8 - 9 October 2014, Heidelberg, Germany

ICH Q 10 Training Course
9 - 10 October 2014, Heidelberg, Germany

Free of charge Quality Manual and ICH Q10/ ISO 9001 Matrix

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

ICH Q9 Training Course

8-9 October 2014, Heidelberg, Germanyy

Objectives

The Guideline ICH Q9 „Quality Risk Management" was finalised in November 2005 (Step 5). Consequently, this guideline has been implemented in the EU, the US (FDA) and in Japan.

The ICH Q9 training course in hand deals with the **practical implementation of the requirements**. Individual examples help to show the application in the following GMP areas:

- Validation
- Change Control/Change Management
- Auditing/Inspections
- Quality Systems

As a complement to the lectures, the closing **workshop** offers the opportunity to practise Quality Risk Management techniques **with a case study**.

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.

Programme

ICH Q 9 Quality Risk Management

- Basic requirements
- Comparison to ISO 14971
- Practical Examples

How to Realise Quality Risk Management in a GMP Environment

- An overview of the diverse techniques (HACCP, FTA etc.)
- Access benefit of some tools
- Examples from the production of drug (medicinal) products and APIs

How to Apply Quality Risk Management in Validation

- Understand why the use of risk management in process validation is now expected
- What does the FDA expect for batch conformance prior to, and post, product approval
- What is the benefit of using the risk management approach versus the traditional 3 batch validation approach?
- What does ICH Q9 mean with respect to quality risk management in validation
- Learn why the quality risk management approach to validation will result in less ongoing process support during production

Design of an Event Handling System based on a Quality System and Quality Risk Management Approach

- The quality system
- Risk management principles
- Events (e. g. deviations, complaints etc.)
- Risk management application
- Outputs

How to implement Quality Risk Management in a Pharmaceutical Company

- The risk-based approach and its impact on key GMP processes (GAMP®5, FDA Guidance on Process Validation, etc)
- ICH Q9 in the context of ICH Q8 and ICH Q10
- The implementation of „quality risk management thinking and doing" on management and shop floor level (tools and experiences)

How to Make a Risk-based Audit Schedule

- Understand how to assess risk between different operations
- Identify priorities for the audit
- Learn how to use a point system to assign audit priorities based on risk
- How to use a template to make a risk-based audit schedule

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 and Chairman of the European Compliance Academy.

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, Apceth GmbH, Germany
Dr Prinz worked with Boehringer Mannheim before he joined Biotest where he was Head of Quality Assurance, responsible for both the pharmaceutical and the medical device division. Since 2003 he works as a freelance consultant and part of his time he is the Senior Supervisor 'Production and Quality Assurance' at Apceth, a biotech company.

Dr Thomas Schneppe, Bayer Pharma 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 Pharma AG.

ICH Q 10 Training Course

9-10 October 2014, Heidelberg, Germany

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.

Programme

ICH Q 10 and FDA´s Guidance on Pharmaceutical Quality Systems

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

Continual Improvement

- Process Monitoring
- Key Performance Indicators (KPIs)
- Trending
- Process Performance and Capability (link to Q8, Q9 and Process Validation)

Monitoring Quality Process Performance and Quality System

- CAPA a tool for continual improvement
- Change Management
- Annual reviews

Responsibility of Senior Management

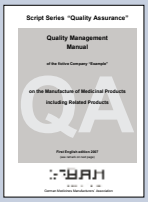
- How to involve the management
- Management Review

Management of Outsourced Activities and Purchased Materials

- How to choose, qualify and monitor Suppliers and Providers
- Supplier Qualification as Part of the Quality System
- Change of Ownership
- Monitoring of the performance
- Implementation of QMS - some milestones

Free of charge

Quality Management Manual of a fictive Company – free of charge for all participants of the ICH Q10 course



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.

ICH Q10 versus ISO 9001 Matrix

As part of the conference binder the participants will also receive a matrix which compares the ICH Q10 Guideline and the international standard on quality management ISO 9001. This matrix is helpful to identify areas that are not covered in one of the two documents.

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) is considered an integral part of a Pharmaceutical Quality System according to the revised Chapter 1 of the EC GMP Guide. Originally developed by FDA's CDRH office for medical devices, CAPA has now been introduced via FDA's Quality System Guidance and ICH Q 10 into the field of drug products and APIs. In the workshop you will learn to understand the CAPA system and its connection to non-conformities and to continual improvement and DMAIC and how to implement a robust CAPA system in a company

Workshop 3
Understanding the process orientation principles of ICH Q10 reflected in FDA´s new Process Validation Guidance
This Workshop will inform you how ICH Q10 (and also ICH Q9 and ICH Q8) has influenced the new FDA Guidance for Industry: Process Validation General Principles and Practices. The FDA states in this document: "FDA encourages the use of modern pharmaceutical development concepts, quality risk management, and quality systems at all stages of the manufacturing process lifecycle". During this Workshop you will not only learn more about this new approach but you will identify the key elements and you will receive relevant information on how to implement this concept into practice

Speakers

Dr Heinrich Prinz, Apceth GmbH , Germany
Dr Prinz worked with Boehringer Mannheim before he joined Biotest where he was Head of Quality Assurance, responsible for both the pharmaceutical and the medical device division. Since 2003 he works as a freelance consultant and part of his time he is the Senior Supervisor 'Production and Quality Assurance' at Apceth, a biotech company.

Dr Bernd Renger, Immediate Past Chairman of the European QP Association; Renger Consulting, Germany
Dr Bernd Renger is a member of the European Compliance Academy (ECA) Advisory Board and Immediate Past Chairman of the European QP Association. Since 2011, he is running his own consultancy business. Before that he was VP of Quality Control at Vetter Pharma-Fertigung. He started his career 1977 at Hoechst AG as a research and development chemist. Since then, he has held several positions at Mundipharma, Byk Gulden (now Takeda) and Baxter BioScience in Vienna.

Dr Thomas Schneppe, Bayer Pharma 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 Pharma 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

These seminars are recognised within the GMP Certification Programme for the module "ECA Certified QA Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification 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 are The ECA Foundation and the ECA Academy?

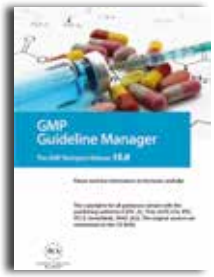
The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy a EUR 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.



ICH Q9 Training Course

Wednesday, 8 October 2014, 10.00 – 17:30 h
(Registration and coffee 09.30 – 10.00 h)
Thursday, 9 October 2014, 09.00 – 12.15 h

Conference fees

ECA Members € 1,090.- per delegate plus VAT
APIC Members € 1,190.- per delegate plus VAT
Non-ECA Members € 1,290.- per delegate plus VAT
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, 9 October 2014, 13:30 – 17:00 h
(Registration and coffee 13.00 – 13.30 h)
Friday, 10 October 2014, 09.00 – 16.00 h

Conference fees

ECA Members € 1,090.- per delegate plus VAT
APIC Members € 1,190.- per delegate plus VAT
Non-ECA Members € 1,290.- per delegate plus VAT
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

NH Hotel Heidelberg
Bergheimer Strasse 91
69115 Heidelberg
Phone +49 (0)6221 1327 0
Fax +49 (0)6221 1327 100

Accommodation

CONCEPT has reserved a limited number of rooms in the conference Hotel.
You will receive a room reservation form when you have registered for the course.
Reservation should be made directly with the hotel.
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:
ECA Members € 891.- per delegate plus VAT
APIC Members € 940.- per delegate plus VAT
Non-ECA Members € 990.- 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.

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
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Oliver Schmidt, Operations Director, at +49 (0) 62 21 / 84 44 23,
e-mail: schmidt@concept-heidelberg.de
For questions regarding reservation, hotel, organisation etc.:
Ms Susanne Ludwig, Organisation Manager, at +49 (0) 62 21 / 84 44 44
e-mail: ludwig@concept-heidelberg.de

Easy Registration

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

Reservation Form:
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e-mail:
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Internet:
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Germany

Registration form (please complete in full)

☐ **ICH Q 9 Training Course**, 8-9 October 2014, Heidelberg, Germany
☐ **ICH Q 10 Training Course**, 9-10 October 2014, Heidelberg, Germany
Please choose **ONE** workshop
- ☐ Workshop 1 How to involve Management in a Quality System
- ☐ Workshop 2 How to establish a CAPA System in a Company
- ☐ Workshop 3 Understanding the process orientation principles of ICH Q10 reflected in FDA´s new Process Validation Guidance

☐ Mr ☐ Ms Title _____

First name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Purchase Order No. (if applicable)

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City Zip Code Country

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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)

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Phone +49 (0)6221 77 00 77, info@tls-heidelberg.de

Lufthansa Bus Airport Shuttle
http://www.transcontinental-group.com/en/frankfurt-airport-shuttles
Tel. +49 (0)6152 – 97 69 099, info@frankfurt-airport-shuttles.de

Train
You can get on the train directly at the airport. Trains leave up to two times per hour and it takes less than one hour to get to Heidelberg. www.bahn.de