Speakers:

Richard M. Bonner
Formerly with Eli Lilly, United Kingdom

Dr Heinrich Prinz
Apceth GmbH, Germany

Dr Bernd Renger
Chairman 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
19 - 20 October 2011, Budapest, Hungary

ICH Q 10 Training Course
20 - 21 October 2011, Budapest, Hungary

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

ECA
European Compliance Academy

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

ICH Q9 Training Course

19-20 October 2011, Budapest, Hungary

Objectives

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.

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.

Moderator

This conference will be moderated by Richard M. Bonner

ICH Q 9 Quality Risk Management

- Basic requirements
- Comparison to ISO 14971

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 his 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. 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, 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

20-21 October 2011, 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.

Programme

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

Continual Improvement

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

Monitoring Quality Process Performance and Quality System

- The Senior Management's responsibility and how to perform Quality Management
- 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 indentify 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, Chairman of the European QP Association; Renger Consulting, Germany
Dr Bernd Renger is a member of the ECA Advisory Board and Chairman of the European QP Association. Since 2011, he is running his own consultancy business. Before that he was Director of Quality Control at Vetter Pharma-Fertigung. He started his career at Hoechst AG as a research and development chemist. Since then, he has held several positions at Mundipharma, Altana Pharma and Baxter.

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 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.

What Are the Benefits of ECA?

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.

First benefit: During the membership, you enjoy a 200 EUR 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, 19 October 2011, 10:00 – 17:30 h (Registration and coffee 09.30 – 10.00 h) Thursday, 20 October 2011, 09.00 – 12.15 h
Conference fees	Non-ECA Members € 1,290.- per delegate plus VAT ECA Members € 1,090.- per delegate plus VAT APIC Members € 1,190.- 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, 20 October 2011, 13:30 – 17:00 h (Registration and coffee 13.00 – 13.30 h) Friday, 21 October 2011, 09.00 – 16.00 h
Conference fees	Non-ECA Members € 1,290.- per delegate plus VAT ECA Members € 1,090.- per delegate plus VAT APIC Members € 1,190.- 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. Reservation should be made directly with the hotel. Please use the following link to make your reservation via POG (Personalised Online Group Page) where you can also modify/cancel your reservation until 6 September 2011 without any penalty: http://www.budapest-westend.hilton.com/ECA1810. 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.
Conference language	The official conference language will be English.

Organisation and Contact

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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**, 19-20 October 2011, Budapest, Hungary

☐ **ICH Q 10 Training Course**, 20-21 October 2011, 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 Understanding the process orientation principles of ICH Q10 reflected in FDA´s new Process Validation Guidance

(Please choose ONE workshop)

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