



SPEAKERS

RICHARD M. BONNER
ECA

DR CHRISTOPHER BURGESS
Burgess Consultancy

NADIA DICKIE
Eli Lilly

DR AFSHIN HOSSEINY
Tabriz Consulting

DR ANDREAS KÖNIG
Aenova Holding

HENNY KOCH
MSD

DR JANICE M. SORETH
FDA, Office of International
Programs at EMA

BRIAN SZUKALA
Transfer Knowledge Partners

Pharma Quality Excellence

ICH Q10 and EU-GMP Chapter 1

**3 Day Master Class on Principles and
Practice of modern Quality Assurance**
15 – 17 November 2011, Budapest, Hungary

HIGHLIGHTS:

- Efficient Implementation of:
 - ICH Q10 and ICH Q9
 - Chapter 1 of the EU Guideline to GMP
 - FDA's Guidance for Industry on Quality Systems
- The new Pharma Quality Assurance and Management Models
- Implementation of a continuous Improvement Processes
- Global Implications in complex Quality Systems
- Managing Compliance in different cultural Environments
- Behavioural GMP
- CAPA Techniques
- Managing costs of Compliance
- SixSigma and Statistics
- The modern Quality Assurance Organisation
- With 4 Workshops and interactive Sessions



Pharma Quality Excellence

15-17 November 2011, Budapest, Hungary

Objectives	This 3-day Master Class brings together well-experienced experts to discuss legislative initiatives and key quality models in the light of efficiency . This will support you turning your quality excellence goals into reality .
Background	<p>The pharmaceutical industry has a strictly regulated environment. The core of the regulations is represented by the GMP rules. However pharmaceutical industry has been facing a lot of new quality approaches, models and techniques over the last few years. FDA's Guidance for Industry on Quality System Approach to Pharmaceutical cGMP, ICH Q10, SixSigma and Lean SixSigma, Risk Management and new integrative quality management models are introducing a new way of quality thinking to the pharmaceutical industry. And the new draft of Chapter 1 of the EU Guideline to GMP integrates the principles of "Pharmaceutical Quality System" as described in ICH Q10. But quality assurance is now more than just meeting regulatory expectations. Quality management is used as an enabler to meet compliance goals and increase GMP awareness but also to improve processes throughout the value chain of a pharmaceutical product. This introduces a new role to the quality assurance department: managing pharmaceutical quality excellence.</p> <p>Managers and Executives must deal with various challenges, have to have brought process knowledge and must be always up to date. Modern quality assurance has thus to be integrated in the operative business.</p>
Target Audience	Managers and Executives from pharmaceutical Quality Assurance and Quality Management but also Business Executives and Production Managers and those involved in continuous improvement projects.
Moderator	Dr Christopher Burgess
Programme	<p>How to realise Quality in the pharmaceutical 21st Century</p> <ul style="list-style-type: none">■ An overview on new approaches, models and techniques■ Benefits and challenges <p>GMP Awareness and Knowledge Management as Part of ICH Q10</p> <ul style="list-style-type: none">■ Interpretation and expectation regarding human interference towards GMP■ The relation of knowledge management and risk mitigation activities and their control■ Continual improvement through proper management of system changes■ Re-active and pro-active points of view of control systems in place <p>Managing Compliance and the Cost of Compliance in a globalising World</p> <ul style="list-style-type: none">■ Intercultural compliance■ Supplier quality vs. quality excellence■ Cultural particularities in GMP understanding■ Import: CoA, CEP, GMP-certificate, audit – what to look for■ The Cost of Compliance<ul style="list-style-type: none">– What areas of compliance we need to cover– How to assess it– Repair cost vs. avoidance cost <p>How to gain Efficiency in the Quality Unit without compromising Quality</p> <ul style="list-style-type: none">■ Systems to reduce deviations■ How do you measure quality?■ How to develop a control strategy■ How to facilitate quality based decisions using risk management techniques <p>A new Pharma QA Management Model in ICH Q10</p> <ul style="list-style-type: none">■ Introduction of the new Quality Management Model■ The set-up■ The benefits■ How to transform present systems into a Q10 compliant system■ Transformation of the key points of compliance

Interactive Sessions:

Risk Assessment/ Risk Management and GMP compliance

How can a modern Quality Assurance support business using GMP tools?

Benefits of measuring Quality by KPIs

Discuss and identify possible measurements / KPI which will support and monitor the development of a not well performing Quality Unit into a „State of the Art“ Quality Unit.

Case Study: Quality Excellence and ICH Q10 in the analytical Laboratory

The Laboratory Quality Matrix

You will be able to attend 2 of these sessions. Please choose the ones you like to attend when you register for the course.

SixSigma and Lean SixSigma – still “in”?

- Benefits for the pharmaceutical Industry
- The new role of the Quality Assurance department
- The link to risk based Quality Management
- Successful techniques

SixSigma and Lean SixSigma – Lessons learned

- How to approach the whole thing
- Efficient implementation
- Examples and success stories

Behavioural GMP (bGMP): a new Paradigm

- The linkage of behavioural safety, organisational development and human error
- Tying the management of compliance into productivity improvement
- Stages of the bGMP concept
- The various tools and techniques



Workshop: Workshop: Techniques for CAPA Investigations

Exercise to review established practices and how to apply some unique techniques for investigations. During this workshop, the bbCi approach will be introduced for performing investigations and determining true root causes with sustainable preventive actions.

What the modern QA Manager should know about Statistics

- Ongoing/data collection and management
- Interpretation, comparison and presentation of data
- Describing process capability and performance
- Control Charts; what is a trend and how to deal with it?
- Quality Metrics
- Documenting the outcomes; are we in control?

In time Management of Quality

- Working to avoid instead of repairing
- How to use PAT
- Risk Management
- Quick workflows

The modern QA Organisation

- Developing a QMS to support business objectives while remaining compliant
- Developing QA organisation to support seamless operations: How can QA manage
 - process validation
 - change management
 - batch disposition
 - inspection readiness

without reducing efficiency and increasing costs

How authorities see the new initiatives

- Is the pharmaceutical industry forgetting the GMP basics?
- New ways of inspecting
- Inspecting in a globalised world
- Information sharing between the inspectorates

Speakers

RICHARD M. BONNER, *ECA, form. Eli Lilly*

Richard M. Bonner is Director Regulatory Affaires at ECA and Advisory Board member of the Qualified Person Association. Previous to his current role he was a Senior Quality Adviser for Eli Lilly and Company. He has 31 years experience within the pharmaceutical industry.

DR CHRISTOPHER BURGESS, *Burgess Analytical Consultancy*

Chris Burgess is an elected member of the USP Council of Experts on General Chapters and member of the Qualified Person Association Advisory Board. During his time in industry he worked mainly for Glaxo (now GSK) in Quality Control, Quality Assurance and Analytical R&D positions. He has recently been appointed as Visiting Professor at the Strathclyde Institute of Pharmacy and Biomedical Sciences (SIPBS) within the University of Strathclyde's Faculty of Science.'

NADIA DICKIE, *Eli Lilly*

Nadia Dickie is a Six Sigma Black Belt for Eli Lilly and Company Ltd.. She is an MBA and has had several years experience in a variety of roles in Financial, HR, CMO management and Compliance.

DR AFSHIN HOSSEINY, *Tabriz Consulting, form. GSK*

Afshin Hosseiny is Managing Director of Tabriz Consulting, U.K.. Before working as a consultant, he was Director of Quality Assurance for the Global Supply Network of Glaxo-SmithKline.

DR ANDREAS KÖNIG, *Aenova Holding, Germany*

Dr Andreas König is Director Quality Management at Aenova Holding GmbH. Until 2009 he was Vice President Global Quality Operations Animal Health at Schering Plough. Before that he was head of QC and QA Fresenius Kabi. and later Global Quality Director at Intervet.

HENNY KOCH, *MSD*

HHenny Koch is Global Clinical Compliance Manager at MSD, NL.

DR JANICE M. SORETH, *Europe/US FDA*

Janice Soreth is Deputy Director Europe, Office of International Programs, U.S. FDA. She has been with the agency for more than 20 years at CDER's director of the division of Anti-Infectives and Ophthalmology as well as working in CBER and the Office of Combination Products/Office of the Commissioner.

BRIAN SZUKALA, *Transfer Knowledge Partners*

Brian Szukala is Managing Director of TKnP Ltd. He was previously Head of Training at Pfizer and Abbott Laboratories and Business Service Director at SeerPharma UK Ltd .

Social Event

On 15 November 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.



Conference Exhibition

The European Compliance Academy offers you the opportunity to present your company, your products and services to your target group almost without any scattering losses. The costs for an exhibition space at this event are € 1,490,-. You will find details and a registration form on our website www.gmp-compliance.org. Just follow the link „Conferences“ on the homepage.

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 EUR 200 discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:

The GMP Guideline 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.

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:


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

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

Tuesday, 15 November 2011, 9.30 h – 17.30 h
(Registration and coffee 9.00 h – 9.30 h)
Wednesday, 16 November 2011, 8.30h – 17.30 h
Thursday, 17 November 2011, 8.30 h – 14.30 h

Venue

Hilton Budapest WestEnd
Váci út 1-3.
1062 Budapest, Hungary
Phone +36 (1) 288 5500
Fax +36 (1) 288 5588

Fees

ECA Members: € 1.790,- per delegate + VAT.
APIC Members: € 1.890,- per delegate + VAT.
EU GMP Inspectorates: € 995,- per delegate + VAT.
Non-ECA Members: € 1.990,- per delegate + 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.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. Please make your reservation via the Personalised Online Group Page <http://www.www.budapest-westend.hilton.com/ECA1411> where you also can modify/cancel your reservation until 4 October 2011. Early reservation is recommended.

Registration

Via the 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
D-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:

Wolfgang Schmitt (Operations Director) at +49-62 21/84 44 39, or per e-mail at w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:


Marion Grimm (Organisation Manager) at +49-62 21/84 44 18, or per e-mail at grimm@concept-heidelberg.de.

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

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

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

 +49 6221 84 44 34

Pharma Quality Excellence, 15-17 November 2011, Budapest, Hungary

Please choose two interactive sessions:

- Risk Assessment/ Risk Management and GMP compliance
 Benefits of measuring Quality by KPIs
 Case Study: Quality Excellence and ICH Q10 in the analytical Laboratory

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

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)!