With FDA Speaker

SPEAKERS

DR CHRISTOPHER BURGESS
Burgess Consultancy

CARMEN DORAN
Novartis Pharma AG

DR AFSHIN HOSSEINY
Tabriz Consulting

DR ANDREAS KÖNIG
Aenova Holding

HENNY KOCH
Qimp Management Systems B.V.

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

DR HIROKAZU SUGIYAMA
F. Hoffmann-La Roche Ltd.

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

10 – 12 October 2012, Vienna, Austria

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 Process
- Global Implications in complex Quality Systems
- Managing Compliance in different cultural Environments
- Behavioural GMP
- CAPA Techniques
- Managing costs of Compliance
- SixSigma and Statistics
- Linking Lean and Quality
- With 4 Workshops and interactive Sessions

ECA
European Compliance Academy

This Master Class is recognised for the ECA GMP Certification Programme „Certified QA Manager". Please find details at www.gmp-certification.eu

Pharma Quality Excellence

10 – 12 October 2012, Vienna, Austria

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

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 L**ean SixSigma, Risk Management** and new **integrative quality management models** are introducing a new way of quality thinking to the pharmaceutical industry.

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**.

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**.

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

How to realise Quality in the pharmaceutical 21st Century

- An overview on new approaches, models and techniques
- Benefits and challenges

GMP Awareness and Knowledge Management as Part of ICH Q10

- 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

Managing Compliance and the Cost of Compliance in a globalising World

- 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
  - What areas of compliance we need to cover
  - How to assess it
  - Repair cost vs. avoidance cost

How to gain Efficiency in the Quality Unit without compromising Quality

- 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

A Process controlled QA Management Model in Compliance with ICH Q10

- Introduction of process controlled Quality Assurance Management
- The set-up
- The benefits
- How to transform present systems into a Q10 compliant system
- Transformation of the key points of compliance

Programme (cont'd)

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?

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.

Statistical Process Control
How to implement and use control charts.

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

Lean Six Sigma: Framework and Application in Roche Parenterals Production
- Business model of project deployment
- Useful analysis & evaluation techniques
- Role of Quality Risk Management
- Leveraging the organisation
- Case studies

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

Linking Lean and Quality
- Introduction to the Novartis Lean approach
- Driving quality via lean and lean via quality
- Examples and learnings from the journey so far

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.

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

DR CHRISTOPHER BURGESS, *Burgess Analytical Consultancy*
Dr Burgess has more than 36 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R&D. He is a "Qualified Person" and a member of the European QP Association Advisory Board. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and is a visiting professor of the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS).

CARMEN DORAN, *Novartis Pharma AG, Switzerland*
Carmen Doran is Head of Process Unit Actives, Pharmaceutical Operations and member of the Site Leadership Team in the largest Novartis Pharma site. Before that Carmen was Global Operations Manager and Head of Operational Excellence, challenging and driving operational performance across 12 sites and 6 global functions.

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 GlaxoSmithKline.

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, *Qimp Management Systems B.V., Netherlands*
Henny Koch is Managing Director at Qimp Management Systems B.V. During 36 years in pharmaceutical industry he held several positions in R&D, Manufacturing and Quality. His last position was 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.

DR HIROKAZU SUGIYAMA, *F. Hoffmann-La Roche Ltd., Switzerland*
Hirokazu Sugiyama studied chemical engineering at the University of Tokyo and earned his PhD from ETH Zurich. Dr Sugiyama is responsible for continuous process improvement within Roche's new Parenterals production facility in Kaiseraugst.

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 10 October 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 € 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.

Lufthansa is Mobility Partner for all ECA Events

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.

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
Wednesday, 10 October 2012, 9.30 h – 17.30 h
(Registration and coffee 9.00 h – 9.30 h)
Thursday, 11 October 2012, 8.30h – 17.30 h
Friday, 12 October 2012, 8.30 h – 14.30 h

Venue
Renaissance Wien Hotel
Linke Wienzeile – Ullmannstrasse 71
1150 Vienna, Austria
Phone +43 1 89102
Fax +43 1 89102 – 300

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. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention "ECA" to receive the specially negotiated rate (single room € 129,- per night, incl. breakfast) for the duration of your stay.

Reservation should be made directly with the hotel not later than 28 August 2012. 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
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www.concept-heidelberg.de

For questions regarding content:
Mr 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.:
Mr Ronny Strohwald (Organisation Manager) at +49-62 21/84 44 51, or per e-mail at strohwald@concept-heidelberg.de.

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

Reservation Form (Please complete in full) +49 6221 84 44 34

Pharma Quality Excellence, 10 – 12 October 2012, Vienna, Austria

Please choose two interactive sessions:
☐ Risk Assessment/ Risk Management and GMP compliance
☐ Benefits of measuring Quality by KPIs
☐ Statistical Process Control

☐ 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)! (As of January 2012)