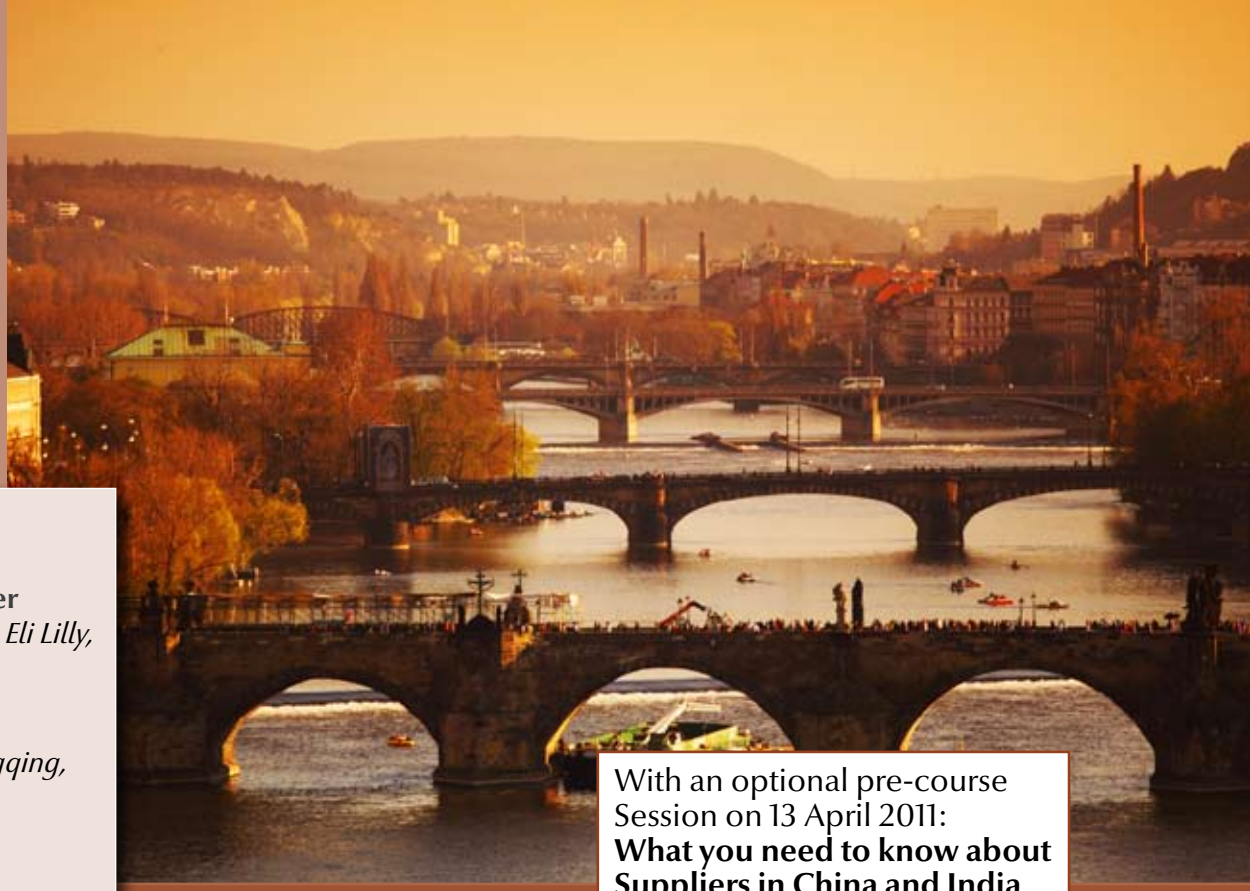

With an optional pre-course Session on 13 April 2011:
What you need to know about Suppliers in China and India

Integrated and Efficient Supplier Qualification

SPEAKERS:

Richard M. Bonner
ECA, Formerly with Eli Lilly, U.K.

York Moeller
J. A. Moeller Chongqing, China

Mukesh Patel
CommQP, U.K.

Wolfgang Schmitt
Concept Heidelberg, Germany

John Taylor
Medicines & Healthcare Products Regulatory Agency (MHRA), U.K.

Dr Reto Theiß
Merck KGaA, Germany

Prague, Czech Republic
14 – 15 April 2011

Highlights

- Regulatory Background and Expectations of the Agencies
- How to increase Efficiency in Supplier Qualification
  - Quality Risk Management
  - Third Party Audits
  - Reduced Testing
- Integration of Suppliers in the Quality System
  - Contracts
  - Change Control
  - Complaints
  - Roles and Responsibilities
- Contract Manufacturers and Laboratories
- Two Workshops on Quality Risk Management in Supplier Qualification
- Optional pre-course Session on Suppliers from China and India on 13 April 2011

ECA
European Compliance Academy

This course is supported by:
QP Association

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

Integrated and Efficient Supplier Qualification

14-15 April 2011, Prague, Czech Republic

Objectives

During this course, you will learn all relevant aspects to implement and/ or improve a comprehensive and integrated Supplier Qualification System which fulfils regulatory GMP requirements. Furthermore, you will get to know possibilities and tools to **increase efficiency and decrease costs** at your company.

This conference will be moderated by Richard M. Bonner

Background

Qualification and audits of suppliers, contract manufacturers and laboratories and other service providers are an important part of each Quality System. But what is required and which steps are really necessary? And is it possible to even decrease audit activities?

According the **EU Guide to GMP** [5.26], starting materials should only be purchased from approved suppliers. And **Directive 2004/27/EC** states that the manufacturer shall only use active substances, which have been manufactured in accordance with the detailed guidelines on GMP for starting materials. But also in contract manufacture and analysis, the contract giver is responsible for assessing the competence of the contract acceptor to follow GMP (EU Guide to GMP [7.3]).

The requirements and efforts to qualify suppliers should therefore not be underestimated. However, it seems that a downright '**audit tourism**' has grown and suppliers and service providers are audited on site frequently and sometimes too often. In the globalising world more and more supplies are coming from countries like **India and China**. And qualifying these suppliers brings new challenges. This adds up to significant expenses for both the audited and the auditing company. **But supplier qualification is not limited to auditing. The whole process of supplier qualification and co-operation should be integrated in the existing Quality System of a company.**

Target Group

This course and its pre-session is designed for all personnel involved in supplier qualification activities at their company and decision makers who want to improve the existing process. It is addressed to persons from Quality Assurance and Control, Procurement, Business Development, Manufacturing, Project Management and R&D.

Social Event

On 14 April, you are cordially invited to a social event in Prague. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Integrated and Efficient Supplier Qualification

14-15 April 2011, Prague, Czech Republic

The Objective of Supplier Qualification

- Regulatory background
- Duties and responsibilities of the QP
- Expectations of the authorities

GMP Pre-requisites for Procurement and Outsourcing activities

- GMP training for procurement staff
- Dealing with brokers
- Contracts
- Change Control
- Complaints
- Roles and responsibilities

Tools for an efficient Supplier Qualification

- Risk management and efficient Supplier Qualification
- Tool box and examples
- Documentation and data management
- Integration of the supplier qualification process in the company
- The use of third party audits

Workshop on Quality Risk Management:
How to develop a risk-based Audit Schedule

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.

Reduced Testing of supplied APIs and Excipients

- What guidance is available on reduced QC testing?
- EU and FDA expectations
- Information required before you start reducing
- Can APIs and excipients be covered within the same approach?
- Practical execution

Outlook: Regulatory Inspections

- Supplier qualification in the light of regulatory inspections
- How should the company document supplier qualification activities
- Acceptance of Third Party Audits
- Challenges of the globalisation

Outsourcing to Contract Manufacturers and Laboratories - what needs to be considered and who's responsible?

- What activities can you out-source
- Is there a difference when you outsource within the EU compared to outside of the EU
- Who initiates the Technical Agreements and what should be included
- Who carries out the validation activities and agrees the acceptance criteria
- What part of the supply chain is covered by GMP and what is GDP or GCP?
- Who has responsibility for what through the supply chain. Is there a difference in legal and ethical responsibilities
- What can happen when things go wrong

Workshop on risk-based Supplier Qualification:

Why is a risk based approach to supplier qualification required?
An interactive workshop to establish where to best concentrate your resources to maximise the assurance of a reliable supply chain.

Pre-course Session: What you need to know about suppliers in China and India

13 April 2011, Prague, Czech Republic

Sourcing from Asia: what Procurement and QA should know

- Trading company vs manufacturer – how do I know who is who
- Manufacturers may have different sites – how to make sure that you audit the plant you are supposed to audit
- Transportation - an often forgotten part of inspections
- GMP Issues of Chinese plants
  1. Own Production vs Purchases from outside
  2. Documentation - reality vs paper
  3. Deviations / CAPA / investigations
  4. Major differences between Chinese GMP and ICH Q7

India and China: Cultural Aspects to consider when doing Business

- Meeting people for the first time - what to do and what not to do
  - The business card – Chinese Names – print your own Chinese name on it?
  - Time – have enough of it
  - The banquette
- Guanxi - Chinese word for "relationship" - relationship vs contract
- How are decisions made inside companies
- How to find out who is really in charge
- The Translator - noticing limits

The Indian and Chinese Pharma Market: an overview (legal structures, authorities)

- Overview about size and number of companies
- What documents make a company legal
- What different forms of companies do exist
- SFDA - what are their powers, what are their limits
- The Chinese Tax and VAT system and its effect on purchases from China

Inspections in Asia

- Challenges and pitfalls
- What to look for
- Infrastructure and Transportation issues

Speakers

Richard M. Bonner, ECA, formerly with Eli Lilly, U.K.
Dick Bonner is Regulatory Affairs Director at the ECA and also 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. Dick Bonner is a Qualified Person in Europe.

York Moeller, J.A.Moeller GmbH & Co. KG, Germany and China
York Moeller is currently located in China to support European and US companies to deal with government authorities, plants and distributors in China. He started his career working for various trading companies in Hong Kong, the U.S. and Germany specialised in APIs and Finished Dosage Forms exporting from China and importing into China. Later on was Plant Manager of a German API producer in China, before he joined Hexal as the country head of China.

Mukesh Patel, CommQP, U.K.
Mukesh Patel is Managing Director of CommQP consultancy services. He is a Leeds University graduate in Chemistry. He has held posts in R&D, Procurement, Regulatory Affairs and Quality Assurance. Mukesh Patel has supplemented his industrial experience with appropriate training and qualifications; he is a Chartered Buyer, Chartered Chemist, permanent provision QP and ISO 9000 lead auditor. Professional membership is held with the Royal Society of Chemistry, Chartered Institute of Purchasing and Supply and Pharmaceutical Quality Group.

Speakers, cont'd

Wolfgang Schmitt, Concept Heidelberg, Germany
Before Wolfgang Schmitt started as Director Operations at Concept Heidelberg in 2006, he worked for Abbott (the former Knoll AG, Germany). Wolfgang Schmitt was Head of Quality Management at SOLIQS (Abbott's global Drug Delivery Business Unit) and later an Associate Director and Qualified Person at Abbott's Global Pharmaceutical Research and Development QA, where he was responsible for GMP/GLP-Compliance.

John Taylor, Medicines & Healthcare Products Regulatory Agency (MHRA), London, U.K.
John Taylor is Quality and Standards Manager Acting and Group Manager, Enforcement and Intelligence of the UK Medicines and Healthcare Products Regulatory Agency (formerly the Medicines Control Agency). John joined the MCA in 1991 after working in the pharmaceutical industry for 24 years in quality assurance, quality control, research and development and regulatory affairs. John Taylor is currently responsible for all quality matters within the Inspection and Enforcement Division. He is a Chartered Chemist, a Fellow of the Royal Society of Chemistry and a member of the British Institute of Regulatory Affairs.

Dr Reto Theiß, Merck KGaA, Germany
Dr Reto Theiß started his career in the pharmaceutical industry in 1997 when he joined Temmler Pharma in Marburg as Deputy Head of the Quality Control and Quality Assurance Department. In 2002 he changed to Merck KGaA in Darmstadt, being responsible for releasing products of the generic branch to the market. Since 2005 he is in charge for Merck's solid products acting as Qualified Person.

Date

Pre-course Session: Suppliers from China and India
Wednesday, 13 April 2011, 9.00 – 18.00 h (Registration and coffee 8.30 – 9.00 h)

GMP Education Course : Efficient Supplier Qualification
Thursday, 14 April 2011, 9.00 – 18.00 h (Registration and coffee 8.30 – 9.00 h)
Friday, 15 April 2011, 8.30 – 15.00 h

Fees

Pre-course Session: What you need to know about suppliers in China and India
ECA Members € 800.- per delegate plus VAT
QP Association Members € 800.- per delegate plus VAT
APIC Members € 845.- per delegate plus VAT
Non-ECA Members € 890.- per delegate plus VAT
EU GMP Inspectorates € 445.- per delegate plus VAT

GMP Education Course: Efficient Supplier Qualification
ECA Members € 1,390.- per delegate plus VAT
QP Association Members € 1,390.- per delegate plus VAT
APIC Members € 1,490.- per delegate plus VAT
Non-ECA Members € 1,590.- per delegate plus VAT
EU GMP Inspectorates € 795.- per delegate plus VAT

Save money when booking both events!

If you book the GMP Education Course "Efficient Supplier Qualification" TOGETHER WITH the Pre-course Session "Suppliers from China and India", the fee will be as follows:
ECA Members € 1,790.- per delegate plus VAT
QP Association Members € 1,790.- per delegate plus VAT
APIC Members € 1,890.- per delegate plus VAT
Non-ECA Members € 1,990.- per delegate plus VAT
EU GMP Inspectorates € 995.- per delegate plus VAT

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on 14 April, lunch on all days and all refreshments. VAT is reclaimable.

Venue of both events

Dorint Novotel Don Giovanni Prague
Vinohradská 157A
130 20 Prague 3, Czech Republic
Phone +420 2 6703 1111, Fax +420 2 6703 6717

Accommodation

CONCEPT HEIDELBERG 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 conference. Please use this form for your room reservation or be sure to mention "VA 6803 ECA Course" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 25 March 2011. Early reservation is recommended.

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
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 Weidemeier (Organisation Manager) at +49-62 21/84 44 46, or per e-mail at weidemaier@concept-heidelberg.de.

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If you cannot attend the conference you have two options:
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Registration form (please complete in full)

☐ **Pre-course Session: Suppliers from China and India,**
13 April 2011, Prague, Czech Republic

☐ **GMP Education Course : Integrated and Efficient Supplier Qualification**
14-15 April 2011, Prague, Czech Republic

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