With an optional pre-course Session on 15 April: What you need to know about Suppliers in China and India

Efficient Supplier Qualification

16 – 17 April 2015, Barcelona, Spain

ECA ACADEMY

This course is supported by:

QP ASSOCIATION

SPEAKERS:

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LEARNING OBJECTIVES:

- 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
  - Communication
- Contract Manufacturers and Laboratories
- The Role of Purchasing
- International Trade Law
  - Applicable commercial legislation
  - Jurisdiction
- **Optional pre-course Session on Suppliers from China and India on 15 April**

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

Efficient Supplier Qualification

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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.

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 GM**P [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 legality, suitability and the competence of the contract acceptor to follow GMP (**EU Guide to GMP** [7.5]).
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 Audience

This course and its pre-course session are 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.

Moderator

Richard M. Bonner

Programme

The Objective of Supplier Qualification

- Regulatory background
- Duties and responsibilities of the QP
- Expectations of the authorities
- Importing Active Pharmaceutical Ingredients into the European Union

International Trade Relations – what you need to know

- International trade law
- Applicable commercial legislation
- Jurisdiction
- Incoterms

GMP Pre-requisites for Procurement and Outsourcing activities

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

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

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.

Case Study: A modular System for qualifying and maintaining Suppliers

- Integrating supplier qualification in the pharmaceutical quality system
- Interfaces with other departments
- Examples

What you need to know about Outsourcing Pharmaceutical Artwork

- Artwork Origination
- Recalls
- Legislation and regulatory guidance
- Artwork studio audits: typical observations
- Outsourcing project: key learnings

Communication as the Key

- The Role of Purchasing
- Co-operation with QA, Manufacturing and the Supplier
- Communication from specification setting to Complaint Handling
- What you need to know about brokers

Workshop on Risk Management in the Supply Chain:

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:

- Frequency of Supplier Audits based on Risk Assessment
- Defining risk in the audit program
- Compliance risk assessment

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

15 April 2015, Barcelona, Spain

Sourcing from Asia : what Procurement and QA should know

- Trading company or manufacturer – how do I know?
- Different manufacturing sites – was the right one audited?
- Transport Qualification
- Typical GMP Issues of Chinese plants
- What to consider when auditing a plant

India and China: cultural Aspects to consider when doing Business

- Meeting people for the first time - what to do and what not to do
- 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 form of companies do exist
- CFDA - what are their powers, what are their limits
- The Chinese Tax and VAT system and its effect on purchases from China

Audits in Asia

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

Social Event

On 16 April, you are cordially invited to a social event in Berlin. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Referenten

Petra Barth, AbbVie GmbH & CoKG, Germany
Petra Barth is Head of QA Systems at AbbVie in Ludwigshafen (the former Abbott). She has more than 20 years experience in health care companies and is currently responsible for AbbVie's supplier qualification programme.

Richard M. Bonner, ECA, form. Eli Lilly, U.K.
Dick Bonner is Chairman of the ECA and the European QP Association. He and also works as a consultant to the Pharmaceutical Industry. Previous to his current roles he was a Senior Quality Adviser for Eli Lilly and Company. 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 has held posts in R&D, Procurement, Regulatory Affairs and Quality Assurance in pharmaceutical industry. Mukesh Patel is a Chartered Buyer, Chartered Chemist, permanent provision QP and ISO 9000 lead auditor.

Philipp Reusch, Reusch Attorneys, Germany
Lawyer Philipp Reusch works with international companies from engineering and health care business. He mainly focuses on contract and product liability. He is also an assistant lecturer at the University for Applied Sciences Cologne.

Dr Franz Schönfeld, Government of Upper Bavaria, Germany
Dr Franz Schönfeld is a GMP inspector at the centralised inspectorate for medicinal products of the government of Upper Bavaria. He is head of the expert working group for APIs and deputy head of the Radiopharmaceutical expert working group at the Central Authority of the Federal States for Health Protection.

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 acting as Qualified Person.

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

Wednesday, 15 April 2015, 9.00 – 17.15 h
(Registration and coffee 8.30 – 9.00 h)

Date GMP Education Course: Efficient Supplier Qualification

Thursday, 16 April 2015, 9.00 – 17.45 h
(Registration and coffee 8.30 – 9.00 h)
Friday, 17 April 2015, 8.30 – 15.00 h

Venue of both events:

Barceló Sants Hotel
Placa dels Paisos Catalans, s/n
Estació de Sants
08014 Barcelona, Spain
Phone +34 93 503 53 00
Fax +34 93 490 60 45

Fees (per delegate plus VAT)

Pre-course Session: What you need to know about suppliers in China and India
ECA Members € 790
QP Association Members € 790
APIC Members € 845
Non-ECA Members € 890
EU GMP Inspectorates € 445

GMP Education Course: Efficient Supplier Qualification
ECA Members € 1,490.
QP Association Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845

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
QP Association Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995.

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. Reservation should be made directly with the hotel. 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

ECA has entrusted Concept Heidelberg with the organisation of this event.

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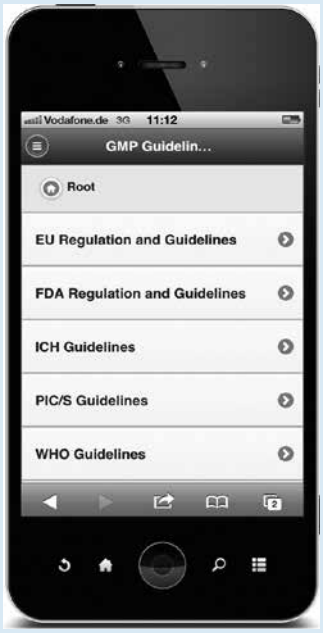

The ECA Foundation has developed a GMP App which offers a comprehensive GMP Guideline database with more than 1,400 GMP Guidelines and ten thousands of pages. Check relevant Guidelines (full text versions) during internal audits, regulatory inspections or GMP compliance meetings – simply on your smartphone or tablet PC. In addition to this wealth of guideline information the GMP App also comprises features like GMP News, a comprehensive GMP Search Engine. To open the app just enter app.gmp-compliance.org in your browser and the WebApp opens immediately.

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

Reservation Form (Please complete in full)

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☐ Pre-course Session **What you need to know about suppliers in China and India** on 15 April 2015
☐ **Efficient Supplier Qualification,**16-17 April 2015 2015, Barcelona, Spain

☐ Mr. ☐ Ms.

Title, first name, surname

Company | Department

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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 %.

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