ECA Academy
Your GMP/GDP Information Source

Efficient Supplier Qualification

With an optional pre-course Session on 27 March 2019: **What you need to know about Suppliers in China and India**

SPEAKERS:

Petra Barth
form. AbbVie

Buket Hekiman Bayraktar
PharmaVision

York Moeller
J.A.Moeller Chongqing, China

Mukesh Patel
CommQP

Philipp Reusch
Reusch Attorneys

Dr Franz Schönfeld
GMP Inspector, Government of Upper Franconia

Dr Reto Theiß
Merck KGaA

28-29 March 2019, Hamburg, Germany

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, Contract Manufacturers and Laboratories in the Quality System
  - CMO Selection
  - Contracts
  - Change Control
  - Complaints
  - Roles and Responsibilities
- The Role of Purchasing
- International Trade Law
  - Applicable commercial legislation
  - Jurisdiction
- **Optional pre-course Session on Suppliers from China and India on 27 March**

This course is supported by

QP Association

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

Efficient Supplier Qualification

28-29 March 2019, Hamburg, Germany

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?

Starting materials should only be purchased from approved suppliers. **EU 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

Wolfgang Schmitt,
CONCEPT Heidelberg (on behalf of ECA)

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
- Responsibilities

GMP pre-requisites for Procurement and Outsourcing Activities

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

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

- What activities can you out-source?
- Differences when outsourcing within the EU compared to outside of the EU
- Initiation and Contents of the Technical Agreements
- Validation activities: tasks and responsibilities
- GMP/GDP interface
- Legal and ethical responsibilities
- What can happen when things go wrong?

Efficient CMO Selection and Qualification

- CMO assessment criteria
- Project management for outsourced activities
- Knowledge management
- Technology transfer assessment
- Essential agreements

Case Studies:

A modular System for qualifying and maintaining Suppliers

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

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

Workshops on Risk Management in the Supply Chain:
When things go wrong: Quality Risk Management to avoid delivery bottlenecks and drug shortage

A risk-based Approach to Supplier Qualification
An interactive session 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

27 March 2019, Hamburg, Germany

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

Workshops:
a) Supply Chain Risk Assessment for China
b) Auditing in India

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

Speakers

Petra Barth,
form. AbbVie GmbH & Co. KG, Germany
Petra Barth has more than 20 years experience in global pharmaceutical business as QC and QA Manager, was acting as Head of QA Systems and front person for international inspections. GMP Systems within her responsibility/ area of expertise are: supplier qualification, inspection management, training, documentation, risk management and internal/external audits.

Buket Hekiman Bayraktar
PharmaVision San. ve Tic. A.S., Turkey
Ms Hekiman Bayraktar works as General Coordinator at PharmaVision, a pharmaceutical contract manufacturing company in Turkey. She is the Secretary General of ISPE Turkey Affiliate since 2011 and was also Chair of ISPE European Affiliate Council for 2013-2014.

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,
District Government of Upper Franconia, 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 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.

Social Event

In the evening of 28 March, 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.

Date

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

Wednesday, 27 March 2019, 9.00 – 17.30 h
(Registration and coffee 8.30 – 9.00 h)

Date

GMP Education Course: Efficient Supplier Qualification

Thursday 28 March 2019, 9.00 – 17.45 h
(Registration and coffee 8.30 – 9.00 h)
Friday, 29 March 2019, 8.00 – 15.00 h

Venue of both events

Barcelo Hotel Hamburg
Ferdinandstr. 15
20095 Hamburg, Germany
Tel. +49 (0) 40 22 63 62 0
Fax +49 (0)40 22 63 62 999
hamburg@barcelo.com

Fees (per delegate plus VAT)

Pre-course Session:
What you need to know about suppliers in China and India
ECA Members € 890
QP Association Members € 890
APIC Members € 945
Non-ECA Members € 990
EU GMP Inspectorates € 495

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 € 1,990
QP Association Members € 1,990
APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,145

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on 28 March, lunch on all 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/POG 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.

CONCEPT HEIDELBERG
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For questions regarding content please contact
Mr Wolfgang Schmitt (Operations Director) at
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For questions regarding reservation, hotel, organisation etc. please contact
Ms Nicole Bach (Organisation Manager) at
+49(0)62 21 / 84 44 22, or per e-mail at
bach@concept-heidelberg.de.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ Pre-course Session **What you need to know about suppliers in China and India** on 27 March 2019, Hamburg, Germany
☐ **Efficient Supplier Qualification,** 28-29 March 2019, Hamburg, Germany
☐ Mr ☐ Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **Purchase Order No. (if applicable)**

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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)
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.