ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GMP Auditor

Speakers


Petra Barth
form. AbbVie


Prabjeet Dulai
GDP & Quality Matters


York Moeller
J.A.Moeller Chongqing, China


Mukesh Patel
CommQP


Philipp Reusch
Reuschlaw


Dr Franz Schönfeld
GMP Inspector, Government of Upper Franconia


Dr Reto Theiß
Merck KGaA

This course ist supported by

QP Association

Efficient Supplier Qualification

With an optional pre-course Session on 06 May:
What you need to know about Suppliers in China and India

07/08 May 2020 | Vienna, Austria

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, Logistic Providers, Contract Manufacturers and Laboratories in the Quality System
  - 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 06 May

Programme

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 Education Course
Efficient Supplier Qualification, 07/08 May 2020

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?

Logistic Providers: Efficient 3PL Selection and Qualification

- Third Party Logistic Provider (3PL) assessment criteria
- How to qualify 3PLs
- Audit or not?
- Information management (deviations, changes etc.)
- Essential agreements

Case Studies:

When things go wrong

- Quality Risk Management to avoid delivery bottle-necks and drug shortage

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

Workshop on Risk Management in the Supply Chain: 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, 06 May 2020

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
- Decision making inside companies
- How to find out who is really in charge
- The Translator - chances and 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 & CoKG, 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.

Prabjeet Dulai
GDP & Quality Matters Ltd., U.K
Prabjeet Dulai is a Consultant Responsible Person at GDP & Quality Matters Ltd. Before that she was the RP and Senior Supply Chain Pharmacist for the UK Ministry of Defence, and prior to this worked as a Pharmacist within the NHS/ private hospital sector, retail and pharmaceutical industry.

York Moeller
J.A.Moeller GmbH & Co. KG, Germany and China
York Moeller supports European and US companies in China to deal with government authorities, plants and distributors. He worked for various trading companies in Hong Kong, the U.S. and Germany, as Plant Manager of a German API producer in China and country head of China for a German pharmaceutical company.

Philipp Reusch
Reuschlaw, Germany
Philipp Reusch is a lawyer focussing on contract and product liability. He is also an assistant lecturer at the University for Applied Sciences Cologne.

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.

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 is Qualified Person. He also worked as Deputy Head of the Quality Control and Quality Assurance Department for Temmler Pharma.

Date

Pre-course Session: Suppliers from China and India
Wednesday, 06 May 2020, 9.00 – 17.30 h
(Registration and coffee 8.30 – 9.00 h)

GMP Education Course:
Efficient Supplier Qualification
Thursday, 07 May 2020, 9.00 – 17.45 h
(Registration and coffee 8.30 – 9.00 h)
Friday, 08 May 2020, 8.00 – 15.00 h

Venue

Austria Trend Parkhotel Schönbrunn
Hietzinger Hauptstr. 10-14
1130 Vienna, Austria
Phone +43 (1) 878 04 0
Email parkhotel.schoenbrunn@austria-trend.at

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 07 May, 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 course. 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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D-69007 Heidelberg
Telefon +49(0) 62 21/84 44-0
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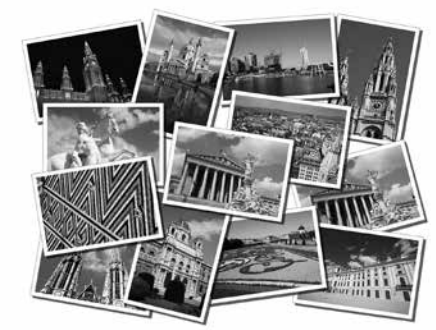
E-Mail: info@concept-heidelberg.de
www.concept-heidelberg.com

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. please contact:
Ms Nicole Bach (Organisation Manager) at +49-62 21/84 44 22, or per e-mail at bach@concept-heidelberg.de.

Social Event

In the evening of 07 May, 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.



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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ Pre-course Session What you need to know about Suppliers in China and India, 06 May 2020,Vienna,Austria
☐ Efficient Supplier Qualification. 07/08 May 2020, Vienna, Austria

Title, first name, surname

Department Company

Important: Please indicate your company's VAT ID Number Purchase Order Number, if applicable

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation 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 HEIDELBERGwill 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 https://www.gmp-compliance.org/privacy-policy). 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.