ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GMP Auditor

Speakers

Dr Melanie Distl
Roche, Switzerland

York Moeller
J.A.Moeller Chongqing
Germany

Mukesh Patel
CommQP
U.K.

Philipp Reusch
Reuschlaw
Germany

Wolfgang Schmitt
Concept Heidelberg
Germany

Dr Franz Schönfeld
GMP Inspector, Government of Upper Franconia
Germany

Dr Reto Theiß
Merck Healthcare
Germany

This course ist supported by

QP Association

Efficient Supplier Qualification

With an optional Live Online pre-course Session on 14 March 2023:
What you need to know about Suppliers in China and India

Live Online Training on 15/16 March 2023

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 Live Online pre-course Session on Suppliers from China and India on 14 March 2023

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

15/16 March 2023

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?

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

Risk Management in the Supply Chain: Frequency of Supplier Audits based on Risk Assessment

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

14 March 2023

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

Examples:

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

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

Question and Answer Sessions

A set of live Q&A Sessions will give you the possibility to interact with the speakers and get answers to your questions.

Speakers

Dr Melanie Distl
Roche, Switzerland
Dr Melanie Distl is Chapter Lead GxP-Supplier Management and Swiss Responsible Person.

York Moeller
J.A.Moeller GmbH & Co. KG, Germany
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.

Mukesh Patel
CommQP, U.K.
Mukesh Patel is Managing Director of CommQP consultancy services. He has held positions in R&D, Procurement, Regulatory Affairs and Quality Assurance in pharmaceutical industry.

Philipp Reusch
Reuschlaw, Germany
Philipp Reusch is a lawyer and expert in the area of product liability, product safety and recall management. He is also a lecturer for product liability and product safety at RWTH Aachen.

Wolfgang Schmitt
CONCEPT Heidelberg GmbH, Germany
Wolfgang Schmitt is Vice President at Concept, a training and information services provider. Previously he worked in the pharmaceutical industry, among other things as GMP auditor and Qualified Person.

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 Healthcare KGaA, Germany
Dr Reto Theiß is Qualified Person and a qualified auditor for Merck Healthcare.

Date of the Live Online Training

Live Online Pre-course Session: Suppliers from China and India
Tuesday, 14 March 2023, 9.00 – 17.30 h
All times mentioned are CET.

Live Online GMP Education Course: Efficient Supplier Qualification
Wednesday, 15 March 2023, 9.00 – 17.00 h
Thursday, 16 March 2023, 9.00 – 15.30 h
All times mentioned are CET.

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

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.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

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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For questions regarding content:
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For questions regarding organisation please contact:
Mr Rouwen Schopka (Organisation Manager) at
+49 (0) 62 21 / 84 44 13, or per e-mail at
schopka@concept-heidelberg.de

Your Benefits:

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

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

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CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ Live Online Training: Pre-course Session What you need to know about Suppliers in China and India
14 March 2023

☐ Live Online Training: GMP Education Course: Efficient Supplier Qualification
15/16 March 2023

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks 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 July 2022).
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 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.