ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GMP Auditor

Speakers


Melanie Distl
Roche


York Moeller
J.A.Moeller Chongqing


Mukesh Patel
CommQP


Philipp Reusch
Reuschlaw


Wolfgang Schmitt
Concept Heidelberg


Dr Franz Schönfeld
GMP Inspector


Dr Reto Theiß
Merck Healthcare

This course ist supported by

QP Association

Efficient Supplier Qualification

With an optional pre-course Session on 12 March 2024:
What you need to know about Suppliers in China and India

13/14 March 2024, Barcelona, Spain

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 12 March 2024

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. 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 sometimes too often. In the globalising world more and more supplies are coming from countries like **India and China**. And qualifying these suppliers brings other 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

13/14 March 2024

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

- Procurement
  - Objectives & priorities
  - EU GMP Chapters and GMP processes applicable to Procurement
  - GMP Training for the Buyer
- Suppliers
  - Supplier qualification
  - Contracts
  - Supplier categorisation
  - Use of Brokers

Outsourcing to Contract Manufacturers and Laboratories - What Needs to be Considered and Who is Responsible?

- Regulatory Framework
  - Regulations
  - Outsourcing EU vs non-EU
  - What if it goes wrong?
- Outsourcing Life-Cycle Management
- Elements of Supplier Qualification
  - Risk Assessment
  - Technical Agreements
  - Audits

Examples and Interaction:

Quality Risk Management in the Supply Chain

- Expectation of the Regulators
- Risk assessments
- Interactive Session
- Frequency of supplier audits based on risk assessment

Case Studies:

Qualifying and Maintaining Suppliers at Roche

- Supplier Management embedded in PharmaTechOps and PQS
- Interface with other departments
- Example – Risk-based approach to Supplier Management at Roche

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

Social Event

On 13 March, you are cordially invited to a social event (city tour and Dinner). This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Testimonials:

„I really enjoyed the topics, the way all the presentations have been structured as well as the way the questions have been answered." | Madalina Batista, IDT Biologika

"Very good content." | Fabiana Frech

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

12 March 2024

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

Interactive Session:

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

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

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 posts 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 Heidelberg, 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 Franconia. 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. 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
Tuesday, 12 March 2024, 9.00 – 17.30 h
(Registration and coffee 8.30 – 9.00 h)

GMP Education Course: Efficient Supplier Qualification
Wednesday, 13 March 2024, 9.30 – 17.30 h
(Registration and coffee 9.00 – 9.30 h)
Thursday, 14 March 2024, 9.00 – 15.30 h

Venue for both events

Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona, Spain
Phone.: +34 (93) 503 53 00
E-Mail: sants@barcelo.com

Fees (per delegate, plus VAT)

Pre-course Session:
What you need to know about suppliers in China and India
ECA Members € 990
QP Association Members € 990
APIC Members € 1,090
Non-ECA Members € 1,190
EU GMP Inspectorates € 495

GMP Education Course: Efficient Supplier Qualification
ECA Members € 1,690
QP Association Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945

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 € 2,190
QP Association Members € 2,190
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1,245

The conference fee is payable in advance after receipt of invoice and includes dinner on 13 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 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.

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. 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.
CONCEPT HEIDELBERG | P.O. Box 10 17 64 | D-69007 Heidelberg
Phone +49 (0) 62 21 / 84 44-0 | Fax +49 (0) 62 21 / 84 44 34
E-Mail: info@concept-heidelberg.de | www.concept-heidelberg.com

For questions regarding content:
Mr Wolfgang Schmitt (Operations Director) at
+49 (0) 62 21 / 84 44 39, or per e-mail at
w.schmitt@concept-heidelberg.de

For questions regarding reservation, hotel, organisation etc., 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.

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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

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

Reservation Form (Please complete in full)

☐ Pre-course Session What you need to know about Suppliers in China and India | 12 March 2024, Barcelona, Spain
☐ GMP Education Course: Efficient Supplier Qualification | 13/14 March 2024, Barcelona, Spain

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.