



Speakers



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Efficient Supplier Qualification



Live Online Training on 11 August 2020



Highlights

- Legal Background
- API Suppliers
- Contract Manufacturers and Laboratories
- Packaging Material and Excipient Suppliers
- Contracts
- Risk-based Approach

- Optimised as Online Event
- With two live discussion Sessions
- Documentation will be sent in advance

Objectives

During this Online Training, you will learn the most important 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. **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 Online Training is designed for all personnel involved in supplier qualification activities at their company and decision makers who want to improve the existing process.

Programme

09.00 – 09.15 h
Introduction

09.15 – 10.10 h
Duties and Responsibilities

- Regulatory background (EU, ICH, FDA)
- Duties and responsibilities
- Importing APIs into the EU
- Remote Audits

10.10 – 10.30 h Break

10.30 – 11.30 h
Outsourcing to Contract Manufacturers and Laboratories

- Points to consider
- Which activities can be outsourced - and how
- Outsourcing outside the EU
- Validation – tasks and responsibilities
- When things go wrong – problems and conflict solving

11.30 – 12.15 h
Efficient Supplier Qualification – A Risk-based Approach

- What is risk?
- Tools that could be used in the qualification process
- Examples for risk assessments in supplier qualification



12.15 – 12.45 h
Live Q&A Session

12.45 – 14.00 h Break


14.00 – 14.45 h
Suppliers of Packaging Material and Excipients

- Applying formalised Risk Assessments
- Risk classification and Supplier Qualification
- Solutions for audit request rejections

14.45 – 15.00 h Break

15.00 – 15-30
Contracts

- Different Types of Contracts
- Parties and Signees
- Staying compliant by staying up to date

 15.30 – 16.00 h
Live Q&A Session

Concept of this Online Training

We have pre-recorded the presentations of this online training for you to ensure a high-quality transmission.

Two live discussion panels:

The online training will include two live discussion rounds (Q&A sessions) with the speakers (approx. ½ hour in the morning and at the end of the day). This offers the possibility to ask questions to the speakers via chat, who will then answer them.

Speakers



Wolfgang Schmitt
Concept Heidelberg
Director Operations

The main focus of his training and consulting activities is on Quality Systems, GMP Legislation and the role of the Qualified Person. Before that he was an Associate Director and Qualified Person at Abbott's Global Pharmaceutical Research and Development Quality Assurance.



Dr Georg Sindelar
msg industry advisors AG
Head of Pharma QMS Consulting

Dr Georg Sindelar is Head of Pharma QMS Consulting. Before that he was Managing Consultant GMP Compliance for the Chemengineering Group, responsible for the areas of Pharma Compliance und Auditing.



Learning based on Videos from Pharma and API Operations

More than 300 companies in 30 countries use GMP eLearning in 12 different languages.

Videos from Real Life

Quite frequently eLearning is based on a lot of text and is very theoretical. Contrary to these systems GMP eLearning consistently uses videos that were produced at various pharma companies (as e.g. Boehringer Ingelheim). In total there are more than 10 hours of video/training materials.

- Based on real life examples you can see how work needs to be done to be GMP compliant and examples for how GMP problems arise.
- You will learn what the reasons are for these arising GMP problems and you will be trained how to behave correctly in the following video.

Applying GMP with Real Life Situations

Videos from real life examples demonstrating GMP situations (as e.g. production processes, cleaning procedures) also facilitate the learning process. Following short video sequences you will need to answer questions. Specifically in the section "Learning" you will need to answer further questions strengthening the learning effect. If your answer is incorrect you will get an explanation why (see example on the right). In the section "Testing" it is tested whether you understood the conveyed contents.

Simple Navigation – Compiling individual Topics/Trainings

The GMP eLearning courses comprise many hours of video materials. From these materials you can either select complete course modules or single chapters. That way you can train the cleaning staff exclusively with the chapters on cleaning and staff in the warehouse with the specific GMP regulations for their area of responsibility.

Please see the website for detailed information:
<https://www.gmp-elearning.com/>

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

Reservation Form (Please complete in full)



Efficient Supplier Qualification - Live Online Training on 11 August 2020

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)

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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 week 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 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 can-

cellation 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.



Date of the Live Online Training

Tuesday, 11 August 2020, 9.00 – 16.00 h

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.

At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 890

APIC Members € 890

Non-ECA Members € 990

EU GMP Inspectorates € 495

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.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can book the recording of the Live Online Training at any time at <https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars>.

Organisation and Contact

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

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