ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Frank Denzler
Vetter Pharma Fertigung GmbH & Co. KG, Germany

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

Carsten Moschner
Dastex, Germany

Stephan Schmitt-Koopmann
sk pharma consulting, Switzerland

Dr Franz Schönfeld
GMP Inspectorate Upper Franconia, Germany

Procurement and Purchase meet GMP

Live Online Training on 9/10 November 2021

Authorities' Expectations, Regulatory Requirements, Practical Implementation

Highlights

- Regulatory Requirements and Expectations
- Documentation Requirements
- GMP Requirements for Raw Materials
- Supplier Contract Management Qualification
- Supplier Qualification
- Requirements on Packaging Materials and Production Equipment
- GDP Effects

GDP Effects on Purchase and Procurement

Objective

During this Live Online Training, experts from purchase, quality management, consultants and authorities will show you

- the critical fields of purchase and procurement for pharmaceutical manufacturing
- examples of the coordination and practical implementation of the GMP requirements on
  - QC
  - supplier qualification
  - packaging materials
  - maintenance.
- how GDP affects procurement and purchase

And last but not least, the speaker team provides you with information about the expectations of the responsible authorities and the relevant guidelines.

Background

During the last years, the developments of computer technologies gave purchasers a lot of possibilities to optimise content management and merchandise management, reduction of suppliers. Direct connection with suppliers systems enabled a faster, clearly arranged and more effective procurement. The World Wide Web, online tendering and auctions made the comparison of suppliers and costs easier than ever before.

But for the manufacturing of products under the regulations of drug licensing and GMP, like drug substances, drug products and medical devices, during all optimisation of purchase and procurement, purchasers must be aware of these regulatory requirements. Especially the change of suppliers, process relevant materials or parts of the qualified production plant must be planned in a direct cooperation with the quality management. Such changes necessities maybe a new validation of the process, a new qualification of the manufacturing plant and for sure, a change control procedure. This can affect additional costs, maybe more than the saving effect of the change and in a worst case; a not coordinated change can cause the lost of a product licensing.

Target Audience

This Live Online Training is for people who are involved in purchase and procurement for GMP regulated manufacturing as well as for responsible persons from QC and QA who are in cooperation with the purchase and procurement of their companies.

Programme

Procurement for GMP Manufacturing – Regulatory Requirements and Expectations

- Which regulations are applicable?
- Marketing authorisation
- Manufacturing and import licensing
- Supplier Qualification: equipment, starting materials, disposables and consumables
- Risk-based qualification and validation

Where does GMP start? Procurement for Development and Clinical Phases

- Considerations for EU and USA?
- Why should we know ICH Q7, Q8, Q9, Q10 and Q11?
- What is essential for development?
- Changes for routine manufacturing?
- Case study

Consumables for GMP Areas – “C-items” and their Impact

- What impact do consumables have in terms of cost and quality?
- Specifications of the user and effective action of the purchasing department
- Risk assessment and evaluation in the event of a possible product change (change control)
- Possible internal cots, depending on the respective consumable, in the case of a product change.

GMP Requirements for Raw Materials

- What are raw materials?
- What is “pharmaceutical grade” for excipients?
- GMP for raw materials – risk assessment
- GMP requirements for final intermediate & APIs
- Supplier qualification & traceability

Requirements of Packaging Materials

- Liabilities
- Limitations
- The challenge for packaging purchasing
- Regulations and their requirements for packaging materials
- New products and their applicators
- Extended challenges for packaging purchasing

Supplier Contract Management

- Quality and risk management
- Technical agreements
- cGMP requirements
- Control of content

Change Control

- What does it mean?
- Impact and Consequences?
- Examples for Typical Changes

Documentation for GMP Materials – What is necessary? Retention Periods

- Regulatory requirements
- Defense against legal claims
- Liabilities
- Limitations

Qualification of Technical Suppliers - a Risk-based Approach

- Technical equipment and utilities
- Analytical equipment & reagents
- Supplies, disposables and consumables - What regulations apply?
- Risk-based qualification and procurement

GDP Effects on Procurement and Purchase

- GDP requirements to manufacturer
- Ideas to handle the requirements
- Discussions between the involved departments


CERTIFICATE

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.

Speakers

Dr Frank Denzler
Vetter Pharma Fertigung GmbH & Co. KG, Germany

Dr Frank Denzler is head of pharmaceutical procurement at Vetter Pharma Fertigung GmbH & Co. KG, an international CDMO to the pharmaceutical industry and specialist in the production of aseptically prefilled syringe systems, cartridges and vials. He owns a PhD in economics and previously worked for several years in management consulting as well as in the chemical industry.

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

Dr Hiltrud Horn is managing director of HORN PHARMACEUTICAL CONSULTING with focus on CMC, GMP and Regulatory Affairs. She started in pharma industry in 1990 and held several managerial positions within Hoffmann-La Roche in Basel and Knoll (Abbott) with global responsibility within QC / QA / Regulatory Affairs / Project Management / Medical Writing.

Carsten Moschner
Dastex GmbH & Co. KG, Germany

Carsten Moschner studied engineering economics at the University for applied Sciences in Karlsruhe. Currently he is CEO of Dastex with a focus on research and development as well as optimising of textile cleanroom garment. Carsten is a member of several expert committees, e.g. deeply involved in the new VDI 2083 chapter about the suitability of cleanroom equipment.

Stephan Schmitt-Koopmann
sk pharma consulting GmbH, Switzerland

Stephan Schmitt-Koopmann has a pharmacist graduation in Germany as well as in Switzerland and additional studied economies at Fernuniversität Hagen. He worked in diverse positions for MSD, Novartis and Merck Switzerland. In 2014 he started his own company and offers consulting services ad interim like Qualified Person, Quality Supplier Management, Q R M, CAPA and more.

Dr Franz Schönfeld
GMP Inspectorate Upper Franconia, Germany

Dr Franz Schönfeld is a pharmacist by profession. In 2003 he joined the local GMP inspectorate in Ansbach before he was transferred to Munich and Bayreuth. He was formerly deputy head of the national experts group for radiopharmaceuticals and is now head of the national expert group for APIs and excipients.

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Reservation Form (Please complete in full)

Procurement and Purchase meet GMP, Live Online Training on 9/10 November 2021

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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Date of the Live Online Training

Tuesday, 09 November 2021,
09.00 h - approx. 17.15 h CET
Wednesday, 10 November 2021,
09.00 h - approx. 15.45 h CET

Technical Requirements

For our Live Online Training Courses and 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.
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Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The 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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