20 YEARS ECA Academy
Your GMP/GDP Information Source

Procurement and Purchase meet GMP

Authorities' Expectations, Regulatory Requirements, Practical Implementation

GDP Effects on Purchase and Procurement

SPEAKERS:

Dr Andrea Hauser
University Hospital Regensburg

Dr Hiltrud Horn
Horn Pharmaceutical Consulting

Stephan Schmitt-Koopmann
sk pharma consulting

Dr Franz Schönfeld
Government of Upper Franconia

Axel Schroeder
Concept Heidelberg

Timo Usinger
Vetter Pharma Fertigung

23/24 October 2019, Vienna, Austria

HIGHLIGHTS:

- Regulatory Requirements and Expectations
- Contract Management and Documentation
- Supplier Qualification
- Requirements on Raw Materials and Containment
- GDP Effects
- Change Control

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Objectives

During this course, experts from purchase, quality management, consultants and authorities will show you the critical fields of purchase and procurement for pharmaceutical manufacturing. Furthermore you become acquainted with examples of the coordination and practical implementation of the GMP requirements on QC, supplier qualification, packaging materials and maintenance. 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 effect 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 course is for those 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.

Social Event

In the evening of the first course day, 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.

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

Qualification of Technical Suppliers - a Risk-based Approach

- Technical Equipment and Utilities
- Analytical Equipment & Reagents
- Supplies, Disposables and Consumables - Which regulations apply?
- Risk-based qualification and procurement

Supplier Contract Management

- Quality– and Risk Management
- Technical Agreements
- cGMP Requirements
- Control of Content

Implementation of procurement in the Quality System – Practical aspects from Disposables to Equipment

- Risk based approach
- Life cycle management
- Procurement of disposables and materials versus purchase of equipment
- Required documentation and SOPs

Change Control

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

Case Study: Purchase and Quality – Integration of both expectations in one Quality System

- Supplier Qualification
- Vetter – a Company Overview
- Balance of expectations
- Classic "Purchase" Processes
- Interaction and Communication between Purchase and Quality at Vetter
- Factors of Success

Documentation for GMP Materials – What is necessary? Retention Periods

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

Requirement on primary and secondary 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

Change Control

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

GDP – Effects on Procurement and Purchase

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

Case Study: Changing consumables – Costs and Benefits shown by examples from cleaning and disinfecting

- GMP Requirements for Disinfectants
- Reasons for a Change and Challenges
- Validation and Costs

Speakers

Dr Andrea Hauser, University Hospital Regensburg

Andrea Hauser is currently Deputy Head of Revenue Assurance and Patients Management. Before this, she was Head of Operations, Head of Production and Head of Quality Assurance at the José-Carreras-Centre for Somatic Cell Therapy, a department of the University Hospital Regensburg. She studied Pharmacy at the University of Regensburg. After that she was working as a GMP inspector at the Government of Upper Bavaria in Munich, where she conducted numerous GMP and GCP inspections mainly in the field of blood, tissue and (stem) cell therapy. Dr Hauser holds the qualification to act as Qualified Person.

Dr Hiltrud Horn, Managing Director Horn Pharmaceutical Consulting, Germany

From 1990 to 1999, she worked at Hoffmann-La Roche, Basel in QC/QA and in Regulatory Affairs. In 1999, she joined Knoll AG as Head of "Regulatory Compliance and CMC Documentation". In 2002, she was working as consultant at Cap Gemini Ernst &Young (biotechnology and life sciences) prior to starting her own business.

Stephan Schmitt-Koopmann, Managing Director sk pharma consulting GmbH

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, German GMP Inspectorate Upper Franconia, Bayreuth

Franz Schönfeld is a pharmacist by profession. After his graduation, he worked at a hospital in Nuremberg and at a retailer in Bayreuth. 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.

Axel H. Schroeder, Operations Director, Concept Heidelberg

Axel Schroeder got his degree in Biology at Ruprecht-Karls University Heidelberg. After 10 years in different positions at Henkel Ecolab GmbH 2005 Basan GmbH as Key Account Manager for Pharmaceuticals and Biotechnology. Since 2008 he is operation director at Concept Heidelberg for microbiology and biotechnology.

Dipl. Kfm. (FH) Timo Usinger, Vice Director Procurement, Vetter Pharma Fertigung GmbH & Co. KG, Ravensburg, Germany

Timo Usinger studied business administration in Pinneberg/Germany and holds a university certification as head of procurement of the European Business School Wiesbaden/Germany. He started his career at the former Hoechst AG, followed by employments at Intervet and Sandoz. 2007- 2014 he was Director Procurement at Vetter Pharma Fertigung in Ravensburg/Germany. In 2014 he became Vice President Procurement.

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23/24 October 2019, Vienna, Austria

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Easy Registration

Reservation Form:
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Date

Wednesday, 23 October 2019, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 24 October 2019, 08.30 – 16.00 h

Venue

Radisson Blu Park Royal Palace Hotel Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43 (1) 891 10 - 0
info.parkroyalpalace.vienna@radissonblu.com

Fees (per delegate plus VAT)

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

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both 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 event. Reservation should be made directly with the hotel no. 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.

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