ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Cheryl Chia
Lotus Phoenix Consulting, Netherlands

Loretta Dougan
Jazz Pharmaceuticals, Ireland

Ulrich Kissel
European QP Association, EQPA
Chairman of the Board of Directors

Sílvia Ribeiro
Hovione, Portugal

Mervi Saukkosaari
Finnish Medicines Agency FIMEA

Carl Spörri
Modum.io, Switzerland

Supply Chain Oversight

Supervision of the Pharmaceutical Supply Chain: Challenges and Opportunities

28/29 October 2020 | Vienna, Austria

Highlights

- GMP/GDP Interface
- Supply Chain Oversight from Development to Life Cycle Management
- Master Data and Block Chain
- Serialisation
- Batch Certification and Release
- Annex 21
- Contracts
- Change Control
- Deviations and Complaints
- Quality Reviews

With a View on the new Annex 21

Objective

This 2-day Master Class brings together well-experienced experts to discuss the latest expectations and best practices for effective and efficient Supply Chain Oversight processes and how to get there.

Background

There is a steady increase in dependence on global supply chains. Pharmaceutical companies not only source starting materials from all over the world, but also outsource manufacturing activities. The finished products are then distributed globally. These complex supply chains with different transport routes and manufacturing locations lead to major challenges in terms of maintaining the quality of materials, intermediates and medicinal products.
This has increased the risk of potential compliance and delivery problems, having a negative impact on a company's business and on the patient. Managing these supply chains and complying with GMP and GDP regulations require a comprehensive supply chain oversight with appropriate risk management measures.
The manufacturer, the Qualified Person (QP) but also the Responsible Person (RP) are primarily responsible for compliance with EU/EEA requirements:

- EU-GMP Annex 16, General principles: "The ultimate responsibility for the performance of a medicinal product over its lifetime, its safety, quality and efficacy, lies with the marketing authorisation holder (MAH)."
- EU-GMP Annex 16, 1.7.2: "The entire supply chain of the active substance and medicinal product up to the stage of certification is documented and available for the QP. This should include the manufacturing sites of the starting materials and packaging materials for the medicinal product and any other materials deemed critical through a risk assessment of the manufacturing process. The document should preferably be in the format of a comprehensive diagram..."

In the meantime, the competent authorities and inspectorates are also focusing on supply chain oversight processes; manufacturers and especially the marketing authorisation holder must know and control every level of the supply chain.

Target Audience

QPs, RPs, Managers and Executives from pharmaceutical Quality and Supply Chain Units but also Senior Management, Business Executives and those involved in improving and controlling the pharmaceutical supply chain.

Moderator

Wolfgang Schmitt
(on behalf of ECA)

Programme

Regulatory Background and the GMP/GDP Interface

- Responsibilities of MAH, QP and RP in the overall supply chain
- What do inspectors expect?

Supply Chain Oversight (1): from Development to Transfer

- How to keep oversight over the pool of suppliers and brokers in the development phase (supplier change controls, ongoing supplier management incl. trending)
- Initiation, creation and management of compliant and useful supply chain diagrams (with examples)
- How to use risk analysis and management
- Transfer of the information: the "QP-QP handshake"

Supply Chain Oversight (2): from Transfer to Life Cycle Management

- Transfer of the information: the "QP-QP handshake"
- Management and change control of compliant and useful supply chain diagrams (with examples)
- How to keep oversight over the pool of suppliers and brokers in the marketing phase (supplier change controls, ongoing supplier management incl. trending)

Master Data in the Supply Chain

- The broader framework on Master Data
- How will this impact the pharmaceutical Supply Chain?
- What does this mean for supply chain organisations?
- What does this mean for the quality organisations supporting the supply chain?
- Become a master of your data!

Block Chain Technology in the Supply Chain

- What is block chain and how could it help supply chains?
- Block chain for supply chains – a must or a maybe?
- Examples of block chain being used in supply chains
- Understand the components of the supply chain based on a hypothetical example (Material flow, Information flow, Capital flow)
- Barriers, challenges and solutions.

Serialisation Issues

- Challenges and problems occurring in the supply chain and how to deal with them

Import and Export

- Annex 21: possible consequences
- The Release to third Countries
  - Who is releasing products in markets outside EU (after EU QP certification) – and how
- Best practices - what needs to be considered

Contract Handling

- Different contracts in the Supply Chain (Forecasting, Supply, Quality/ Technical Agreement ...)
- Who needs to sign
- Contract handling: how to keep them up to date, how to avoid contradictions

Case Study: Supply Chain Oversight at Hovione

- Risk management and control
- Supply Chain tracking

Change Control and Certification for global Markets

- How to deal with change control challenges when regular approvals can take several months or years to cover all the relevant countries worldwide
- How to support decision making
- The link to ICH Q12

From Incident to Quality Review

- Different types of queries/complaints
- Who deals with which types of queries/complaints?
- Examples of distribution complaints
- Investigation and CAPAs
- Trending
- Quality Reviews

Speakers

Cheryl Chia
Lotus Phoenix Consulting, Netherlands
Consultant

Cheryl Chia is Consultant for GMP and GDP compliance in the pharmaceutical supply chain.

Loretta Dougan
Jazz Pharmaceuticals, Ireland
Associate Director & QP

Loretta Dougan is Associate Director Quality Assurance and Qualified Person for IMPs.

Ulrich Kissel
European QP Association, EQPA
Chairman of the Board of Directors

Ulrich Kissel is QP and Chairman of the Board of Directors of the EQPA. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

Sílvia Ribeiro
Hovione, Portugal
Product Lifecycle Specialist

Before starting as a Product Lifecycle Specialist at Hovione, Sílvia Ribeiro was Senior QRM Specialist at 4Tune Engineering.

Mervi Saukkosaari
Finnish Medicines Agency FIMEA
Senior Pharmaceutical Inspector

Mervi Saukkosaari is Head of Section and Senior Pharmaceutical Inspector with more than 20 years experience in the pharmaceutical industry.

Carl Spörri
Modum.io, Switzerland
Chief Marketing Officer

Senior executive with over 10 years of professional experience, mainly in the management consulting and technology sector.

Social Event

In the evening of the first conference 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.

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

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Reservation Form (Please complete in full)

Supply Chain Oversight, 28/29 October 2020, Vienna, Austria

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.
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- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
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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 http://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.

Date

Wednesday, 28 October 2020, 9.00h – 17.45h
(Registration and coffee 8.30h – 9.00h)
Thursday, 29 October 2020, 8.30h – 15.30h

Venue

Radisson Blu Park Royal Palace Hotel
Schlossallee 8
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Phone +43/1/89110 9 200
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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 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 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.

Conference language

The official conference language will be English.

GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. 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.

Organisation and Contact

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