ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Cheryl Chia
Lotus Phoenix Consulting, Netherlands

Simon Dössegger
Modum.io, Switzerland

Loretta Dougan
Jazz Pharmaceuticals, Ireland

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

Mervi Saukkosaari
Finnish Medicines Agency FIMEA

Supply Chain Oversight

Supervision of the Pharmaceutical Supply Chain: Challenges and Opportunities

Live Online Training on 28/29 October 2020

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 Live Online Training 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

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

Live Q&A Sessions

Six live discussion panels: The online training includes six Questions&Answers sessions with the speakers. This provides the opportunity to ask questions to the speakers, who will then answer them.

Speakers

Cheryl Chia
Lotus Phoenix Consulting, Netherlands
Consultant
Cheryl Chia is Consultant for GMP and GDP compliance in the pharmaceutical supply chain.

Simon Dössegger
Modum.io, Switzerland
Chief Executive Officer
Simon Dössegger is CEO with a strong background on visual sensor and navigation systems.

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.

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.

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Reservation Form (Please complete in full)

Supply Chain Oversight | Live Online Training on 28/29 October 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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If you cannot attend the conference you have two options:
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Date of the Live Online Training

Wednesday, 28 October 2020, 9.00h – 17.45h
Thursday, 29 October 2020, 8.30h – 16.00h

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 € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
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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