ECA Academy
Your GMP/GDP Information Source

Speakers

Canice Kearney
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Quality Oversight for Virtual Companies

Live Online Training on 09 November 2023

Highlights

- MAH Responsibilities
- Challenges and possible Solutions
  - Change Control
  - Deviations
  - PQR
  - Batch Certification
  - Risk Management
- Supply Chain Maps
- GDP Interface

Quality and Supply Chain Oversight
for Marketing Authorisation Holders and Virtual Companies

Objectives

Hear and discuss the expectations and best practices for effective and efficient Quality Oversight processes and how to get there. This will support you turning your company's quality excellence goals into reality.

Background

Some Marketing Authorisation Holders but also innovative start-ups and Research & Development organisations outsource most, if not all, manufacturing, testing and distribution activities of their product(s) and are virtualizing their business. Quality Oversight in such a Virtual Company is challenging, but essential to ensure that products are safe, effective and of the correct quality.

There are some good reasons for such an approach. It gives smaller organisations the opportunity to bring their own product(s) to the market and keep the focus on research and development and it also helps attracting investors. The actual employees can concentrate on core competencies. For larger companies, it offers more flexibility and a good way to quickly add new products to the portfolio and develop markets faster.

Of course, such a business model also brings some challenges. One needs a high degree of trust with the business partners in the supply chain, must be able to deal with differences in corporate and quality culture and, above all, have the necessary oversight of the quality and supply chain of all activities and products.
Just as it is with other business areas, management has the responsibility to ensure that systems are in place to effectively monitor the state of control in order to intervene with timely decisions to manage risk, achieve goals, and add stakeholder value. It is of utmost importance to detect and heed possible problems early enough.

In 2021 EMA has published a reflection paper entitled "Good Manufacturing Practice and the Marketing Authorisation Holder", which was slightly updated 2022. The goal was to provide clarity on the different responsibilities and their practical significance for MAHs. Ultimately, the aim was to summarise and, if necessary, explain in one document the responsibilities that are described in various places in the relevant GMP documents such as the EU-GMP Guidelines or the respective Directives.

Target Audience

QA Managers and Executives from MAHs/ Virtual Companies including Senior Management and Business Executives and those involved in improving the Pharmaceutical Quality System.

Moderator

Wolfgang Schmitt
Concept Heidelberg (on behalf of ECA)

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1. Introduction and Purpose

This Reflection Paper is focussed on the GMP-related responsibilities that apply to Marketing Authorisation Holder (MAH) companies. While it is recognised that many MAH companies are not directly engaged in the manufacture of medicinal products themselves, the current European Commission (EC) Guide to GMP (hereafter referred to as the 'GMP Guide') refers, in several places, to MAHs and their responsibilities in relation to GMP.

In general, these responsibilities range from responsibilities that relate to outsourcing and technical agreements, to ones that require the MAH to perform certain specific tasks (e.g. evaluating the results of product quality reviews, agreeing irradiation cycles with manufacturers, etc.). These responsibilities are spread over the various chapters and annexes of the GMP Guide, and are quite numerous.

(Excerpt from the EMA Reflection Paper on Good Manufacturing Practice and Marketing Authorisation Holders)

Programme

Quality and Supply Chain Oversight for Virtual Companies – what is different and what are the Challenges?

- What does quality oversight mean and what is expected?
- What aspects of the supply chain are relevant and how is sufficient oversight achieved?
- How to handle more than one quality system
- How to manage differences in culture and language

Supply Chain Maps – Examples of Complexities involved

- What is required of a Supply Chain Map (SCM)?
- Control and format of SCMs and setting the scope of responsibilities
- Achieving value from use of SCMs – and aligning company's approach for supply

Specific Quality System Aspects for Virtual Companies

- General principles relating to virtual company quality systems and how they should interact with other companies QMS
- Detailed review of likely points of interaction (e.g. change controls, deviations/non-conformances, complaints & recall, preparation of the Product Quality Review, audits.....)
- How to ensure effective and efficient interaction and communication
- What are the challenges to overcome?

5. Areas of the EC Guide to GMP that relate to MAHs
As noted in the Introduction, there are various references within the GMP guide to MAH-related responsibilities. These span a number of different chapters and annexes, and in this Reflection Paper, they are grouped together under a number of different themes. These are set out below. While there is some duplication across the different themes, it is considered helpful to consider the responsibilities and activities in this way.

A number of the legislative provisions that exist within EU medicines legislation which concern the GMP-related responsibilities of MAHs are also included within the various themes, where relevant. The themes are:

- Outsourcing and Technical Agreements
- Audits and Qualification Activities
- Communication with Manufacturing Sites (e.g. MA Dossier Information, Variations, Regulatory Commitments, etc.)
- Product Quality Reviews
- Quality Defects, Complaints and Product Recalls
- Maintenance of Supply of Medicinal Products
- Continual Improvement Activities

(Excerpt from the EMA Reflection Paper on Good Manufacturing Practice and Marketing Authorisation Holders)

Batch Certification – Minimum Requirements & Best Practices

- Arrangements for QP Certification for virtual companies
- Manage deviation reporting and change control implementation in virtual companies
- Batch Certification – Considerations for Outsourcing
- Case studies, examples of effective arrangements

Use of Quality Risk Management

- Objective of QRM and how best to use this tool
- When to use QRM proactively and how to ensure this is effective
- Examples of when QRM has to be used reactively and how to make informed, scientific decisions

Marketing Authorisation Holder (MAH) Responsibilities

- The ultimate responsibility for the performance of a medicinal product
- Articulating MAH responsibilities in a complex organization
- Effective MAH governance

Post Product Release Oversight Responsibilities

- Virtual companies' responsibilities after certification and release of medicinal product
- Establishing arrangements for effectively managing defect reporting, potential market actions, supervisory authority engagement

GDP Interface

- Reminder of GDP guidance available for APIs and products
- How this interface should work to ensure product reaches patient in suitable condition
- Challenges to overcome when working in a virtual company

Questions and Answers Session

A set of live Q&A Sessions will give you the possibility to interact with the speakers and get answers to your questions.

Speakers

Canice Kearney
Takeda, Ireland
Canice Kearney is QP and Head of Quality, Biologics External Supply at Takeda (formerly Shire) with QA, QC, Microbio, Disposition and Operational Excellence responsibilities with global teams.

Sue Mann
Sue Mann Consultancy, U.K.
Sue Mann is a Qualified Person and a QP Assessor in the U.K. working on behalf of the MHRA, representing the Royal Pharmaceutical Society. She was Vice President of International Quality Assurance at Shire Pharmaceuticals before founding her company in 2009.

Testimonials

"Very good course especially the questioning round gives good examples of how "real life" for virtual companies are running" | Lone Jespersen, Niras, Denmark

"It was a very interesting seminar with relevant input for me. I am already an experienced QP, but I still got some new input!" | Dr Nina Langoth-Fehringer, Austria

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Reservation Form (Please complete in full)

Quality Oversight for Virtual Companies
Live Online Training on 09 November 2023

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Date of the Live Online Training
Thursday, 09 November 2023, 9.00h – 17.00h CET

Technical Requirements
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Fees (per delegate, plus VAT)
ECA Members EUR 990.-
APIC Members EUR 1090.-
Non-ECA Members EUR 1.190.-
EU GMP Inspectorates EUR 595.-
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.

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

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