



GMP Webinar

The new EMA Reflection Paper on GMP and Marketing Authorisation Holders

Date:

Thursday, 23 April 2020, 14.00 – 15.30 h CEST

Speaker:

David Cockburn

(European QP Association, former Chair of the GMP/GDP Inspectors Working Group)



ECA has entrusted
CONCEPT HEIDELBERG with the
organisation of this webinar.

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Background

After long discussions, the European Medicines Agency EMA has published a **Reflection Paper on Good Manufacturing Practice and Marketing Authorisation Holders** (EMA/457570/2019).

Business models have been changing over the years and many companies hold a Marketing Authorisation, but not a Manufacturing Authorisation. For some it is not easy to understand how Good Manufacturing Practice (GMP) applies to their overall responsibilities for the product. This can be difficult to comprehend when reading the GMP guide or the applicable legislation. The new Reflection Paper is intended to provide clarity.

On behalf of the European QP Association (EQPA), David Cockburn commented EMA's Reflection Paper. Comments were officially sent to EMA as an EQPA feedback.

Educational Objectives

The goal of this webinar is to give attendees a comprehensive yet compact overview of the current reflection paper and have a closer view on:

- What is the issue?
- What is a Reflection Paper?
- What are the main messages?
- What views has EQPA conveyed in its response to the Paper?
- What happens next?

Target Audience

The webinar is aimed at executives and employees from Marketing Authorisation Holders (MAHs) and Manufacturing Authorisation Holders who want to gain a better understanding of the reflection paper and its possible consequences.

Speaker



David Cockburn

European Qualified Person Association (EQPA)

David Cockburn is Board Member of the European QP Association. He was previously a principal inspector for GMP and GDP at MHRA, UK and later joined European Medicines Agency where he was Head of Manufacturing and Quality Compliance as well as Chair of the GMP/GDP IWG .

Fees (plus VAT)

Single participation: € 199,- for ECA Members

Single participation: € 249,- for non-ECA Members

(This fee does not include the ECA Membership. You will find more about the ECA Membership at <https://www.gmp-compliance.org/about-the-academy>).

Participation of a Group

You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC.

Group Participation (fee per person):

3-10 Persons EUR 211,15

11-20 Persons EUR 186,75

more than 20 Persons EUR 161,85

Registration

By mail, fax, e-mail or online on the Internet at www.gmp-compliance.com. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

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 plugin. 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.

Presentation/Certificate

The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Organisation/Contact

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Do you have any questions?

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Registration for the GMP Webinar: "The new EMA Reflection Paper on GMP and Marketing Authorisation Holders" on Thursday, 23 April 2020, 14.00 – 15.30 h CEST

Speaker: David Cockburn

Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:

- Single Participation**
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 - 3-10 Persons
 - 11-20 Persons
 - more than 20 Persons

**Important:
Deadline is 12 noon on
22 April 2020**

Title, First Name, Last Name

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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.

2. If you have to cancel entirely we must charge the following processing fees:

Cancellation until 2 weeks prior to the conference 10 %, until 1 week prior to the conference 50 %, within

1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to

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Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. 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).

German law shall apply. Court of jurisdiction is Heidelberg.