



GMP Webinar

Regulatory Opportunities in times of Covid-19

Date:

Wednesday, 20 May 2020, 14.00 – 15.30 h

Speaker:

Dr Josef Hofer, EXDRA GmbH, Germany

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

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de



Background

On 10 April 2020, the EMA, HMA and EC issued the first version of the "QUESTIONS AND ANSWERS ON REGULATORY EXPECTATIONS FOR MEDICINAL PRODUCTS FOR HUMAN USE DURING THE COVID-19 PANDEMIC" document in order to provide guidance to marketing authorisation holders (MAHs) on regulatory expectations and flexibility during the COVID-19 pandemic (latest revision issued on 17th April 2020). The "Practical guidance of the CMDh for facilitating the handling of processes during the COVID-19 crisis" is intended to give further explanations and practical guidance on how to address, apply and implement the provisions given by the Q&A document.

Educational Objectives

This webinar will give you a comprehensive overview of the information laid down in the Q&A document issued by the EMA, HMA and EC and the practical guidance issued by the CMDh. The handling of Marketing Authorisation procedures, sunset clauses, changes as well as renewals in times of Covid-19 will be discussed and explained.

- Regulatory options and opportunities for medicinal products
- Specific requirements, adaptations and interpretations
- Regulatory tools and procedures
- Practical guidance

Target Audience

This webinar is designed for all persons involved in the development, compilation and maintenance of pharmaceutical dossiers of medicinal products and will be of interest to personnel from Development, Quality and Regulatory Affairs.

Speaker



Dr Josef Hofer, EXDRA GmbH, Germany

Dr Hofer is Managing Director of EXDRA GmbH (Excellence in Drug Regulatory Affairs). He is working for and in international pharmaceutical industry since 1980. Dr Hofer holds a lectureship at the University in Bonn for the Master Course in Drug Regulatory Affairs.

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 € 211,15
11-20 Persons € 186,75
more than 20 Persons € 161,85

Registration

By mail, fax, e-mail or online on the Internet at <https://www.gmp-compliance.org/>. 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

CONCEPT HEIDELBERG, P.O. Box 10 17 64, D-69007 Heidelberg,
Tel. +49(0)6221/84 44-0, Telefax +49(0)6221/84 44 34
info@concept-heidelberg.de, www.gmp-navigator.com

Do you have any questions?

For questions regarding content please contact:
Ms Anne Günster, phone +49(0)6221/84 44 50
Email: guenster@concept-heidelberg.de

For questions regarding technical/organisational aspects please contact:
Ms Julia Grimmer, phone +49(0)6221/84 44 44
Email: grimmer@concept-heidelberg.de

Registration for the Webinar "Regulatory Opportunities in times of Covid-19" on Wednesday, 20 May 2020, 14.00 – 15.30 h CEST

Speaker: Dr Josef Hofer, EXDRA GmbH

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

Please tick:

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

**Important:
Deadline is 12 noon on
19 May 2020**

Title, First Name, Last Name

Company

Department

VAT ID No. (mandatory)

Street

Postal Code/City

Phone

Fax

E-Mail (mandatory for your registration)

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 cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will

receive a full refund of fees paid.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.

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!)