



GMP Webinar

Switzerland and the EU

The Differences in GMP and GDP

Date:

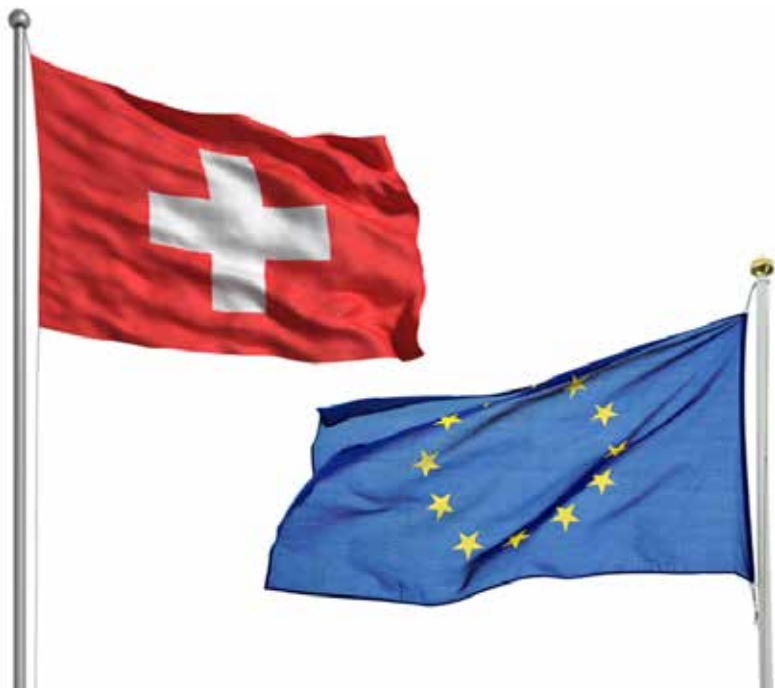
Wednesday, 15 July 2020, 14.30 -16.00 h CEST

Speaker:

Christian Schmidt, gempex

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

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Background

According to Annex 1, letters c and d, of the Medicinal Products Licensing Ordinance (MPLO), most parts of EU-GMP is valid in Switzerland. What might sound easy is not always the case. Not all of the current EU-GMP guidance is listed and sometimes it is not possible to implement updates in a timely manner.

In individual cases, there are also divergent requirements or different interpretations by the authorities.

Educational Objectives

Learn and discuss the following topics:

- The Role of SwissMedic and the local inspectorates
- Specific differences and how to deal with them
- RP and QP
- Implementation of new EU Guidance documents in Switzerland
- The Mutual Recognition Agreement (MRA) : facilitation and constraints

Target Audience

This Webinar has been designed for QA/GMP personnel and management functions who would like to get a comprehensive overview on the differences between Suisse and EU GMP/ GDP.

Speaker



Christian Schmidt

gempex GmbH, Switzerland

Christian Schmidt is Senior Consultant. He spent more than 20 years in various areas of the Quality Unit at Bayer Pharma.

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 € 211,65

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 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.

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: "Switzerland and the EU"
on Wednesday, 15 July 2020, 14.30 -16.00 h CEST

Speaker: Christian Schmidt

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 for registration is
12 noon on 14 July 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 %.

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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!)