



# GMP Webinar

## **APIs & Excipients: Handling and Life Cycle Management in times of Covid-19**

Date:  
Tuesday, 28 July 2020, 14.00 – 15.30 h CEST

Speaker:  
Manfred Karner, Takeda, Vienna, Austria

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

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## Background

Especially, in times of the Covid-19 pandemic, GMP Compliance and Life Cycle Management of APIs & Excipients are of high importance. For ensuring the GMP-compliant handling new strategies as well as risk-based approaches need to be evaluated and established.

## Educational Objectives

This GMP webinar will give you a comprehensive overview of the regulatory requirements and GMP-compliant handling of APIs & Excipients. Despite the topics like processing and qualification, risk-based approaches and new strategies will be discussed and explained:

- Regulatory requirements
- Handling and procurement
- Supplier qualification and evaluation
- Life Cycle Management and maintenance
- Risk-based approaches and strategies
- GMP compliance

## Target Audience

This webinar is designed for persons working in the Quality Assurance, Quality Control, Production, Regulatory Affairs and Development departments. It will also be of interest for personnel from suppliers, contract manufacturing companies and consultants.

## Speaker



### Manfred Karner, Takeda, Vienna, Austria

Mr Karner has been working for Takeda (former Baxter / Baxalta / Shire) in Vienna since 1996. After various management functions in Local Quality (including Head Receiving & Inspection + Product Release) he switched in 2014 to Global Quality Management and had there different management roles. Currently he is leading the Direct & Indirect Material department in Global Quality Auditing & Supplier Management. His responsibilities currently are qualifying suppliers and creating quality agreements and material specifications for Takeda.

## 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 211,65  
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 <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

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## Do you have any questions?

For questions regarding content please contact:  
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Registration for the Webinar "APIs & Excipients: Handling and Life Cycle Management in times of Covid-19" on Tuesday, 28 July 2020, 14.00 – 15.30 h CEST

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Please fax to CONCEPT HEIDELBERG, +49 (0)6221/84 44 34 or you register online at [www.gmp-compliance.org](http://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  
27 July 2020**

Title, First Name, Last Name

Company

Department

VAT ID No. (mandatory)

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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.

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