



# GMP Webinar

## Highly Potent Compounds – Safe & GMP-compliant Handling

Date:

Tuesday, 30 June 2020, 14.00 – 15.30 CEST

Speaker:

Dr Harald Stahl, GEA

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

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Image: GEA

## Background

Exposure to active pharmaceutical ingredients must be kept within acceptable limits. The protection of employees must be achieved primarily by technical measures and not through personal protective equipment. Several containment solutions like glove boxes, isolators, special valves and transfer ports are available. This equipment has to fit to the surrounding, the product requirements and the organisational circumstances. Therefore detailed planning is necessary.

But GMP also has requirements for contamination or the avoidance of contamination / cross contamination as far as possible (see chapters 3 (Premises & Equipment) and 5 (Production) of the EU GMP Guidelines. By introducing the PDE concept (Permitted Daily Exposure) by the European Medicines Agency, occupational medicine and GMP requirements are now based on the same scientific basis, namely on the question: how much exposure is uncritical for a person (whether patient or employee)? This important question has to be answered for both, dedicated and multipurpose equipment.

## Educational Objectives

The aim of this webinar is to make you a competent partner for dealing with highly active substances - both from an occupational safety and a GMP (avoidance of cross-contamination) point of view:

- Exposure and how to calculate
- Equipment and containment concepts
  - Closed product handling
  - Sampling
  - Material transfer
- The PDE/ADE concept: how much contamination is allowed?
- Avoiding of cross contamination
  - Air born contamination
  - Contamination of surfaces
- Verification of the tightness of a containment system

## Target Audience

This Webinar aims at persons from production, engineering and quality, responsible for

- Occupational safety
- Cleaning concepts and contamination prevention
- Design of new manufacturing areas

as well as engineering and plant-construction companies working in containment projects.

## Speaker



### Dr Harald Stahl, GEA

Dr Harald Stahl worked in the Pharmaceutical Development of Schering AG in Germany. At that time his main interest was the aseptic production of pellets. Since 1995 he served within GEA Process Technology in various

positions. Presently he owns the position of a Group Director Application & Strategy Management of GEA. He has published more than 20 papers on various aspects of containment and pharmaceutical production.

## 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 [www.gmp-compliance.com](http://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 "Highly Potent Compounds – Safe & GMP-compliant Handling" on Tuesday 30 June 2020, 14.00 – 15.30 h CEST  
Speaker: Dr Harald Stahl**

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  
29 June 2020**

Title, First Name, Last Name

Company

Department

VAT ID No. (mandatory)

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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).

German law shall apply. Court of jurisdiction is Heidelberg.