



# GMP Webinar

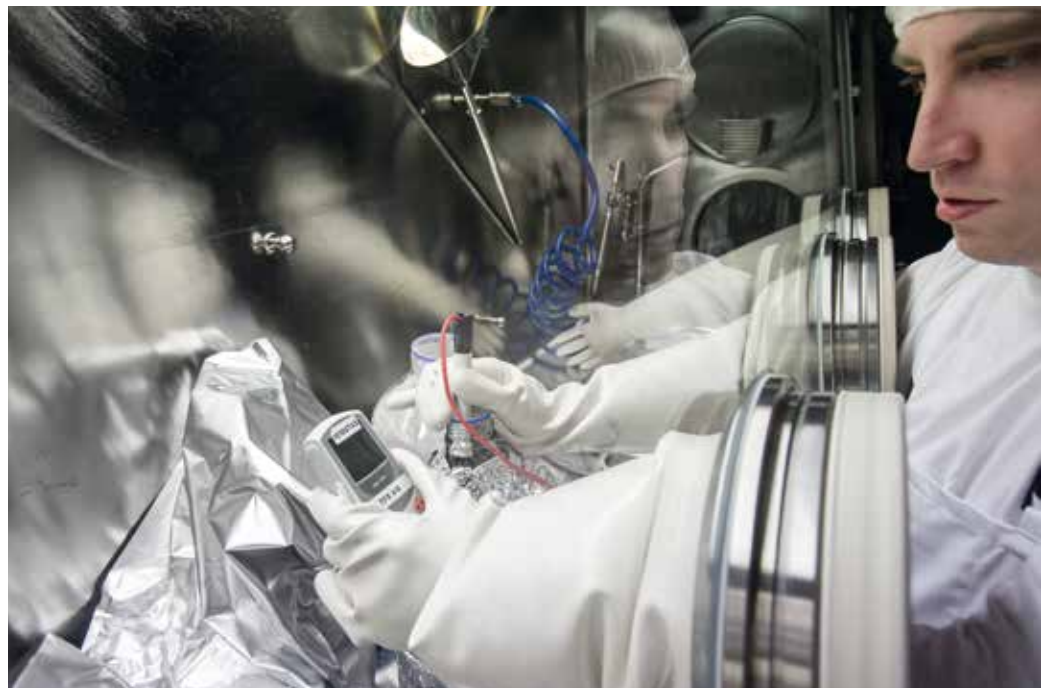
## **Annex 1 - Barrier Systems: Developments for RABS and Isolators**

Date:

Thursday, 06 August 2020, 14.00 -15.30 h CEST

Speaker:

Dr Friedrich Haefele, form. Boehringer Ingelheim Pharma,  
Member of the ECA Annex 1 Task Force



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

With the current revision of the specifications for aseptic processing and the requirement for clear strategies to minimise the risk of contamination by microbial and cellular impurities (e.g. pyrogens, endotoxins) and by visible and non-visible particles, there is a new focus on barrier systems such as RABS and isolators. Such strategies should be considered as a life cycle approach and alternative approaches instead of RABS and isolators should be rationally justified. This development is also reflected in the current draft of Annex 1.

## Educational Objectives

During the webinar you will have the opportunity to

- understand the regulatory requirements (EMA, FDA) for aseptic processing equipment,
- compare the different approaches of conventional cleanroom, RABS and isolator designs and understand their specific advantages and disadvantages (design, qualification, monitoring, cleaning, disinfection),
- learn benchmark practices between the participants.

In addition, the following topics will be covered during this webinar:

- The differences and similarities between other regulatory requirements and the recent revision of Annex 1
- The operational difficulties and practical solutions of component and product transfer in RABS and isolators and how they are considered in monitoring and aseptic process simulation programs.
- The different practices in different industries.

## Target Audience

This webinar is aimed at employees from Production, Engineering, Quality assurance, Quality Control, and Authorities who are involved in the preparation, implementation, operation and monitoring of Aseptic Processing facilities on the background of the revised Annex 1.

## Speaker



### Dr Friedrich Haeefe, form. Boehringer Ingelheim Pharma, Germany

Friedrich Haeefe is a Pharmacist and got his Dr. rer.nat. at the University of Erlangen-Nürnberg. He has more than 30 years of experience in management of drug manufacturing, quality assurance and market supply e.g. at Altana Pharma AG (now Takeda) in Singen, Germany and as VP Operations Drug Product at Boehringer Ingelheim Biotechnology. His focus was on aseptic processing and sterile biopharmaceuticals.

## 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

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](mailto:info@concept-heidelberg.de), [www.gmp-navigator.com](http://www.gmp-navigator.com)

## Do you have any questions?

**For questions regarding content please contact:**  
Mr Axel H. Schroeder, Phone +49(0)6221 / 84 44 10,  
Email: [schroeder@concept-heidelberg.de](mailto:schroeder@concept-heidelberg.de)

## For questions regarding organisational aspects please contact:

Ms Isabell Neureuther, Phone +49(0)6221 / 84 44 49  
Email: [neureuther@concept-heidelberg.de](mailto:neureuther@concept-heidelberg.de)

**Registration for the GMP Webinar "Annex 1 - Barrier Systems: Developments for RABS and Isolators" on Thursday 06 August 2020, 14.00 -15.30 h CEST**  
**Speaker: Dr Friedrich Haeefe**  
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**  
**05 August 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:

- We are happy to welcome a substitute colleague at any time.
  - 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.