



# GMP Webinar

## **Annex 1 – Sterilization and Sterile Filtration**

Date:  
Thursday, 28 May 2020, 14.00 – 15.30 CEST

Speaker:  
Dr Rainer Gnibl, GMP Inspector, Local Government of Upper Bavaria

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

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## Background

Annex 1 "Manufacture of sterile medicinal products" of the EU GMP Guide is currently being revised. A first draft of the revised version was published in 2017 and released for public comment, resulting in thousands of comments. A revised version was published in February 2020 and is open for limited comment by selected stakeholders.

## Educational Objectives

This webinar will inform you about the current status of the revision regarding changes and enhancements in the field of sterilization and sterile filtration. As an example, the filter test is mentioned. "The integrity of the sterilized filter should be checked before use" is stated in Annex 1. In this context, the requirement for the Pre-Use-Post-Sterilization Integrity Test (PUPSIT) is made to avoid "blinded" filter errors in the pure post-filtration test. For this purpose, it was discussed whether the risk of not using PUPSIT was lower than the risk of the integrity test negatively affecting the performance of the sterile filter. Accordingly, the webinar deals with the following topics:

- Definitions
- Requirements
- Validation
- PUPSIT - Pre-Use-Post-Sterilization Integrity Test

## Target Audience

This Webinar is of interest to professionals from pharmaceutical and biopharmaceutical manufacturers, authorities and suppliers with responsibilities in

- Quality Assurance and Quality Control
  - Inspection and Auditing
- or who are involved in
- Sterile/Aseptic Manufacturing
  - Contamination Control and Monitoring
  - Process Simulation/Media Fill

## Speaker



### Dr Rainer Gnibl

#### GMP-Inspector for EMA and local Government, Germany

Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government of Upper Bavaria and the EMA and performs GMP inspections worldwide. Rainer Gnibl is head

of the nationwide expert group EFG2 "GMP Inspection" and is responsible for "Third Country Inspections" at the Government of Upper Bavaria. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

## 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 211,15

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?

### For questions regarding content:

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Ms Isabell Neureuther, Phone +49(0)6221 / 84 44 49

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## Registration for the GMP Webinar "Annex 1 – Sterilization and Sterile Filtration"

on Thursday, 28 May 2020, 14.00 – 15.30 CEST, Speaker: Dr Rainer Gnibl

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**
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- 3-10 Persons
  - 11-20 Persons
  - more than 20 Persons

**Important:**  
Deadline is 12 noon on  
27 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.

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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.