



GMP Webinar

Annex 1 – Requirements for personnel in the context of the Contamination Control Strategy

Date:

Thursday, 17 September 2020, 14.00 – 15.30 h CEST

Speaker:

Dr Bettina Rietz-Wolf, GMP Inspector,
Local Government of Baden-Württemberg



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 with regard to the topic of personnel in conjunction with contamination control (CCS Contamination Control Strategy). The current draft emphasizes in many cases that the networking and coordination of the individual measures, from design of airlocks to personnel clothing and gowning to personnel training and up to appropriate monitoring, is crucial for success and they must result in a coherent and coordinated overall concept. Accordingly, this webinar covers the core requirements:

- Requirements for personnel in the context of Contamination Control Strategy
- Air locks for Personnel
- Protective garments
- Qualification and Disqualification
- Gowning Qualification
- Monitoring of personnel

Target Audience

The webinar is aimed at managers and employees from the pharmaceutical and biopharmaceutical industries, who want to get a compact and comprehensive overview of the current requirements in the new Annex 1 with focus on personnel.

Speaker



Dr Bettina Rietz-Wolf
GMP Inspector for EMA and local Government, Germany

Dr Bettina Rietz-Wolf is pharmacist and GMP Inspector for the District Government of Baden-Württemberg and the EMA and performs GMP inspections worldwide. Bettina Rietz-Wolf was head of the nationwide expert group EFG3 "Manufacturing of sterile products".

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. 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

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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 "Annex 1 – Requirements for personnel in the context of the Contamination Control Strategy" on Thursday 17 September 2020, 14.00 – 15.30 h CEST, Speaker: Dr Bettina Rietz-Wolf

Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:

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Important:
Deadline is 12 noon on
16 September 2020

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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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