ECA Academy
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GMP Webinar
Annex 1 – New Requirements for Clean Rooms & HVAC Systems

Date:
Tuesday, 9 June 2020, 10.00 – 11.30 h CEST

Speaker:
Dr Jean Denis Mallet, Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS

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

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Background
Annex 1 of the EU GMP Guide "Manufacture of sterile medicinal products" is the most important guideline for sterile manufacturing of medicinal products. It is currently under revision with a first version having been published for public comments in 2017. After thousands of comments had been received a revised version was published in February 2020 which is now open for commentation by selected stakeholders. Many changes can be found in the new document especially when compared to the former official version of the Annex 1. This is also true for the premises, clean rooms and HVAC systems which are necessary to ensure aseptic/sterile conditions.

Educational Objectives
In this webinar it will be shown where the differences and new requirements are, compared to former versions of the EU GMP Annex 1:

Premises
- Supervision from outside the critical cleanrooms
- Clarification on the need for several airlocks and the related transfers
- Management of differential pressure (cascade or not)
- The importance of visualisation of the airflow patterns
- Disinfection of cleanrooms

HVAC-Systems
- Electronic particulate counting ... and microbial, too ?
- What is cleanroom classification, cleanroom qualification, cleanroom monitoring?

Equipment
- Anticipating the progressive disappearing of the classical clean rooms
- Sterilization or disinfection of equipment

Utilities
- More detailed requirements from the new Annex 1

Target Audience
The target group of this webinar are professionals in engineering, production and quality assurance responsible for setting up or operating GMP-compliant premises for the manufacture of sterile medicinal products.

Speaker

Dr Jean-Denis Mallet, Former head of the French Inspection Department AFSSAPS, Pharmaplan
Jean-Denis Mallet was previously the Head of the Pharmaceutical Inspection Department at the French Health Products Regulatory Agency (Afssaps=ANSM). He also used to work in or with the pharmaceutical industry at various positions including QA, Production, and Engineering. Now he works for Pharmaplan.

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 – New Requirements for Clean Rooms & HVAC Systems" on Tuesday, 9 June 2020, 10.00 – 11.30 h CEST
Speaker: Dr Jean Denis Mallet
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at 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 08 June 2020

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