ECA Academy
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GMP Webinar
Annex 1 – Revised Draft
A brief Summary

Date:
Thursday, 30 April 2020, 14.00 – 15.30h CEST

Speaker:
Dr Ingrid Walther, Pharma Consulting Walther,
Lead of ECA Annex 1 Task Force

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

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Background

The Annex 1 "Manufacture of Sterile Medicinal Products" of the EU GMP Guideline is currently under revision. A first draft of the revised version was published in 2017 and open for public comment, which lead to thousands of comments. In February 2020, a revised version has been published, which is open for review and comments by selected interest groups.

Educational Objectives

This webinar will update on the current status and give an overview of the modifications that have been implemented compared to the 2017 version. Furthermore, it will give some hints how review groups see the updates and which concerns are still persistent.

- General view of Review Groups
  - positive aspects
  - "difficult" aspects
- Specific requirements and aspects regarding (examples):
  - Barrier technologies
  - Cleanroom classification and qualification
  - Trending requirements in EM and personnel
  - Aseptic process simulation (media fills)
  - Quality control – sterility testing

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 Ingrid Walther, Pharma Consulting Walther, Former Head of the Business Unit iv Drugs and Oncology, Fresenius Kabi

Dr Walther was employed in various positions at Fresenius and has long years of experience in the fields of research and development, quality assurance/quality control and the management of strategic projects. In 1997 she assumed a position as head of the Business Unit Validation and GMP Compliance at Pharmaplan GmbH. Later she became responsible for consulting projects and became COO. In 2007, she re-joined Fresenius, heading the business unit Drugs & Oncology. Since July 2009 she works self-employed as GMP-Compliance Consultant.

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

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 plug-in. 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: "Annex 1 – Revised Draft - A brief Summary"
on Thursday, 30 April 2020, 14.00 – 15.30h CEST
Speaker: Dr Ingrid Walther
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 29 April 2020

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