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GMP Webinar

Annex 1 - Quality Risk Management using the example of the Contamination Control Strategy (CCS)

Date:
Thursday, 23 July 2020, 14.00 – 16.00 h CEST

Speaker:
Dr Franz Schönfeld, GMP/GDP Inspector, Government of Upper Franconia

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, which resulted in thousands of comments. A revised second version was published in February 2020 and is open for limited comment by selected stakeholders.

Educational Objectives

This webinar teaches the basics of quality risk management and its practical application using the example of contamination control (CCS Contamination Control Strategy) according to the current draft for the revision of Annex 1 of the EU GMP guidelines. It explains the importance and the networking of risk-minimizing measures in the areas of personnel, design and processes within the overall concept of avoiding microbial contamination for the efficient planning and production of sterile dosage forms. Accordingly, this webinar covers the core requirements for

- Quality Risk Management
- Contamination Control Strategy
- Personnel
- Design
- Process flows

Target Audience

This webinar is addressed to employees of pharmaceutical and biopharmaceutical manufacturers, authorities and suppliers with responsibility in
- Quality assurance and quality control
- Inspections and audits

or who are active in
- Sterile/aseptic production
- Contamination control and monitoring
- Process Simulation/Media Fill

Speaker

Dr Franz Schönfeld, GMDP inspector for EMA and local authorities, Germany

Dr Franz Schönfeld is currently a GMP and GDP inspector with the government of Upper Franconia. He is also head of the Expert Group (EFG) 7 for Active Pharmaceutical Ingredients and Excipients at the Central Authority of the Federal States for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) and member of the GMDP Inspectors Working Group at the European Medicines Agency (EMA) in Amsterdam. He also holds a teaching position at the University of Erlangen-Nuremberg.

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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 - Quality Risk Management using the example of the Contamination Control Strategy (CCS)"
on Thursday, 23 July 2020, 14.00 – 16.00 h CEST, Speaker: Dr Franz Schönfeld**
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at 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 22 July 2020

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