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GMP Webinar
Annex 1 - Container Closure Integrity Testing

Date:
Thursday, 20 August 2020, 14.00 – 15.30 h CEST

Speaker:
Matthias Schaar, Technical Steward Microbiology, Novartis Pharma


Image: Bosch

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

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de

Background

Container Closure Integrity in pharmaceutical sterile production is a requirement to maintain sterility of the drug product. After the USP chapter <1207> had a major update in 2017 with regard to testing methods and testing recommendations the new Draft of Annex 1 "Manufacture of sterile medicinal products" of the EU GMP Guide also implemented a more detailed discussion about Container Closure integrity testing. The first revised version published in 2017 resulted in discussions about testing strategies which leaded to a new revised version published in February 2020.

Educational Objectives

This webinar will give you a short overview about Container Closure requirements and method discussions and focuses the planned implementations in Annex 1 considering both drafts with regard to Container Closure 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

Matthias Schaar
Technical Steward Microbiology, Novartis Pharma

Matthias Schaar has a university degree of applied sciences in Biotechnology. He started his career in the Microbiological department in Novartis Pharma Stein in 2007. Since this time he was responsible to implement a Media Fill concept and environmental monitoring program in a new facility from a Quality Assurance perspective. Furthermore, he leaded a QC team within the microbiological department performing microbiological Container Closure Integrity tests, bioindicator incoming controls and sterile filter validations as well as taking care of microbiological infrastructure and qualifications. Also, he supported the production in qualification and validation of sterilization processes such as heat sterilization, ethylenoxid and gamma.

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 211,65
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
CONCEPT HEIDELBERG, P.O. Box 10 17 64, D-69007 Heidelberg,
Tel. +49(0)6221 / 84 44-0, Telefax +49(0)6221 / 84 44 34
info@concept-heidelberg.de, www.gmp-navigator.com

Do you have any questions?
For questions regarding content please contact:
Mr Axel H. Schroeder, Phone +49(0)6221 / 84 44 10,
Email: schroeder@concept-heidelberg.de

For questions regarding organisational aspects please contact:
Ms Isabell Neureuther, Phone +49(0)6221 / 84 44 49
Email: neureuther@concept-heidelberg.de

Registration for the GMP Webinar "Annex 1 - Container Closure Integrity Testing"
on Thursday, 20 August 2020, 14.00 – 15.30 h CEST
Speaker: Matthias Schaar
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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  ☐ 3-10 Persons
  ☐ 11-20 Persons
  ☐ more than 20 Persons

Important: Deadline is 12 noon on 19 August 2020

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