ECA Academy
Your GMP/GDP Information Source

Speaker

Arjan Langen
GE Healthcare, The Netherlands

Arjan Langen has over 20 years of experience within the field of pharmaceutical microbiology. He worked for several pharmaceutical and biotech companies (Nobilon, DSM, MSD) and had various local and global roles within QC, QA, manufacturing and auditing. Currently he is a Director Sterility Assurance at GE Healthcare, responsible for the global Sterility Assurance program. Besides he is a member of the ECA Annex 1 Task Force and of the Dutch Society of Pharmaceutical Microbiology. He is microbiologist by training, qualified IRCA/QCI auditor and Green Belt certified.

Risk Assessment in Contamination Control Workshop

From ICH to Annex 1 – Risk Evaluation as Part of Contamination Control Strategies

29 September 2023 | Barcelona, Spain

Image: HEIPHA Dr. Müller

Highlights

- ICH Q8, Q9 and Q10 Principles
- How to apply Risk Assessment in Contamination Control
- Example of a Contamination Control Strategy
- Short Interactive Session (Participants do an FMEA on a Certain Topic)

Risk Assessment in Contamination Control Workshop

Background & Objective

Risk-based approaches have gained considerably in importance in all branches in recent years. Pharmaceutical production, quality assurance and quality control would be unthinkable without them. Starting with the FDA initiative "cGMPs for the 21st Century" for the introduction of the risk-based approach, through the subsequent ICHQ9 guideline on risk management, which can now be found as Part III of the EU GMP guidelines, to the revised Annex 15 with a wealth of risk analyses, these principles are anchored everywhere. With the revision of Annex 1, risk management is also increasingly becoming part of the main guideline for the manufacture of sterile pharmaceutical products.

In this workshop on the principles, regulations and application of risk assessment in the context of contamination control, you will gain insight into the relevant underlying guidelines and guides as well as valuable pointers for practical implementation using practical examples.

The following areas are covered:

- General introduction on risk assessments
- ICH Q8, Q9 and Q10 principles
- How to apply risk assessments in contamination control
- Example of a Contamination Control Strategy
- Interactive session: FMEA

Target Audience

The workshop is designed for personnel of pharmaceutical companies, their suppliers and representatives of authorities with responsibilities in Contamination Control, Aseptic Manufacturing, Quality Assurance, Quality Control, Internal Quality Audits, External Inspections.

Programme

General Introduction on Risk Assessments

- Principles of ICH Q9
- Patient safety and product quality
- Dos and don'ts
- Tools and methods

ICH Q8, Q9 and Q10 Principles

- Quality by Design (QbD)
- Criticality of quality attributes and process parameters
- Control strategy life cycle
- Knowledge management

How to apply Risk Assessments in Contamination Control

- Pro-active vs. reactive
- FMEA for equipment and processes
- Risk assessments for impact assessments
- HACCP for contamination control

Example of a Contamination Control Strategy

- Contamination control master file
- Reference document
- Annual report

Short Interactive Session (Participants do an FMEA on a Certain Topic)

- Executing an FMEA (on a sterilizer or isolator)
- Evaluation – what went well and what were the challenges?

Date

Friday, 29 September 2023, 09.00 – 15.00 h
(Registration and coffee 08.30 - 09.00 h)

Venue

Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 (0)93 503 53 00
Email sants@barcelo.com

Fees (per delegate, plus VAT)

ECA Members € 990
APIC Members € 1,040
Non-ECA Members € 1,090
EU GMP Inspectorates € 545
The fee is payable in advance after receipt of invoice and includes lunch and all refreshments. VAT is reclaimable.

Save up to 400 € by booking both the **Contamination Control Strategies** conference on 27/28 September 2023 and the **Risk Assessment in Contamination Control post-conference workshop**!

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Please register online at **www.gmp-compliance.org.**

Presentations / Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG
P.O.Box 10 17 64, 69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0, Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Mr Axel H. Schroeder (Operations Director) at
+49(0)62 21/84 44 10, or at
schroeder@concept-heidelberg.de

For questions regarding organisation etc. please contact:
Ms Isabell Helm (Organisation Manager) at
+49(0)62 21/84 44 49, or at
helm@concept-heidelberg.de