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Live Online Training

Speaker

Arjan Langen
Director Sterility Assurance,
GE Healthcare, The Netherlands

Risk Assessment in Contamination Control

Live Online Training on 29 September 2022

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

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)

With live Q&A Session

Background/Objectives

Risk-based approaches have considerably gained 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 the new online course 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 course 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

Speaker

Arjan Langen,
Director Sterility Assurance,
GE Healthcare, The Netherlands

Arjan Langen has over 25 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 that works on the detailed review of the draft revision text of Annex 1. He is microbiologist by training, qualified IRCA/QCI auditor and Green Belt certified.

Programme

Introduction and Organisationals

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?

Evaluation and Conclusion / Q&A Session

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GERMANY

Reservation Form (Please complete in full)

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Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

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Date of the Live Online Training

Thursday, 29 September 2022, 09.00 – 15.30 h, CEST

Technical Requirements

We use WebEx Events for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 890
APIC Members € 950
Non-ECA Members € 990
EU GMP Inspectorates € 445
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering Recordings

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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