ECA Academy
Your GMP/GDP Information Source

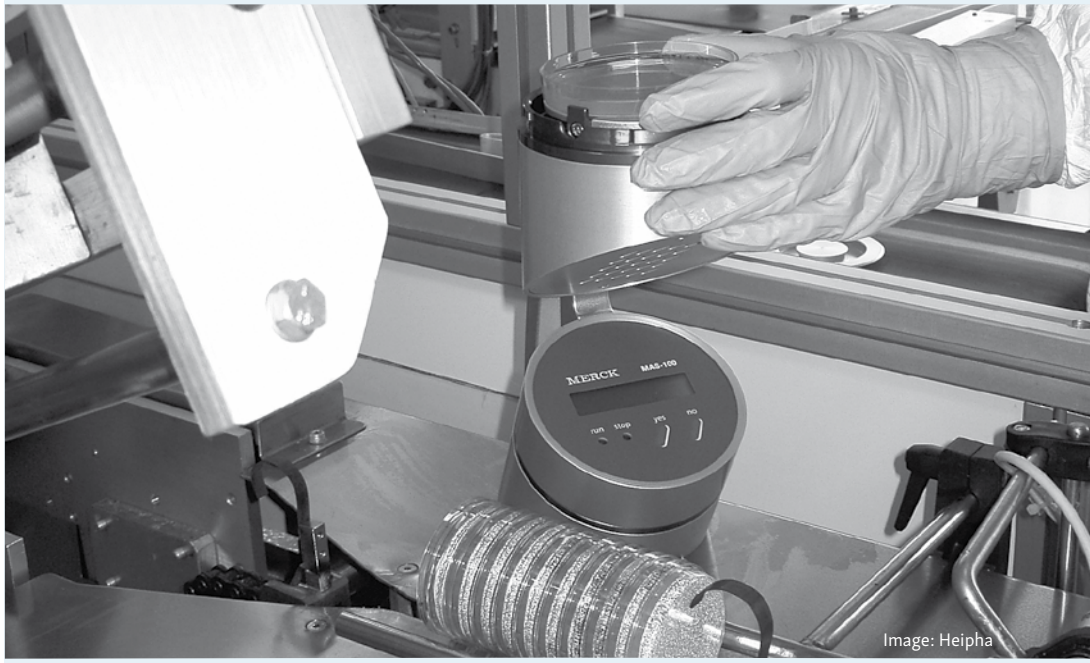
Live Online Training

Speaker

Arjan Langen
Director Sterility Assurance,
GE Healthcare, The Netherlands

Risk Assessment in Contamination Control

Live Online Training on 03 September 2020



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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

Programme

09.00 – 09.15 h
Introduction and Organisationals

09.15 – 10.00 h
General Introduction on Risk Assessments

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

10.00 – 10.45 h
ICH Q8, Q9 and Q10 Principles

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

10.45 – 11.00 h Break

11.00 – 12.00 h
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

12.00 – 13.00 h Break

13.00 – 13.30 h
Example of a Contamination Control Strategy

- Contamination control master file
- Reference document
- Annual report

13.30 – 14.30 h
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?

14.30 – 14.45 h Break

14.45 – 15.30 h
Evaluation and Conclusion / Q&A Session

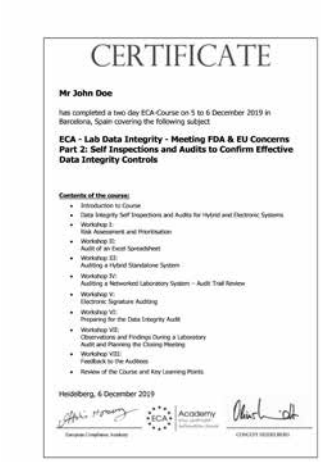
Speaker

Arjan Langen,
Director Sterility Assurance,
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 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.

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.



CERTIFICATE

Mr John Doe

has completed a two day ECA-Course on 5 to 6 December 2019 in Barcelona, Spain covering the following subject

ECA - Lab Data Integrity - Meeting FDA & EU Concerns Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls

Contents of the course:

- Introduction to Course
- Data Integrity Self Inspections and Audits for Hybrid and Electronic Systems
- Workshop I: Risk Assessment and Prioritisation
- Workshop II: Audit of an Excel Spreadsheet
- Workshop III: Auditing a Hybrid Standalone System
- Workshop IV: Auditing a Networked Laboratory System – Audit Trail Review
- Workshop V: Electronic Signature Auditing
- Workshop VI: Preparing for the Data Integrity Audit
- Workshop VII: Observations and Findings During a Laboratory Audit and Planning the Closing Meeting
- Workshop VIII: Feedback to the Auditees
- Review of the Course and Key Learning Points

Heidelberg, 6 December 2019

ECA Academy

Learning based on Videos from Pharma and API Operations

More than 300 companies in 30 countries use GMP eLearning in 12 different languages.

Videos from Real Life

Quite frequently eLearning is based on a lot of text and is very theoretical. Contrary to these systems GMP eLearning consistently uses videos that were produced at various pharma companies (as e.g. Boehringer Ingelheim). In total there are more than 10 hours of video/training materials.

- Based on real life examples you can see how work needs to be done to be GMP compliant and examples for how GMP problems arise.
- You will learn what the reasons are for these arising GMP problems and you will be trained how to behave correctly in the following video.

Applying GMP with Real Life Situations

Videos from real life examples demonstrating GMP situations (as e.g. production processes, cleaning procedures) also facilitate the learning process. Following short video sequences you will need to answer questions. Specifically in the section "Learning" you will need to answer further questions strengthening the learning effect. If your answer is incorrect you will get an explanation why. In the section "Testing" it is tested whether you understood the conveyed contents.

Simple Navigation – Compiling individual Topics/Trainings

The GMP eLearning courses comprise many hours of video materials. From these materials you can either select complete course modules or single chapters. That way you can train the cleaning staff exclusively with the chapters on cleaning and staff in the warehouse with the specific GMP regulations for their area of responsibility.

Please see the website for detailed information:
https://www.gmp-elearning.com/

If the bill-to-address deviates from the specifications on the right, please fill out here:

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GERMANY

Reservation Form (Please complete in full)

Risk Assessment in Contamination Control - Live Online Training on 03 September 2020

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

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
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CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Thursday, 03 September 2020,
09.00 – 15.30 h CEST

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.

Fees (per delegate, plus VAT)

ECA Members € 890
APIC Members € 950
Non-ECA Members € 990
EU GMP Inspectorates € 445

The conference 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 a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can book the recording of the Live Online Training at any time at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

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