ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Franz Schönfeld,
District Government of Upper Franconia, Germany
Dr Franz Schönfeld is a GMP and GDP inspector at the local inspectorate for medicinal products and active substances of the District Government of Upper Franconia. He is head of the expert working group for APIs at the Central Authority of the Federal States for Health Protection.

Katharina Stoib,
QC MEC, Roche Diagnostics, Germany
Katharina studied at the University for Applied Sciences Weihenstephan. In the past she worked for Hexal and Acino. She joined Roche in 2012 as QA engineer. After positions as manager QA and as Deployment Lead Quality Management Systems she became in 2021 Manager Quality Control Microbiology and in 2022 she took over the additional position as Site Implementation Lead for Annex 1 in Penzberg.

Dr Ingrid Walther,
Walther Pharma Consulting, Head of the ECA Annex 1 Task Force
Dr Walther joined Fresenius AG in 1986. She was employed in various positions and has long years of experience in the fields of R&D, QA/QC and the management of strategic projects. In 1997 she assumed a position as head of the Business Unit Validation and GMP Compliance at Pharmaplan GmbH. In a subsequent position at Pharmaplan, she became responsible for consulting projects and became COO. In 2007, she re-joined Fresenius, heading the business unit iv Drugs & Oncology. Since July 2009 she runs her own business as consultant.

ECA Contamination Control Strategy Guide

How do I use the CCS template in practice?

Live Online Training on 27 March 2024

Free of charge for registered Participants of the PharmaCongress 2024

Highlights

- Regulatory Expectations
- Structure and Scope of the CCS Guide
- How to use the CCS Template
- Use of the Guide and Template with Integration of Existing Risk Assessments and SOPs

Objectives

In addition to the regulatory expectations and the general structure and application of the ECA Contamination Control Guide, this workshop explains how to use the included template for a CCS document and examples for the practical creation of a CCS document. Practical experience will be shared how to use the template to integrate your existing system of contamination control measures and how to evaluate possible gaps.

Background

The final revision of EU GMP Annex 1 contains, among many other innovations and additions, a clear requirement for a contamination control strategy. This refers to a series of measures to control microbial load, pyrogens and particles, derived from the current product and process understanding, implemented to ensure process performance and product quality. The Contamination Control Strategy should include parameters and attributes related to APIs, excipient and drug product materials and components, facility and equipment operating conditions, in-process controls, final product specifications and associated methods and frequency of monitoring and control. A total of 16 elements to be considered is listed in Annex 1.

The requirement in the current Annex 1 for a CCS is the first time that an overarching concept has to be in place and been demanded of manufacturers that integrates the various contamination control measures into a coordinated concept. This concept considers these measures, which are often the responsibility of different areas of the company such as production, quality assurance or quality control, in their entirety. This takes account of the fact that these measures and individual concepts interact with each other and that changes often have an impact on other areas. Like a butterfly effect.

Therefore, the ECA has prepared a guiding document to support you in drawing up such a contamination control strategy. It can be used for both, the coordination of measures for an existing plant and for the creation of a CCS for a new plant.

Target Audience

The workshop is aimed at all employees of the pharmaceutical industry who are involved in the preparation of a CCS and also at representatives of the regulatory authorities, involved in the inspection of the fulfilment of such requirements.

Programme

Inspector's View on a CCS

- Requirements of Annex 1
- Inspector´s expectations
- Implementation: CCS integration in existing environment

The CCS Template – Practical Use Part 1

- The aim of the Guideline
- Structure of content structure in connection with Annex 1
- Structure of the Template/Attachment3

The CCS Template – Practical Use Part 2

- Practical Use - Filling in the Template
- Gap-assessment based on the Template
- Ready to present your CCS

Case Study: Use of the Guide and Template with Integration of Existing Risk Assessments and SOPs

- Practical use of the CCS Guide
- Evaluation of existing relevant documents
- Building an hybrid CCS by integrating existing Risk Assessments and SOPs

Date of the Live Online Training

Wednesday, 27 March 2024,
11.00 – 16.30 h CET

Technical Requirements

We use Webex 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 € 590
APIC Members € 640
Non-ECA Members € 690
EU GMP Inspectorates € 345
The fee is payable in advance after receipt of invoice.

Participants of the Pharma Congress 2024 can take part in this Live Online Training FREE OF CHARGE!

Registration

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.

Organisation and Contact

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