ECA Academy
Your GMP/GDP Information Source

Speakers

Walid el Azab
Lead of the ECA CCS Task Force,
Steris Corporation, Belgium

Dr Rainer Gnibl
GMP Inspector, Government of
Upper Bavaria, Germany

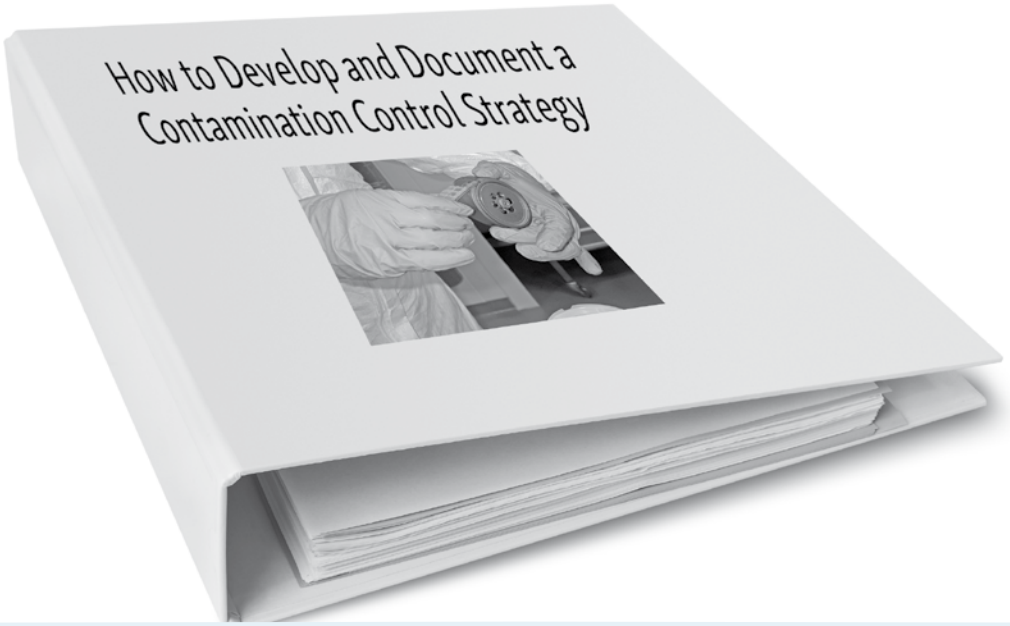
Isabelle Hoenen
Lilly, France

Robert Schwarz
FH Campus Vienna, Member of the
ECA CCS Task Force, Austria

Dr Ingrid Walther
Pharma Consulting Walther,
Head of the ECA Annex 1 Task Force,
Germany

The ECA Contamination Control Strategy Guide – How to use!

Live Online Training on 26 April 2022



A requirement of the revised Annex 1

Highlights

- Regulatory Expectations
- Relevant Guidelines and Documents
- Structure and Scope of the CCS Guideline
- GAP Analysis
- How to use the CCS Template
- Panel Discussion and Q&A

Free of charge for registered participants of the PharmaCongress 2022

Programme

Objective

In addition to the regulatory expectations and the general structure and application of the ECA's Contamination Control Guideline, this workshop explains how to use the parts and examples for the practical creation of a CCS and how to use it to integrate your existing system of measures and evaluate possible gaps.

Background

The latest draft of the revision of EU GMP Annex 1, among many other innovations and additions, contains the following statement:

"Contamination Control Strategy (CCS) - A planned set of controls for microorganisms, pyrogens and particulates, derived from current product and process understanding that assures process performance and product quality. The controls can include parameters and attributes related to active substance, excipient and drug product materials and components, facility and equipment operating conditions, in- process controls, finished product specifications, and the associated methods and frequency of monitoring and control."

With the requirement of the revised Annex 1 for a "Contamination Control Strategy", for the first time an overarching concept is demanded from the manufacturers that the various measures of contamination control are integrated into a coordinated concept that 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 into account the fact that these measures and individual concepts interact with each other and that changes often have an impact on other areas.

The ECA has therefore produced a guide to help you draw up such a Contamination Control Strategy. It is usable to coordinate measures of an existing plant as well as to create 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 who are involved in the inspection of such requirements.

Moderator

Axel H. Schroeder, Concept Heidelberg

Programme

Inspectors View on a CCS
Dr Rainer Gnibl, Government of Upper Bavaria

- Requirements from Annex 1
- Inspector's expectations
- Implementation: CCS integration in existing environment

Beyond Annex 1 - Helpful Regulatory Documents for CCS
Robert Schwarz, FH Campus Vienna

- The EU-GMP Guideline itself
- FDA regulations
- Best practice papers

The ECA Guide – Structure and Use
Walid El Azab, Steris, Chair ECA CCS Task Force

- Multidisciplinary team work approach
- Guide scope & purpose
- Structure & use

Approach for a Gap Analysis
Isabelle Hoenen, Lilly

- Content structure
- Analysis
- Points to consider

The CCS Template – Practical Use
Dr Ingrid Walther, Chair ECA Annex 1 Task Force, Pharma Consulting Walther

- Content structure in connection with Annex 1
- Practical Use - Filling in the Template
- Ready to present your CCS

Speakers

Walid el Azab
Steris Corporation, Lead of the ECA CCS Task Force, Belgium
Walid El Azab is an Industrial pharmacist, a Qualified Person and Lean Six Sigma green belt. He provides technical support related to cleaning, disinfectants and sterility assurance.

Dr Rainer Gnibl
GMP Inspector, Government of Upper Bavaria, Germany
Dr Rainer Gnibl is EU-GMP inspector in Germany and performs GMP inspections worldwide also on behalf of the European Medicines Agency (EMA).

Isabelle Hoenen
Lilly, France
Isabelle received her Doctorate in Pharmacy and Master's Degree in Industrial Microbiology from the University Louis Pasteur, Strasbourg in 1994. Prior to Lilly, she worked as an aseptic practices trainer at Rhone Poulenc Rorer near to Paris. In 1995, Isabelle joined the Quality Department at Lilly Fegersheim where she occupied several roles including Environmental Monitoring Team Leader, Sterility Assurance Specialist, Project Leader, Quality Lead for a Global Worldwide Cartridge lines implementation program. Since June 2017, Isabelle works as Quality Consultant for Sterility Assurance, providing deep compliance and technical expertise during site and global assessments, projects, investigations, technical audits, regulatory inspections and new requirements. Isabelle is also active in several technical and scientific industries associations such as A3P, PHSS, PDA, EFPIA, LEEM (with among other topics, special interest on the new revision of the EU GMP Annex 1).

Robert Schwarz
FH Campus Vienna, Member of the ECA CCS Task Force, Austria
Robert has 20 years hands-on experience in aseptic processing, contamination control and cleanroom technology. He graduated in bioengineering and biotechnological quality management and joined Baxter, Vienna in 2001 where he led the environmental monitoring team 4 years. 2005 - 2018 he gathered more in-depth knowledge of GxP compliance incl. profound quality assurance expertise in his function as validation specialist being responsible for equipment qualification, sterilization validation and cleaning validation (with an SME function since 2016) at Baxter and Shire. Since 2010 he additionally shares his experience as a university lecturer. Additionally he is frequently spotted as a speaker at congresses and conferences and recognized as a contributor in various scientific publications. In 2019 he started his business as freelancing trainer and consultant.

Dr Ingrid Walther
Pharma Consulting Walther, Head of the ECA Annex 1 Task Force, Germany
Dr Walther joined Fresenius AG in 1986. She was employed in various positions and has long years of experience in the fields of research and development, quality assurance/ quality control 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.

Additional Panelists from the CCS Task Force

Luigi Scaffidi, Boehringer Ingelheim
Dr Christine Arbesser-Rastburg, formerly Takeda
Vimal Sachdeva, WHO
Arjan Langen, GE Healthcare

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Live Online Training on 26 April 2022

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Date of the Live Online Training
Tuesday, 26 April 2022, 13.00 – 17.30 h CEST

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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 PharmaCongress 2022 can register free of charge for this Live Online Training!

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

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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.

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The official conference language will be English.

Your Benefit: 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.

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