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GMP Certification Programme
Certified Technical Operations Manager

Speakers

Nikolaus Ferstl
Facility Engineering Services

Dr Markus Keller
Fraunhofer Institute for Manufacturing Engineering and Automation (IPA)

Robert G. Schwarz
GXP TrainCon, Vienna

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Cross Contamination Control

Implementation of a Cross Contamination Control Strategy

Live Online Conference on 27/28 May 2025

Highlights

- Regulatory Requirements: Contamination Control Strategy & Cross Contamination
- Sources of Cross Contamination
- Containment Solutions - Avoiding Exposure - Minimizing Cross Contamination
- Segregation of Material & Processes
- Cross Contamination through poor Organisation
- Cross Contamination through poor HVAC Design
- Cross Contamination through poor Equipment Design
- Cleaning & Cleaning Validation
- Relevant Documentation: CCS, HBEL, QRM

Objective

This GMP training aims at unveiling possible risks of cross contamination during the production process of pharmaceutical products and APIs. This is especially important for patients' safety, product quality and to be in compliance with chapters 3 and 5 of the EU GMP regulation as well as the new EU GMP Annex 1. The prevention of cross contamination is part of the contamination control strategy and has to be documented accordingly, taking into consideration QRM principles according to ICH-Q9.

You will learn

- how to detect possible risks
- how to avoid cross contamination
- how to prove the avoidance of cross contamination
- how to document a regulatory compliant strategy

Background

Cross Contamination is one of the highest risks for patients using pharmaceutical products. Not only the presence of small amounts of antibiotics or other highly potent compounds in medicinal products can cause severe damage, but also carryover of one product into another pharmaceutical product is of high risk to the patient. According to the Medicines & Healthcare Products Regulatory Agency in the United Kingdom for example, product contamination is the second to third highest reason for recalls in the UK in recent years.

The EU commission already reacted on that in 2015 by updating the chapters 3 (premises & equipment) and 5 (production) with the focus on minimizing the risk of cross contamination. Already three years before a new EMA Guide on setting health-based exposure limits was published. This new guide has massive impact on the dedication of facilities and also on the calculation of limits for cleaning validation. Limits for the maximum carryover now have to be calculated by considering the toxicological/pharmacological properties of each single product, answering the question: how much cross contamination is allowed. The latest document addressing cross contamination is the revised EU GMP Annex 1. It contains several paragraphs dealing with cross contamination and contamination in general which includes a risk-based Contamination Control Strategy (CCS) aligned with Quality Risk Management principles according to ICH Q9.

Reasons for cross contamination can be manifold and caused by technical as well as organisational deficiencies. Insufficient cleaning of equipment, poor facility design or inappropriate design of the HVAC system may be reasons as well as contamination via personnel or primary packing material. But also, the design of the production process itself can be the cause for cross contamination, for example due to open product handling during transfer or sampling operations in shared plants without adequate measures.

It is therefore extremely important to mitigate the risk of cross contamination, starting already at the design phase of processes and equipment. In addition, it is essential to understand how contamination risks can be detected.

Some measures include quality oversight walks in production areas or reviewing the documents (SOPs, technical drawings, etc.) already during process development, design qualification and additionally on a regular basis which has to be predefined.
This mitigation of cross contamination risks should be included and regularly reviewed – and updated if required – as part of the contamination control strategy (CCS) which has to be documented accordingly.

Target Audience

This training is aimed at production, QA and engineering departments of pharmaceutical companies to maintain product quality and patient safety in a regulatory compliant production life cycle. Suppliers for the pharmaceutical industry are also addressed in order to better understand the requirements of their customers.

Moderator

Robert G. Schwarz

Programme

Regulatory Requirements: Contamination Control Strategy & Cross Contamination

- The view of EMA
- The view of US-FDA
- Shared facilities regulations
- Contamination and sterile products

Sources of Contamination – Modes of Cross Contamination – Segregation

- Do different sources mean different impact?
- Where cross contamination could occur and different likelihoods
- Is segregation a no brainer?
- Cross contamination in Biotech

Containment Solutions – Avoiding Exposure – Minimizing Cross Contamination

- Exposure and how to calculate
- Equipment and containment concepts
  - Closed product handling
  - Sampling
  - Material transfer
- The PDE/ADE concept: how much contamination is allowed?
- Avoiding of cross contamination
  - Air born contamination
  - Contamination of surfaces
- Verification of the tightness of a containment system

Cross Contamination through poor Organisation

- Organisational points to consider
- The human factor
- The importance of training and motivation

Cross Contamination through poor HVAC Design

- Airborne particles
- Pressure / hygienic zones – maintaining over pressure
- The clean corridor concept
- Simulation and visualisation of air flow
- Classification of ventilation systems
- Concepts for HVAC systems
- Components of AHUs (filters, Duct work, etc...)
- Classification and change of filters
- Control and monitoring strategies

Cross Contamination through poor Equipment Design

- Cleanability of equipment as the key to avoiding cross-contamination
- In-line cleanability? – Cleanability for parts that are disassembled?
- Importance of drainability (cross-contamination by product and detergent residues)
- Gap-free and dead-space-free design of system components
  - Components (connections, valves, pumps, sensors)
  - Mixing and preparation vessels, bioreactors
- Cross-contamination due to lack of technical support
  - Deterioration of surface quality
  - Wear of static and dynamic seals

Cleaning & Cleaning Validation

- Poor cleaning – main reason for cross contamination
- Dealing with multipurpose strategies in cross contamination control
- Cross Contamination – main focus of cleaning validation

Documentation: CCS, HBEL assessment, QRM

- Cross contamination control and CCS
- HBEL – from the environmental risk to patient's risk
- Cross contamination control – it is all about QRM

Speakers

Nikolaus Ferstl
Facility Engineering Services

Nikolaus Ferstl has a bachelor degree in mechanical engineering. He has been working for M&W (former LSMW), for example as Senior Project Manager and as deputy head of the subsidiary in Vienna. From 2009 to 2024, he was Technical Director of the University Hospital Regensburg and a freelance consultant for building and cleanroom technology. Today, he is Managing Director of the Facility Engineering Services GmbH.

Dr Markus Keller
Fraunhofer Institute for Manufacturing Engineering and Automation (IPA)

Dr Markus Keller is a biologist and project manager at the Fraunhofer Institute for Manufacturing Engineering and Automation (IPA), Department of Cleanroom and Microproduction. His area of expertise includes the qualification of plants with regard to their cleanroom suitability.

Robert G. Schwarz
GXP TrainCon, Austria

Robert Schwarz, graduate in "Bioprocess Engineering" and "Biotechnological Quality Management", was responsible for environmental monitoring as well as validation of decontamination systems at Baxter (now Shire. Since 2010 he is working as a lecturer in the field of biotechnology with a focus on validation/qualification, aseptic process methods and cleanroom technology at the University of Applied Sciences Vienna.

Dr Harad Stahl
GEA

Dr Harald Stahl worked in the Pharmaceutical Development of Schering AG in Germany. Since 1995 he served within GEA Process Technology in various positions. Presently he owns the position of a Group Director Application & Strategy Management of GEA. He has published more than 20 papers on various aspects of pharmaceutical production.

Your Benefit

This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

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Reservation Form (Please complete in full)

Live Online Training: Cross Contamination Control
27/28 May 2025

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)

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If you cannot attend the conference you have two options:
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German law shall apply. Court of jurisdiction is Heidelberg.

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Date Live Online Training
Tuesday, 27 May 2025,
09.00 to approx. 17.00 h
Wednesday, 28 May 2025,
09.00 to approx. 15.00 h
All times mentioned are CEST.

Technical Requirements
We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events 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 EUR 1,890
APIC Members EUR 1,990
Non-ECA Members EUR 2,090
EU GMP Inspectorates EUR 1,045
The conference fee is payable in advance after receipt of invoice.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21607.

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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