ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Validation Manager

Speaker

Robert Schwarz
FH Campus Vienna, Austria

Cleaning Validation

Live Online Training on 9/10 September 2021

Highlights

- Regulatory Requirements
- Hygienic Equipment Design
- Cleaning Process Development
- Cleaning Validation, incl. Practical Approaches
- Sampling
- Handling Deviations and OOS
- Segregation and Shared Facilities
- Cleaning Validation in Biologics and Biotech Production

New: with 2 interactive live workhops

Background

In the manufacture of medicinal products and APIs, the cleaning of facilities and equipment is an important measure to avoid contamination and cross contamination. In compliance with the GMP regulations, cleaning is performed and documented according to the described procedures. In the past, cleaning effectiveness was often monitored only visually. However, residuals of APIs and excipients as well as of detergents are increasingly an issue in inspections and audits. The success of cleaning procedures has to be validated. In addition to the FDA "Guide to Inspection – Validation of Cleaning Validation Processes", the PIC/S document PI 006 and Annex 15 address cleaning validation in a separate chapter. Moreover, the ICH Guideline Q7 "GMP for APIs" also requires cleaning validation – as well as two guidelines by APIC, the association of European API manufacturers.

A Guideline from EMA on Dedicated Facilities and Exposure Limits for Cleaning Validation and the revised Annex 15 deal now with a PDE (Permitted Daily Exposure) approach

Objective

Many questions relative to cleaning validation are still open and have to be answered within the companies:

- How should the cleaning validation concept look like to be GMP-compliant and cost-effective?
- Which risk analyses are applicable to cleaning validation?
- How helpful can a riboflavin test be?
- Which maximum value is scientifically acceptable, especially in the field of APIs?
- Which sampling procedure is appropriate for which process and facility?
- How can you cut costs by means of bracketing?
- How are critical areas defined?
- Is cleaning evaluation the solution for infrequently manufactured products?
- Which microbiological maximum values are valid in the areas of non-sterile dosage forms and APIs?
  and
- What are special aspects of cleaning validation in biotech API plants?

These questions will also be discussed with the help of practical examples.

Target Audience

This course is directed at staff of R&D, production and quality assurance involved in cleaning validation. It also addresses engineering companies and manufacturer of cleaning devices/equipment interested in learning more about the pharmaceutical industry's viewpoint and in exchanging experiences.

To ensure a high quality transmission the presentations of this seminar was recorded in advance.

Q & A sessions
Four Q &A sessions (two on day 1 and on day 2) ensure interaction and that your questions are answered

Programme

Day 1

Regulatory Requirements

- EU GMP Guideline Part I, II and III
- EU GMP Guideline Annex 15
- EMA "Shared Facilities Guideline" (incl. PDE concept)
- PIC/S PI 006
- APIC Cleaning Validation Guidance for APIs
- PDA TR 29 – "Points to Consider for Cleaning Validation
- FDA 21 CFR 211.67
- FDA Guide to Inspection – Validation of Cleaning Processes

Practical Pre-Requisites I – Hygienic Equipment Design

- What is hygienic design?
- Material aspects
- WIP/CIP aspects
- Riboflavin test

Practical Pre-Requisites II – Cleaning Process Development

- Developing a cleaning process – which steps are necessary?
- TACT
- Which residues are common
- Type and selection of cleaners
- CIP vs WIP vs manual cleaning
- Cleaning Documentation

Cleaning Validation – incl. Practical Approaches

- Cleaning Validation Concepts
  - Bracketing
  - Hold time studies (DHT, CHT)
- Cleaning Validation Risk Management
- Cleaning Validation Plan
- Cleaning Validation Report
- Cleaning Validation life cycle (Revalidation, Ongoing Cleaning Verification)
- Cleaning Evaluation

Day 2

Sampling during Cleaning Validation

- How to define sampling points?
- Sampling techniques
  - Swab
  - Rinse
  - Coupons
- Analytical requirements

Live Workshop – Setting Sampling Points

- Setting sampling points on a risk-based approach – what to consider
- Sampling point selection based on sampling technique and analytical method
- Different sampling points for different purposes

Handling Deviations and OOS during Cleaning Validation and Ongoing Cleaning Verification

- What is an OOS, what a deviation regarding Cleaning Validation?
- GMP-compliant documentation of OOS and deviations
- CAPA

Live Workshop – Case studies of Non-Conformities during Cleaning Validation and Ongoing Cleaning Verification

- Is always the cleaning process to blame?
- Which actions are adequate based in the investigation and root cause?
- Actions dfepending on the time-point of detecting the Non-Conformity
- Does a Non-Conformity mean revalidation?
- Does a Non-Conformity always lead to batch rejection?

Special Topics of Cleaning Validation

- Segregation & shared facility guideline
- Cleaning Validation in Biologics & Biotech production
  - Differences between chemical and biotech APIs
  - Acceptance criteria for biotech APIs
  - Analytical methods to detect biotech APIs in Cleaning Validation

Speaker

Robert Schwarz
FH Campus Vienna, 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's 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.

GMP and GDP In-house Training Programme

What are GMP/GDP In-house Training Courses?
GMP/GDP in-house Training Courses are an ideal solution and a cost-effective way to train a larger number of people (ten or more) than you would normally want to send to an external course. You determine date and time, and the training is provided in your premises – or, alternatively, online, as most of the trainings can also be conducted via Internet.

Why GMP/GDP In-house Training?
Our GMP/GDP in-house trainings help your employees to put the GMP/GDP requirements into practice, to understand why they have to observe GMP/GDP rules and to develop a positive attitude towards GMP/GDP. In discussing of questions, your staff becomes familiar with the GMP/GDP rules, and solutions to concrete problems are found.

The courses you can choose from
Training content depends on your individual needs and ideas. A course can take into account the specific situation in your company and considers the latest GMP publications. Then both the training course's content and structure are tailored to the target group - also considering group-dynamic effects.

Now online
Almost all of our in-house trainings can also be conducted online. This allows for maximum flexibility since your employees can take part in the same session no matter where they are located.

Please visit our website www.gmp-compliance.org for more information.

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Reservation Form (Please complete in full)

Cleaning Validation - Live Online Training on 9/10 September 2021

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 of the Live Online Training

Thursday, 9 September 2021,
09.00 h – 17.00 h
Friday, 10 September 2021,
09.00 h – 16.30 h

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 € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
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.

Organisation and Contact

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

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