ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Validation Manager

Speaker

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Cleaning Validation

Current GMP for Cleaning Validation

Live Online Training, 28/29 April 2026

Post-Course: Impact of Annex 1 Revision on Cleaning Validation

Live Online Training, 30 April 2026

Highlights

- Regulatory Requirements
- Impact of Annex 1 Revision on Cleaning Validation (as optional Post-Course)
- Hygienic Equipment Design
- Cleaning Process Development
- Sampling
- Cleaning Validation, incl. Practical Approaches
- Handling Deviations and OOS
- Segregation and Shared Facilities
- Cleaning Validation in Biologics and Biotech Production

Main Course: Cleaning Validation

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.

The Annex 1 revision and its Contamination Control Strategy (CCS) also has an impact, especially on Cleaning Validation for sterile dosage forms.

Objective

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

- What 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 residue value is scientifically acceptable?
- 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 verification the solution for infrequently manufactured products?
- Which microbiological maximum residue 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

The Main Course and the Post-Course are directed at staff of R&D, production and quality assurance involved in cleaning validation. They also address engineering companies and manufacturers of cleaning devices/equipment interested in learning more about the pharmaceutical industry's viewpoint and in exchanging experiences.

Programme

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"
- ISPE Cleaning Validation Life Cycel – Applications, Methods, and Controls
- 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

Sampling during Cleaning Validation

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

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

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

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 on the investigation and root cause?
- Actions depending 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

Post-Course: Impact of Annex 1 Revision on Cleaning Validation

Background

The Annex 1 Revision of is in operation since 25 August 2023. The new Contamination Control Strategy (CCS) affects also the Cleaning Validation.

Objective

With the revised version of Annex 1 that became effective in August 2023, this course aims at giving you an overview of important changes that impact cleaning and Cleaning Validation which may not be seen at the first glance. As integral topic of the new Contamination Control Strategy (CCS), it will also be in the main focus of authorities during inspections of sterile medicinal products. Some of the strategies in Annex 1 may even become "state of the art" for non-steriles in the upcoming years. This is already explicitly mentioned in the scope of the new Annex 1. It will be elaborated how to align your Cleaning Validation strategy with this, highlighting points to consider when implementing those changes in requirements into your daily Cleaning Validation business.

Programme

With the Post-Course we cover:

- Regulatory requirements of Annex 1 regarding Cleaning Validation & Cleaning (incl. potential topics stated "between the lines")
- Annex 1, Annex 15 and EMA "Shared facilities Guideline" – harmonized, extended requirements or even contradictions!?
- Annex 1 & Cleaning Validation – practical approaches

Q & A sessions

Five Q &A sessions (two on day 1 and on day 2 of the main course and one in the post course) ensure interaction and that your questions are answered.

Speaker

Robert G. 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 for 4 years. From 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 has been additionally sharing 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 freelancer and founded his consulting company GXP-TrainCon in 2022.

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.

Dates of the Live Online Events

Main Course: Cleaning Validation
Tuesday , 28 April 2026, 09.00 – 17.00 h (CEST)
Wednesday , 29 April 2026, 08.30 – 16.30 h (CEST)

Post-Course: Impact of Annex 1 Revision on Cleaning Validation
Thursday, 30 April 2026, 09.00 – 12.30 h (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)

Main Course: Cleaning Validation

ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice.

Post-Course: Impact of Annex 1 Revision on Cleaning Validation

ECA Members € 590
APIC Members € 690
Non-ECA Members € 790
EU GMP Inspectorates € 395
The conference fee is payable in advance after receipt of invoice.

We will offer you a **discount of € 200** if you book both training courses together.

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 22432. To avoid incorrect information, please give us the exact address and full name of the participant.

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.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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

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P.O. Box 101764
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Main Course: Cleaning Validation

☐ *28/29 April 2026*

Post-Course: Impact of Annex 1 Revision on Cleaning Validation

☐ *30 April 2026*

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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