ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Validation Manager

Speakers

Dr Martina Breuer
Haupt Pharma Münster GmbH, Germany

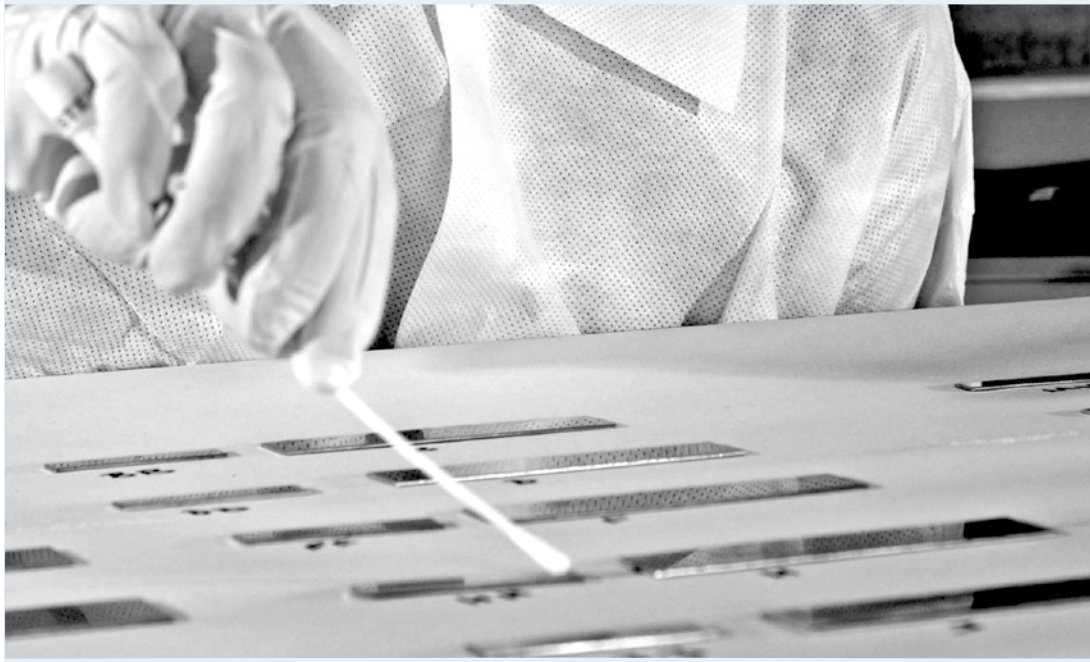
Walid El Azab
STERIS Corperation, Belgium

Peter Mungenast
Merck, Germany

Robert Schwarz
FH Campus Vienna, Austria

Cleaning Validation

03/04 September 2020, Hamburg, Germany



With 4 Parallel Workshops

Highlights

- APIs and Pharmaceuticals
- Cleaning Validation Concepts
- Cleaning validation protocol and report
- Risk Management
- Pitfalls and findings in inspections/Warning Letters
- Is cleaning evaluation accepted by GMP
- Special Aspects of Cleaning Validation
- Validation of holding times
- Acceptance Criteria: PDE vs others
- Technical and Organisational Aspects on Equipment
- Cleaning Validation in Biotech API Plants

Free Download: ECA's Good Practice Guide „Integrated Qualification and Validation"

Programme

Objective

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

Background

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

- What does the cleaning validation concept have to 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 seldom manufactured products?
- Which microbiological maximum values are valid in the areas of non-sterile dosage forms and APIs?
  and
- 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 interested in learning more about the pharmaceutical industry's viewpoint and in exchanging experiences.
Note: The number of participants is limited.

Accessories: Please bring along a pocket calculator.

4 Parallel Workshops

4 Parallel workshops, concentrating on medicinal products, chemical and biological manufactured APIs, and about the organisation of cleaning validation guarantee the practical orientation.

Please choose your workshop when registering.

Programme

Cleaning validation landscape from start to end

- Cleaning design and processes
  - Type and selection of cleaners
  - Soil residue evaluations (Worst Case selection)
- Determination of the critical parameter (SMART objective)
- Sampling selection based on a risk-based assessment
- Cleaning documentation life cycle

Cleaning Validation Concepts

- Introduction of relevant Guidelines
- CV Concepts
- CV Risk Management
- CV Plan
- CV Report
- CV Revalidation, CV Verification
- Typical inspection findings, warning letters

Cleaning Validation in Biotech API Plants

- What is different between chemical and biotech APIs?
- Acceptance criteria for biotech APIs
- What is the adequate analytical method to detect biotech APIs in cleaning validation

Special Aspects of Cleaning Validation

- Acceptance criteria
- Cleaning methods: CIP, WIP, manual cleaning
- Random Controls
- Hold time studies: DHT, CHT
- Validation of analytical methods used for CV

Cleaning Evaluation and Validation in Chemical API Production

- Differences regarding cleaning in API production to the production of medicinal products
- The challenges of API production
  - Acceptance criteria
  - Adequate sampling
- Is cleaning evaluation accepted by GMP?

Technical and Organisational Aspects on Equipment Regarding Cleaning Procedures

- Design and material aspects
- Requalification
- CIP aspects
  - Riboflavin test
  - Maintenance

How to write a Cleaning Validation Protocol

- Team and project validation creation (benchmarking best practice)
- GMP requirements and best practice for a protocol redaction and content
- Quality attribute to be tested for non- and sterile manufacturing
- Sampling and analysis methods overview
- Examples through a case study – validation and implementation in routine

Social Event

In the evening of the first day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers

Dr Martina Breuer
Haupt Pharma Münster GmbH

Martina Breuer studied pharmacy at the University in Munster. She has more than 20 years experience in pharmaceutical industry and was employed in various positions in Quality control, Production and in Quality assurance. Since 2008 she is Head of Quality assurance at the Aenova site in Munster responsible for the quality system to be compliant with EU-GMP and CFR requirements.

Walid El Azab
STERIS Corperation, Belgium

Walid El Azab is a Technical Services Manager for the Life Sciences Division of STERIS Corporation. He currently provides technical support related to cleaning chemistries, disinfectants and sterility assurance products and their application and validation. His areas of expertise include both upstream and downstream biopharmaceutical operation and validation. Walid has held various positions including Project Manager, Inspection Readiness Manager, Quality and Regulatory Manager, and Qualified Person (QP). Walid earned a Master's degree in Industrial Pharmaceutical Sciences from the University of Liege, Belgium and is green belt certified.

Peter Mungenast
Merck KGaA

He studied Biology and Chemistry at the University in Karlsruhe. Then he worked in different functions for Merck KGaA. Since 1996 in the Quality Assurance department responsible for cleaning validation, training and different projects.

Robert Schwarz
FH Campus Vienna, Austria

Robert Schwarz studied biotechnology and quality management. After working in a medicinal lab as medical/technical analyst Robert Schwarz joined Shire (formerly Baxter), Vienna in 2001. Until 2005 he was coordinator of environmental monitoring. From 2005 until 2018 he was validation specialist responsible for equipment qualification, sterilisation validation and cleaning validation. Additionally since 2010 he is university lecturer in the field of biotech (core topics validation/qualification, aseptic processing, cleanroom technologies and QC).

If the bill-to-address deviates from the specifications on the right, please fill out here:

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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Cleaning Validation, 03/04 September 2020, Hamburg, Germany

WORKSHOPS: Please indicate your choice (tick only one)

☐ *Workshop 1: Cleaning Validation regarding Medicinal Products*
☐ *Workshop 2: Cleaning Validation regarding chemical API manufacturing*
☐ *Workshop 3: Cleaning Validation regarding biological API manufacturing*
☐ *Workshop 4: Develop a Cleaning Validation procedure from start to end*

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week 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 January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date
Thursday, 03 September 2020, 09.00 h - 18.00 h
(Registration and coffee 08.30-09.00 h)
Friday, 04 September 2020, 08.30 h - 16.00 h

Venue
Barceló Hotel Hamburg
Ferdinandstrasse 15
20095 Hamburg, Germany
Phone +49 (0) 40 22 63 62 0
Email hamburg@barcelo.com

Fees (per delegate, plus VAT)
ECA Members € 1,650
APIC Members € 1,750
Non-ECA Members € 1,850
EU GMP Inspectorates € 925

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the conference. Reservation should be made directly with the hotel.
Early reservation is recommended.

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

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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