

With 4 Parallel Workshops

## SPEAKERS:



**Dr Martina Breuer**  
*Haupt Pharma Münster  
GmbH*



**Walid El Azab**  
*STERIS Corporation, Belgium*



**Peter Mungenast**  
*Merck*



**Robert Schwarz**  
*FH Campus Vienna, Austria*

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06-07 February 2019, Prague, Czech Republic

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## LEARNING OBJECTIVES:

- 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



# Cleaning Validation

06-07 February 2019, Prague, Czech Republic

## 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 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.**

## Learning Goals

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.

**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.



## 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.**

## 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

## 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 Corporation, 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).

## Social Event




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



## Easy Registration

 **Reservation Form:**  
**CONCEPT HEIDELBERG**  
 P.O. Box 10 17 64  
 69007 Heidelberg  
 Germany

 **Reservation Form:**  
 + 49 6221 84 44 34

 **e-mail:**  
 info@concept-heidelberg.de

 **Internet:**  
 www.gmp-compliance.org



Reservation Form (Please complete in full)

### Cleaning Validation

06-07 February 2019, Prague, Czech Republic

- 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

Mr  Ms

Title, first name, surname

Company

Department

**Important: Please indicate your company's VAT ID Number**

**PO Number if applicable**

Street/P.O. Box

City

Country

Zip Code

Phone

Fax

E-Mail (please fill in)

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

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 Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg  
 GERMANY

#### 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 %
    - until 1 weeks prior to the conference 50 %
    - within 1 week prior to the conference 100 %
- CONCEPT HEIDELBERG reserves the right to change the materials, in-

structors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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**Important:** This is a binding registration and above fees are due in case of cancellation or non-appearance, if you cannot take part.

you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. 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.

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#### Date

Wednesday, 06 February 2019, 09.00 h - 18.00 h  
 (Registration and coffee 08.30 - 09.00 h)  
 Thursday, 07 February 2019, 08.30 h - 16.00 h

#### Venue

Corinthia Hotel Prague  
 Kongresova 1  
 14069 Prague 4, Czech Republic  
 Phone +420 (261) 191 111  
 Email [prague@corinthia.com](mailto:prague@corinthia.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](http://www.gmp-compliance.org).

#### Conference Language

The official conference language will be English.

#### Organisation

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#### For questions regarding content:

Mr Sven Pommeranz (Operations Director) at +49(0)62 21 / 84 44 47, or per e-mail at [pommeranz@concept-heidelberg.de](mailto:pommeranz@concept-heidelberg.de).

#### For questions regarding reservation, hotel, organisation etc.:

Mr Ronny Strohwald (Organisation Manager) at +49(0)62 21 / 84 44 51, or per e-mail at [strohwald@concept-heidelberg.de](mailto:strohwald@concept-heidelberg.de).