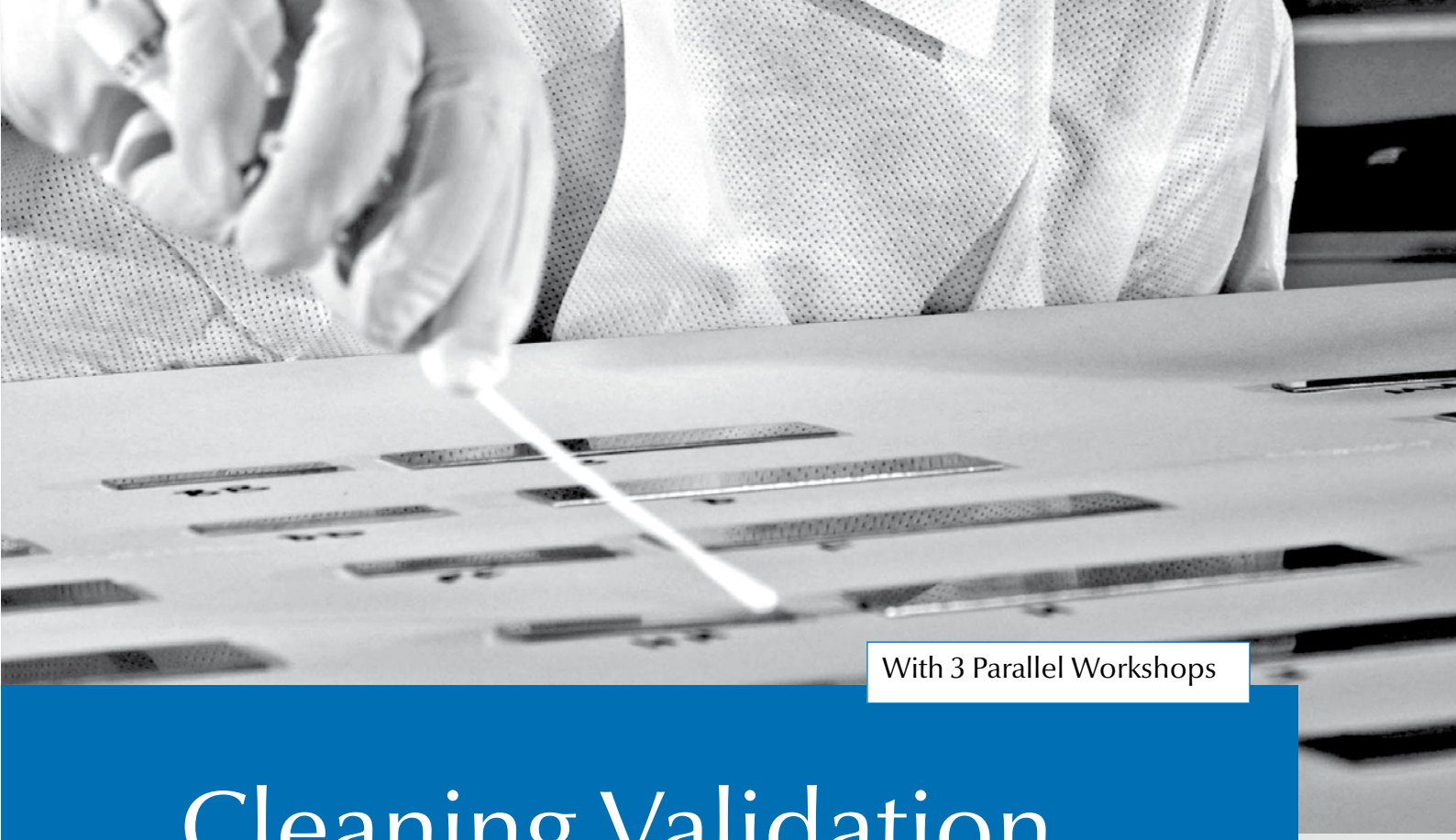


With 3 Parallel Workshops

Cleaning Validation

15 - 16 April 2015, Munich, Germany

SPEAKERS:

Dr Martina Breuer
Haupt Pharma Münster GmbH

Walid El Azab
Steris Cooperation, Belgium

Peter Mungenast
Merck

Dr Hermann J. Peters
QLR Consultancy

LEARNING GOALS:

- APIs and Pharmaceuticals
- Concepts
- Cleaning validationplan and report
- Risk Management
- Pitfalls and findings in inspections/Warning Letters
- Cleaning Evaluation
- Is cleaning evaluation accepted by GMP
- Special Aspects of Cleaning Validation
- Validation of holding times
- Acceptance Criteria
- Technical Aspects
- Design and CIP Aspects
- Cleaning Validation in Biotech API Plants
- Workshop regarding biological manufactured APIs

NEW

ECA ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified Validation Manager“. Please find details at www.gmp-certification.eu

Cleaning Validation

15-16 April 2015, Munich, Germany

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 Draft Guideline from EMA on Dedicated Facilities and Exposure Limits for Cleaning Validation and the Annex 15 draft 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.

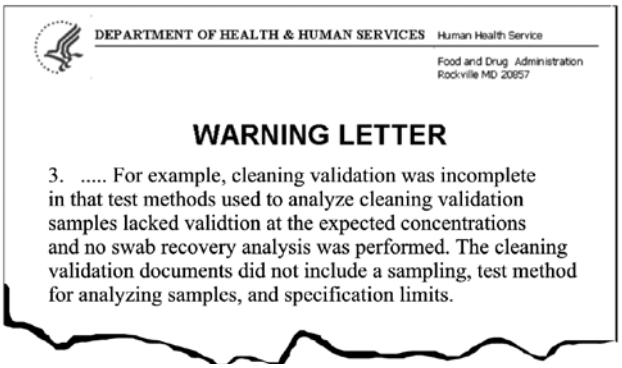
3 parallel workshops – concentrating on medicinal products, chemical and biological manufactured APIs – guarantee the practical orientation.

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.



DEPARTMENT OF HEALTH & HUMAN SERVICES Human Health Service

Food and Drug Administration
Rockville MD 20857

WARNING LETTER

3. ..... For example, cleaning validation was incomplete in that test methods used to analyze cleaning validation samples lacked validtion at the expected concentrations and no swab recovery analysis was performed. The cleaning validation documents did not include a sampling, test method for analyzing samples, and specification limits.

Programme

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

Social Event

On 15 April 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.

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 Cooperation, 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.

Dr Hermann J. Peters

QLR Consultancy, Ulm

Hermann Peters studied chemistry in Karlsruhe (Diploma), Philosophy in Munich (B.A.) and Life Sciences at the Frankfurt University (PhD Life Sciences). He worked for more than 26 years in a Biopharmaceutical CMO focused on active substances from mammalian cell cultures and on aseptic filling. He established Quality Assurance and Regulatory Affairs, acting most time as Vice President Quality Assurance/ Regulatory Affairs and finally as Senior Advisor. Since Dec. 2014 he is an independent consultant, founder and principal of QLR Consultancy.

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

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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Cleaning Validation,15-16 April 2015, Munich, 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

☐ 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 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 %,
- 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, instructors, 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.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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)

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

Wednesday, 15 April 2015, 10.00 h - 18.00 h
(Registration and coffee 09.30-10.00 h)
Thursday, 16 April 2015, 08.30 h - 15.30 h

Venue

Holiday Inn Munich -City Centre
Hochstraße 3
81669 Munich, Germany
Phone +49 (0)89 - 4803 0
Fax +49 (0)89 – 448 7170

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 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

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

CONCEPT HEIDELBERG
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