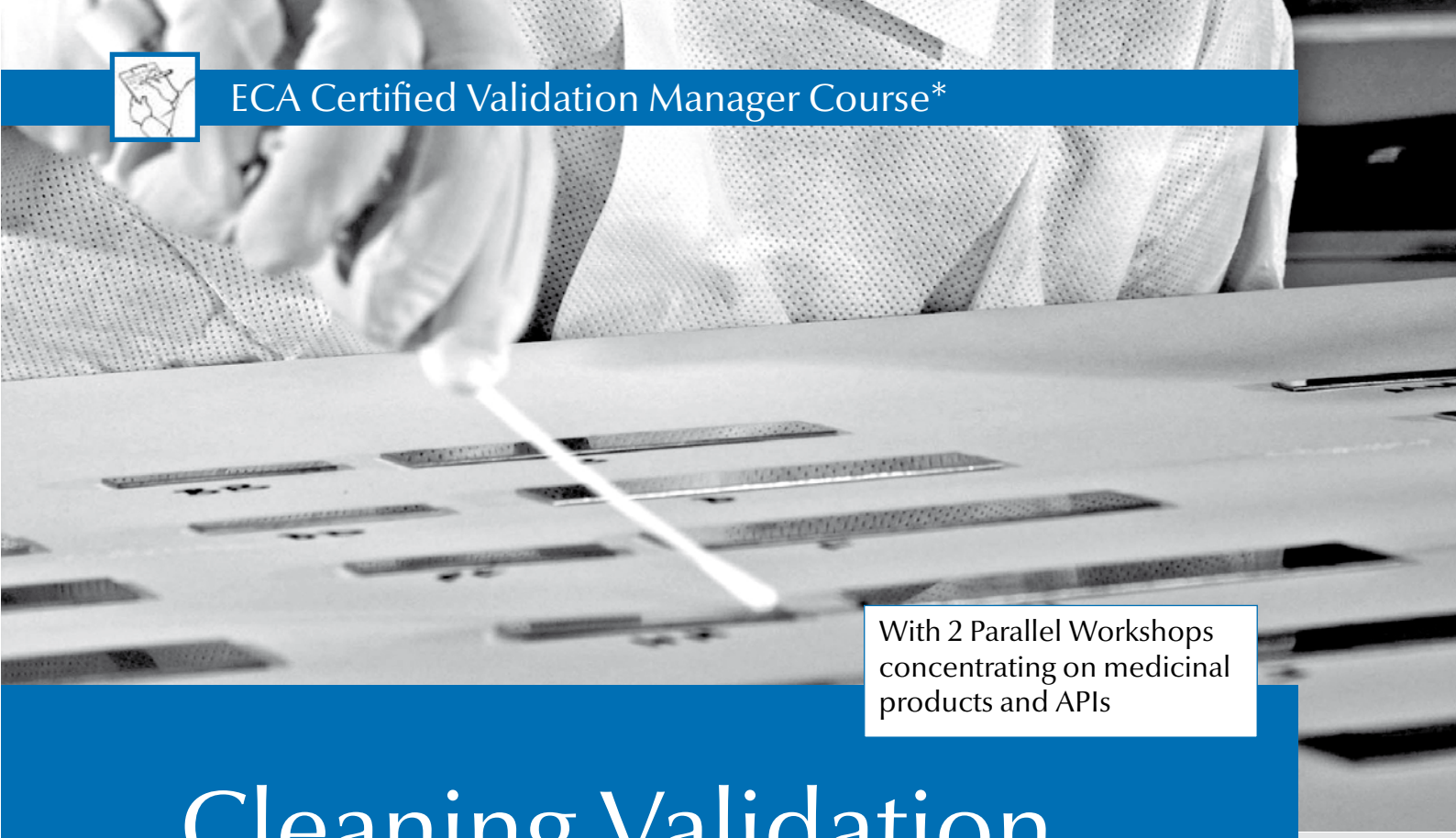
ECA Certified Validation Manager Course*



With 2 Parallel Workshops concentrating on medicinal products and APIs

# Cleaning Validation

19-20 April 2012, Budapest, Hungary

## SPEAKERS:

Peter Mungenast
*Merck*

Stefan Schneider
*Ecolab Engineering*

Dr Hans-Peter Volkland
*GMP Experts*

## LEARNING GOALS:

- APIs and Pharmaceuticals
- Concepts
  - Cleaning Validation Master Plan
  - Pitfalls and findings in mock inspections
- Development of Cleaning Procedures
  - How are cleaning procedures developed?
- Cleaning Evaluation
  - Is cleaning evaluation accepted by GMP
- Technical Aspects
  - Design and CIP Aspects
- Special Aspects of Cleaning Validation
  - Cleaning Validation for tensides
  - Validation of holding times
- NEW Cleaning Validation in Biotech API Plants

ECA
EUROPEAN COMPLIANCE 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

19-20 April 2012, Budapest, Hungary

## 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.

## Learning Goals

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

- How does a cleaning procedure have to be designed for validation, and who is in charge?
- 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?
- 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 do you integrate the analytical laboratory into cleaning validation?
- How are critical areas defined?
- Is cleaning evaluation the solution for seldom manufactured products?
- How can the cleaning of an old or upgraded site be validated?
- Which microbiological maximum values are valid in the areas of non-sterile dosage forms and APIs?
- Which deficiencies can be found in mock inspections?

and

- How do facilities need to be designed to be cleanable in the first place?

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

## Target Group

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.**

## Workshops

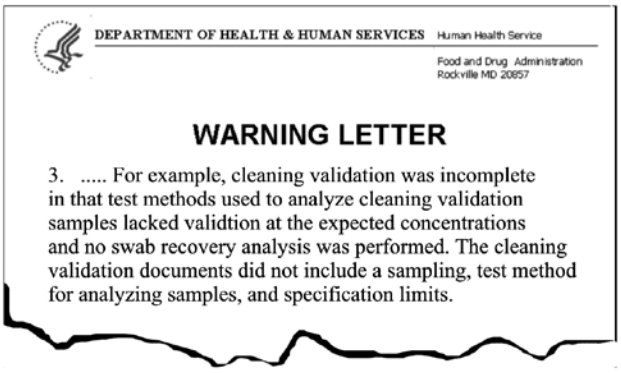
2 Parallel workshops – concentrating on medicinal products and APIs - guarantee the practical orientation. Please choose your workshop when registering.

## Accessories

Please bring along a pocket calculator.

## Moderator

Dr Hans-Peter Volkland



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

- Guidelines, interpretations
- Cleaning Validation Masterplan
- Cleaning Validation Plan
  - Risk assessment
  - Evaluation of acceptance criteria
  - Bracketing
  - Sampling
  - Analytical aspects
- Cleaning Validation Report
- Pitfalls and findings in mock inspections regarding cleaning validation

Dr Hans-Peter Volkland
*GMP Experts*

### Development of Cleaning Procedures

- How are cleaning procedures developed?
- Who is responsible for the development of cleaning procedures?

Dr Hans-Peter Volkland
*GMP Experts*

### Cleaning Evaluation and Validation in the 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?

Peter Mungenast
*Merck KGaA*

### Technical Aspects on Equipment Regarding Cleaning Procedures

- Design aspects
- Material aspects
- CIP aspects

Stefan Schneider Ecolab
*Engineeering GmbH*

### Special Aspects of Cleaning Validation

- Cleaning validation of equipment in use
- Cleaning validation for tensides
- Acceptance criteria for the microbial status
- How about acceptance criteria in non-sterile production (semisolids, solids, APIs)?
- Recovery rates
- Validation of holding times

Dr Hans-Peter Volkland
*GMP Experts*

### 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

Dr. Hans-Peter Volkland
*GMP Experts*

## Speakers

### Peter Mungenast

*Merck KGaA, Germany*

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.

### Stefan Schneider

*Ecolab Engineering GmbH, Siegsdorf*

Stefan Schneider is responsible Project Manager for Pharma in the Food & Beverage Division of Ecolab Engineering. He has more than 20 years of experience in Engineering and spent 11 years within the pharmaceutical industry. Ecolab Engineering handles development, production and sales of complete measuring, metering and application systems. Ecolab Engineering offers individual solution concepts for all market-specific requirements, in systems association with Ecolab.

### Dr Hans-Peter Volkland

*GMP Experts, Germany*

Dr Volkland studied Chemistry at the University of Constance and graduated in microbiology (ETH Zürich). He worked for several years in R&D and in various quality positions (QA, QC, Validation, Qualification). In 2001 he joined PCS (Pharmaceutical Consultancy Services) as Senior Consultant and Senior Auditor. In 2006 he set up his own consultancy company, Pharma and API Consulting (PAAC). In 2009 he founded GMP Experts which provides GMP consulting, auditing and training for the pharma and API business.

### What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

### What Are the Benefits of ECA?

**First benefit:** During the membership, you enjoy a 10 % discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

**Second benefit:** The GMP Guidelines Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

### How Do You Become a Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. There are no obligations for the member! Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website http://www.gmp-compliance.org

## 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, 19-20 April 2012, Budapest, Hungary**
WORKSHOPS: Please indicate your choice (tick only one)
☐☐ Workshop 1: Cleaning Validation regarding Medicinal Products
☐☐ Workshop 2: Cleaning Validation regarding 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)

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

**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)!

### Date

Thursday, 19 April 2012, 10.00 h - 18.15 h
(Registration and coffee 09.30-10.00 h)
Friday, 20 April 2012 08.30 h - 16.15 h

### Venue

Hilton Budapest WestEnd
Váci út 1-3
1062 Budapest, Hungary
Phone +36 1 288 5500
Fax + 36 1 288 5588

### Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT (does not Include ECA Membership).
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
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. Please make your reservation via the Personalised Online Group Page **http://www.budapest-westend.hilton.com/ECA1804** where you also can modify/cancel your reservation until 5 March 2012 (room rate € 125,- per night, incl. breakfast, excl. VAT and city tax). 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

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