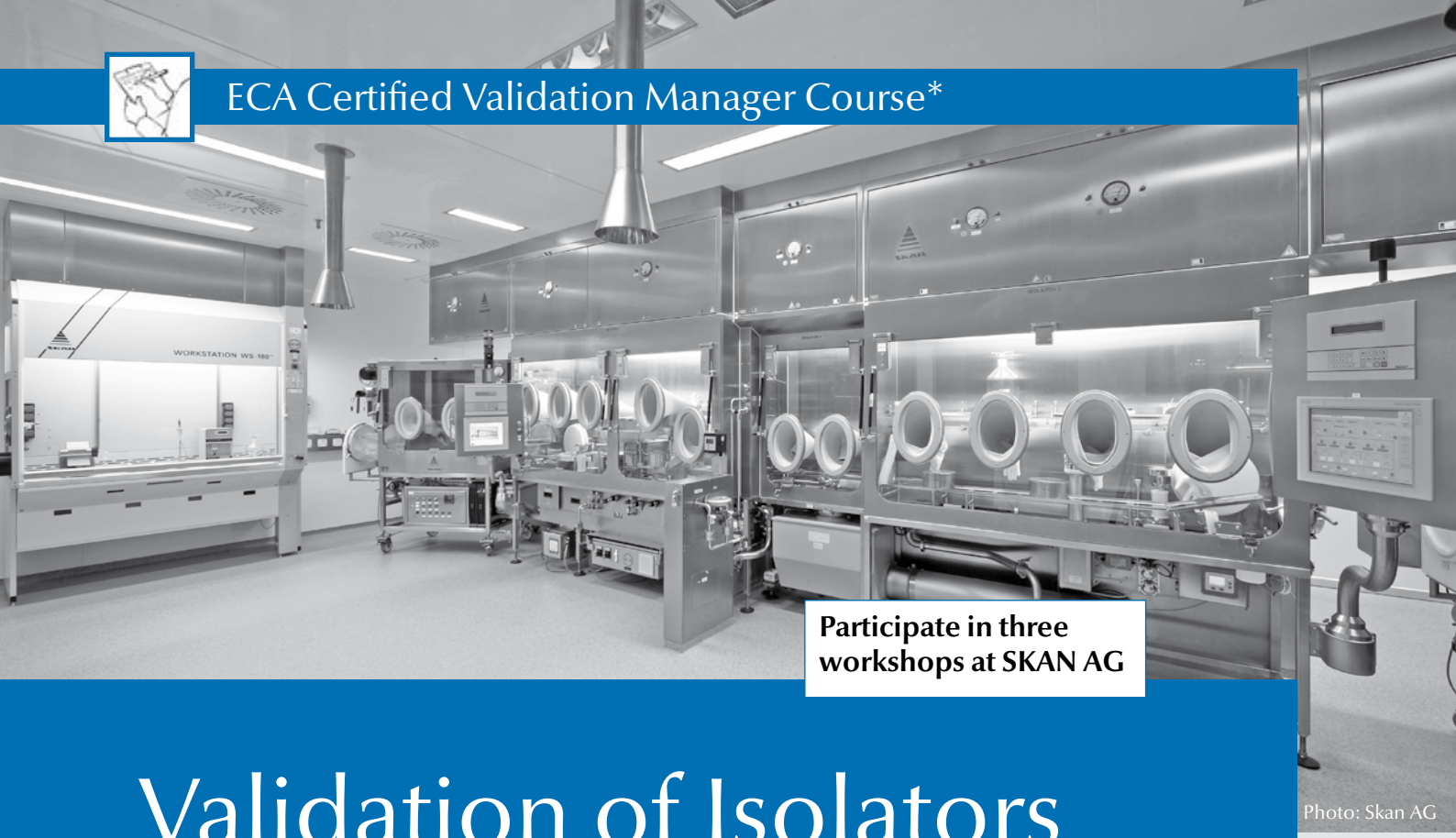
ECA Certified Validation Manager Course*



Participate in three workshops at SKAN AG

Validation of Isolators

Photo: Skan AG

19 – 20 October 2010, Basle, Switzerland

SPEAKERS:

Dr Hans-Jürgen Bässler
Skan

André Bösiger
Skan

Angela Gessler
Skan

Dr Timo Krebsbach
Labor L+S

Herwig Muehleder
Wyeth BioPharma

Volker Sigwarth
Skan

Christian Vogt
Novartis Pharma Stein

PROGRAMME:

- Regulatory Requirements for Isolators for Aseptic Use
- Qualification: Users' point of view
- Qualification: Suppliers' point of view
- Isolator mock-up
- Process Development of Isolator Decontamination
- Relevance of Physical Glove Integrity Testing to Microbiological Contamination of Isolator Systems
- Sterility Testing – Comparison Isolator vs. Cleanroom
- Microbiology in Filling and Sterility Isolators

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

Validation of Isolators

19 – 20 October 2010, Basle, Switzerland

Learning Goals

Why should you attend this event?

- You get an update on the validation of **isolators for aseptic manufacture and for sterility testing**
- You get to know the results of recent studies on the validation of isolators
- You have the opportunity to discuss your individual questions personally with experts
- You can translate the theory directly into practice during 3 workshops at the manufacturing site of Skan in Allschwil

Each participant takes part in all 3 workshops. The workshops are held at the plant of Skan AG, partly including operational isolators. This brings the participants as close to daily practice as possible.

Background

The use of isolators is increasing both in sterility testing and in the production of sterile medicinal products, particularly in aseptic manufacture. It ensures a greater microbiological safety of the products, but at the same time requires increased inputs as regards the qualification of these systems and the validation of the production processes.

In 2004, Annex 1 to the FDA Guidance for Industry „Sterile Drug Products Produced by Aseptic Processing" defined new regulatory requirements on using this technology, as did the PIC/S document PI 014-3 „Isolators used for Aseptic Processing and Sterility Testing".

Target Group

This GMP Education Course addresses those employees from the pharmaceutical industry and from suppliers of **isolators for aseptic manufacture and for sterility testing** involved in the qualification and validation of these systems, especially from the areas

- Engineering / Production
- Quality Assurance
- Qualification/ Validation
- Microbiology

The number of participants is limited.

Please understand that, for competitive reasons, not all firms can register their employees for this event.

Programme

Regulatory Requirements for Isolators for Aseptic Use

- Regulatory bodies
- US laws and regulations
- European laws and regulations
- Guidelines

Qualification: Users point of view

- URS requirements
- What to consider regarding documentation
- Our requirements on qualification (FAT testing, Commissioning test, actual validation, cycle development)
- Support required from the vendor in order to achieve qualification requirements
- Examples on what we did to meet the requirements.
- How to operate an isolator in an optimal way (monitoring, glove handling, set-up, tools, waste handling, etc.)

Qualification: Suppliers point of view

- What do we need from our customers?
- Technical risk management
- From URS to engineering – technical details and solutions
- Testing – IQ, OQ

Isolator mock-up

- Purpose of mock-up
- What is required before starting a mock-up
- How to document a mock-up
- What simulations need to be included in the mock-up
- Execution of the mock-up itself
- How to ensure that mock-up results are properly implemented in the design
- Examples for our mock-up to underline the points above

Process Development of Isolator Decontamination

- Overview of current regulations and standards
- Basis and selection of suitable biological indicators as sensor for the Inactivation Effect
- Physical process parameters and their boundaries influencing the decontamination target
- Development and quantification of decontamination cycles
- Realistic data and additional studies of H2O2 decontamination

Relevance of physical glove integrity testing to microbiological contamination of Isolator systems

- Regulatory Background
- Physical methods for glove integrity tests and their boundaries
- Microbiological contamination risk
- Routine program for glove integrity testing

Sterility Testing – Comparison Isolator vs. Cleanroom

- Sterility testing in a cleanroom
  - Sample preparation
  - Material transfer
  - Personnel transfer
  - Qualification of operators
  - Monitoring
  - Cleaning and disinfection
- Sterility testing in an isolator
  - Requirements for the isolator
  - Background of the isolator
  - PQ of an isolator
  - Qualification of operators
  - Test performance
  - Monitoring
  - Testing the tightness of gloves
  - Test for gas-tightness of primary packaging materials

Microbiology in Filling and Sterility Isolators

- Environmental monitoring
- Media Fills
- Sterility tests
- Integrity of gloves and sleeves
- Validation studies
- OOS results in isolators

Social Event

On 19 October 2010 you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies and the speakers in a relaxed atmosphere.

Workshop Session at Skan AG

Workshop 1: Hans Jürgen Bässler / André Bösiger / Herwig Muehleder

Validation Planning for an Aseptic Isolator

- Test master plan (IQ/OQ)
- IQ / OQ test protocols
- Operational qualification - procedures
- Handling of deviations

Performance of Selected Qualification Tests

- Basic SOP for testing
- Execution of tests
- Generate test records
- Drawing up the test report
- Glove testing

Workshop 2: Volker Sigwarth / Angela Gessler

Development and Quantification of H_2O_2 Decontamination Cycles

- Establish the requirements of a decontamination cycle
- Design a qualification strategy
- Work out the necessary physical and microbiological tests and their chronology
- Interpretation of test results and reaction on deviations
- Write a transparent qualification report
- Workshop including a real isolator system

Workshop 3: Christian Vogt

Isolators in Routine

- Handling in isolators
- Personnel at isolators
- RTP system
- Environmental monitoring in isolators
- Frequency of decontaminations
- Problems in isolators from the point of view of a user

You will take part in all three workshops!
The workshops will take place at SKAN AG in Allschwil. After the workshops at appr. 17.00 h, a bus shuttle service will bring the participants to the airport, the train station or the hotel.

Speakers

Dr Hans-Jürgen Bässler
Skan AG, Basle, Switzerland

The qualified biologist Dr Bässler has been working in different positions of the pharmaceutical industry for more than 35 years. He is responsible for the pharmaceutical isolator technology with Skan AG. He can look back on many years of experience with isolators and their decontamination with gases like hydrogen peroxid or peracetic acid. This topic has also been the subject of several publications that he has written or co-written. In numerous lectures he has managed to direct the attention of experts to the decontamination with H_2O_2.

André Bösiger
Skan AG, Basle, Switzerland

André Bösiger is Technical Sales Manager in the Industrial Division of Skan AG, Switzerland. He studied Mechanical Engineering at the Technical School (TSM) Basel and Economics (HF-NDS) at the Kaderschule Basel. In 2000 he joined the Project Engineering Department of Skan AG where he worked as a Project Manager in the Industrial Division for Isolator Technology. He realised many large Projects for different Customers all over the World as Syringe Filling Line Isolators with E-Beam, Vial Filling Line Isolators with Transfer- and Freeze Dryer Loading Isolators. 2004 he changed into Sales Department – with the main focus to Ireland, UK and Asia.

Angela Gessler
Skan AG, Basle, Switzerland

Angela Gessler studied Hygiene Technology at the Technical University of Albstadt-Sigmaringen and was awarded her degree as Dipl.-Ing. (FH) for her investigation of the glove integrity tests at Novartis Pharma AG and Skan AG. As the Head of Cycle Development at Skan AG she is now responsible for the cycle development and microbiological qualifications of isolator systems.

Dr Timo Krebsbach
Labor L+S AG, Bad Bocklet, Germany

After completing his studies in biology and obtaining his doctorate at the University of Bonn, Timo joined Labor L+S AG in 2002. He is the head of the sterility testing department at L+S and responsible for sterility tests performed in a cleanroom as well as in isolators.

Herwig Muehleder
Wyeth BioPharma, Dublin, Ireland

Project engineer and leader in realising Wyeths second Syringe Filling Line with new Skan E-Beam System at Grange Castle near Dublin.

Volker Sigwarth
Skan AG, Basle, Switzerland

Volker Sigwarth studied medical engineering at the Technical University of Ulm and was awarded his degree as Dipl.-Ing. (FH) for his investigation of factors influencing hydrogen peroxide (H_2O_2) decontamination. As a member of the R&D group at Skan AG, he has been responsible for the development, integration and qualification strategy of the H_2O_2 decontamination method SIS 700. Since 2009 Mr Sigwarth is CEO of Skan AG, Basle.

Christian Vogt
Novartis Pharma Stein AG, Basle/Stein, Switzerland

Christian Vogt studied Biology at the University of Constance and at the Texas A&M University, where he graduated in microbiology. In 2006 he joined the Novartis Pharma AG in Basel and is now responsible for sterility testing and microbiological QA and QC at the Novartis Pharma site in Stein, Switzerland.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme for the module "ECA Certified Validation Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG.

ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

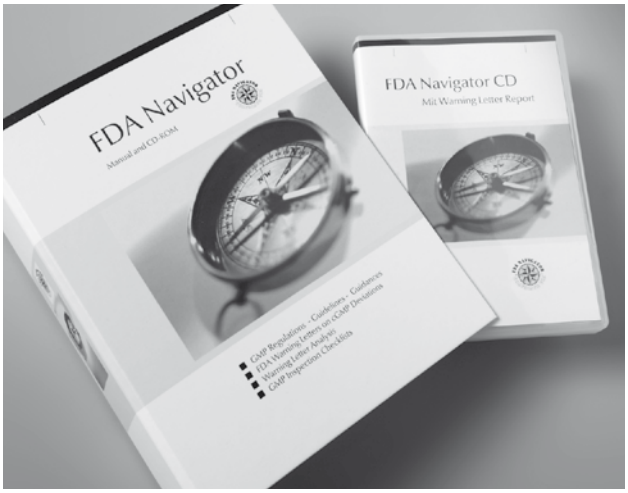
What Is ECA?

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 Guideline 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. 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



FDA Navigator with Warning Letters Report

The FDA Navigator comprises a CD-ROM and a handbook

- On the CD, you will find the 200 most important GMP regulations, guidelines and interpretations by FDA, all in all about 5,000 pages
- Warning letters on GMP deviations of the years 2002 to 2009
- Warning Letters Report with detailed analysis
- Inspection checklist based on the cGMP Guide in German and English (incl. reference to CFR paragraphs)

The Tree Structure: All documents are arranged in a clear tree structure. Thus you can find the desired document click by click.

Search Function: You can search all documents on the FDA Navigator CD for keywords, e.g. for „validation", „deviation", „stability". The search results include guidelines, FDA presentations and warning letters

Price:
€ 399 (Annual update € 199) Non ECA Members
€ 260 (Annual update € 130) ECA Members

You can place your order in the Internet at www.gmp-compliance.org or you use the reservation form on this folder.

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:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Validation of Isolators, 19 – 20 October 2010, Basle, Switzerland

☐ Mr. ☐ Ms.

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **Purchase Order No, if applicable**

Street/P.O. Box

City | Zip Code | Country

Phone/Fax

E-Mail (please fill in)

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 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)!
   - 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

Date

Tuesday, 19 October 2010, 09.30 h – 18.00 h
(Registration and coffee 09.00 h – 09.30 h)
Wednesday, 20 October 2010, 08.30 h – 17.00 h
After the workshops on 20 October at appr. 17.00 h, a bus shuttle service will bring the participants to the airport, the train station or the hotel.

Venue

Mercure Hotel Europe Basel
Clarastraße 43
4005 Basle, Switzerland
Phone +41 61 690 80 80
Fax +41 61 690 88 80

Fees

Non-ECA Members € 1,790 ,- per delegate plus VAT
ECA Members € 1,611,- per delegate plus VAT
EU GMP Inspectorates € 895,- per delegate plus VAT.
APIC Members € 1,700,- per delegate plus VAT (does not include ECA membership)

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 has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the course. Please use this form for your room reservation or be sure to mention "VA 6406 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 21 September 2010. 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

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