ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Sterile Production Manager

Speakers


Christian Doriath
SKAN, Switzerland


Theresa Ladwig
SKAN, Switzerland


Julia Pauly
GP Grenzach Produktion, Germany


Benoît Ramond
Microbiologic Expert (formerly Sanofi, France)


Ruben Rizzo
SKAN, Switzerland


Katharina Schlereth
Labor LS, Germany


Yves Scholler
SKAN, Switzerland


Claudia Wegmann
Cilag, Switzerland

Isolator Technology Workshop

Engineering – Validation - Operation

15-16 November 2022 | Basel, Switzerland

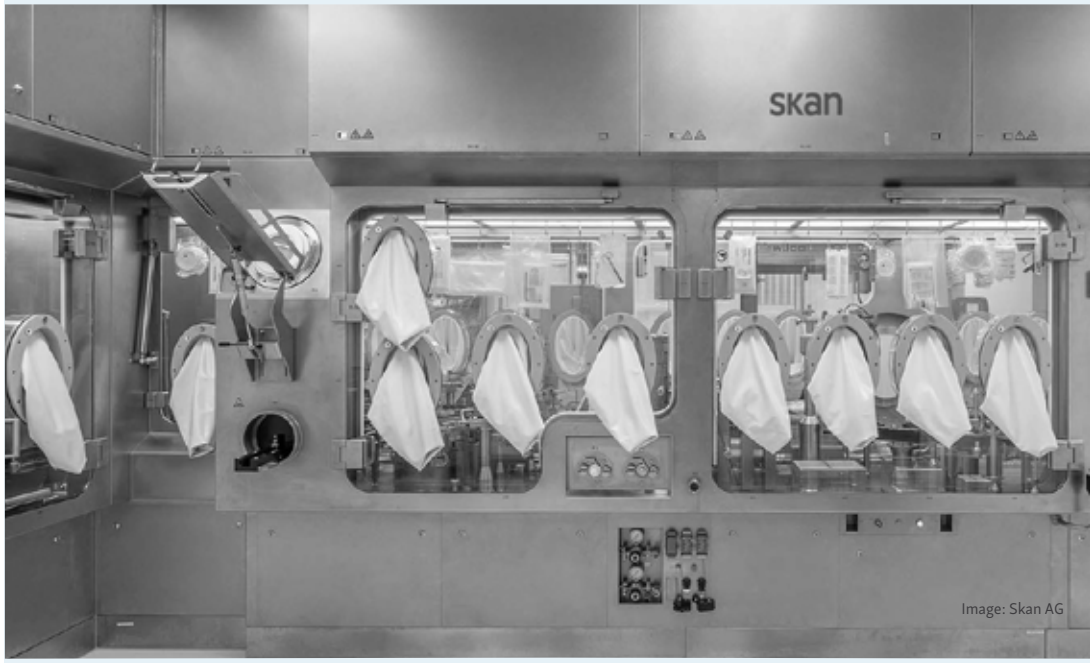

Image: Skan AG

Highlights

- Regulatory requirements and trends
- New Annex 1 requirements
- From the conceptual design to the validated equipment
- Mock-Up study
- Process development of isolator decontamination
- Bioindicators
- Troubleshooting in isolator technology
- Glove integrity testing
- Sterility testing in isolators
- Aseptic / toxic isolators
- Isolators used in Aseptic Fill Finish Manufacturing

Participate in three workshops at SKAN AG

Objectives

Why should you attend this event?

- You get an update on **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, Appendix 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 Audience

This GMP Education Course addresses those employees from the pharmaceutical industry and from suppliers **for aseptic (toxic) manufacture and for sterility testing** involved in the engineering, validation and operation 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 companies 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
- Basic Isolator definitions

Image: Skan AG

Isolator Application / Projects: From the Conceptual Design to the Validated Equipment incl. Mock-Up Study

- Key decisions
- What do we need from our customers?
- From URS to engineering – technical details and solutions
- Process challenges and features
- FAT – Installation – Qualification
- 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
- Examples for our mock-up to underline the points above

Annex 1 - Risk Analysis and Consideration of Transfer Material and Environmental Monitoring

- Contamination Control Strategy & Quality Risk Management Principles
- Environmental monitoring program
- Gloves/Sleeves management program
- Transfer materials & personnel interventions
- Aseptic processing validation management

Bioindicators / Process Development of Isolator Decontamination

- Overview of current regulations and standards
- Basis and selection of suitable biological indicators as sensor for the inactivation effect
- Development and quantification of decontamination cycles
- Influence of H_2O_2 to routine processes

Troubleshooting in Isolator Technology

- The place of the isolator in a pharmaceutical process
- The influence of critical parameters on the decontamination process
- The reliability and reproducibility of biological indicators
- The expectations of regulators

Isolators Used for Sterility Testing

- Requirements for the isolator
  - Background of the isolator
  - Performance Qualification
  - Qualification of operators
  - Test for gas-tightness of primary packaging materials
- Handling in isolator
  - Capacity
  - Testing the tightness of gloves
- Microbiological Monitoring
  - Sample plan
  - Contamination level; contamination source
  - OOS/CAPA (example)

Isolator Technology and Challenges in Sterility Testing

Isolators Used in Aseptic Fill Finish Manufacturing

- Isolator technologies in a parenteral production
- Preparation of an isolator used for aseptic filling
- Implementation of a new isolator
  - Design / Mock-up / From qualification to validation

Workshop Session

Workshop 1

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

Glove Integrity Testing

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

Workshop 2

Development and Validation of H2O2 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

Image: Skan AG

Workshop 3

Isolators according EU Annex 1

- 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 workshops!
The workshops will take place at SKAN AG in Allschwil. After the workshops, at appr. 16.15 h, a bus shuttle service will bring the participants to the airport (appr. 16.35 h), the German train station (appr. 16.50 h), the Swiss train station (appr. 17.15 h) or the hotel.

Speakers

Christian Doriath, SKAN AG, Basel, Switzerland

Christian Doriath joined SKAN in 2012 after more than 20 years spent on isolator technology in the pharmaceutical industry at various positions, maintenance, validation, research, technical services. Since October 2018 he is Head of Process Validation Microbiology at SKAN.

Theresa Ladwig, SKAN AG, Basel, Switzerland

2007 Theresa Ladwig joined SKAN AG as a Project Engineer in the department Cycle Development and performed Cycle Development and Microbiological Qualifications all over the world. From 2013 to 2018 she was Head of Process Validation Microbiology. Today she supports the Sales Team for Europe of Skan AG.

Julia Pauly, Grenzach Produktions GmbH, Grenzach-Wyhlen, Germany

Between 2014 and 2017 at Novartis Pharma AG in the Biological and Microbiological Services department. Since 2017 at Grenzach Produktions GmbH as QA expert, since 2020 there as GMP Compliance expert in Quality Control Microbiology.

Benoît Ramond, Microbiologic Expert (formerly Sanofi, France)

Between 2004 and 2022 he was microbiology expert in Sanofi group. In his function he had also a leading role in the RMM strategy development within Sanofi group.

Ruben Rizzo, SKAN AG, Basel, Switzerland

Ruben Rizzo studied chemistry and pharma technology. He worked for Novartis Pharma (Stein) as a Production Expert in the R&D before he joined SKAN AG in 2014 as Sales Manager in the Process Solution for Isolator Technology. He is responsible for the area of Switzerland, Spain, Italy and Portugal.

Katharina Schlereth, Labor LS AG, Germany

Katharina studied Biology at the University Würzburg. 2009 she joined Labor L+S AG in Bad Bocklet, Germany, where she is responsible for sterility testing. Her current position is Division Head, Microbiological Testing of Sterile Products.

Yves Scholler, SKAN AG, Basel, Switzerland

Yves Scholler studied mechatronics at the Trinational Engineering School (FTI) in Muttenz (CH), Mulhouse (F) and Lörrach(D). He joined SKAN AG in 2007 and is now Head of Sales Europe in the Process Solution for Isolator Technology.

Claudia Wegmann Cilag AG, Schaffhausen, Switzerland

Principal Engineer - Technical Operations/Parenterals Claudia has been working at Cilag AG for more than 15 years. Since 2013 in Technical operations (former Qualification & Validation) in different functions responsible for aseptic process simulations, sterilization and decontamination processes, new product introductions and different projects.

Date of the Event
Tuesday, 15 November 2022, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 16 November 2022, 08.15 h – 16.15 h

After the workshops on 16 November 2022 at appr. 16.15 h, a bus shuttle service will bring the participants to the airport, the train stations or the hotel.

Venue
Pullman Basel Europe
Clarastrasse 43
4058 Basel, Switzerland
Phone +41(0)61 6908 080
Fax +41(0)61 6908 880

Fees (per delegate, plus VAT)
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
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 when you have registered for the event. Please use this form for your room reservation or be sure to mention "ECA" to receive the specially negotiated rate which is valid till October, 17, 2022. 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.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

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

CONCEPT HEIDELBERG
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69007 Heidelberg, Germany
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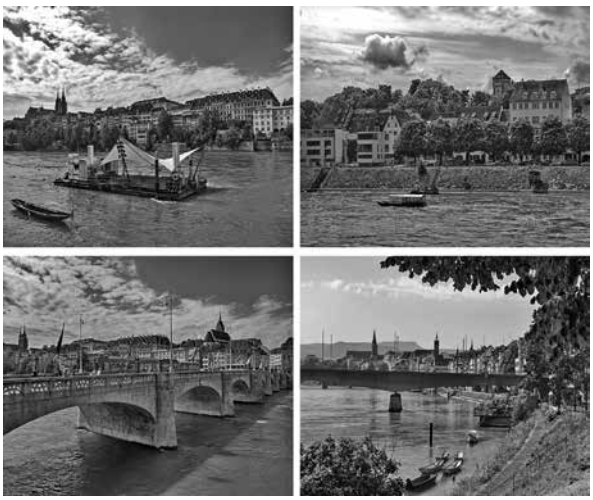
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Andreas Mangel (Operations Director) at
+49(0)62 21/84 44 41, or per e-mail at
mangel@concept-heidelberg.de

For questions regarding reservation, hotel, organisation etc. please contact:
Mr Rouwen Schopka (Organisation Manager) at
+49(0)62 21/84 44 13, or at schopka@concept-heidelberg.de

Social Event
On 15 November 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.



Your Benefits

Internationally Acknowledged Certificate from ECA Academy
The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

This Training Course is recognized for the GMP/GDP Certification Scheme
Building on your education the ECA GMP/GDP certification programmes provide you with the appropiate supplement to acquire this qualification. This Live Online Training is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

This could be of interest for you as well

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:
- Basic GMP
- Biopharmaceuticals
- Quality Assurance
- Validation/Qualification
- Sterile Manufacturing
- Data Integrity
- Technical Operations

and more...

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

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

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Isolator Technology Workshop, 15-16 November 2022, Basel, Switzerland

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)

PE/1107202

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks 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 HEIDELBERGwill 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 July 2022).
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 https://www.gmp-compliance.org/privacy-policy). 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.