ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Sterile Production Manager

Speakers


Dr Patricia Desmaris
Merck Group


Christian Doriath
SKAN


Theresa Ladwig
SKAN


Johannes Oberdörfer
Boehringer Ingelheim Pharma


Benoît Ramond
Sanofi


Ruben Rizzo
SKAN


Katharina Schlereth
Labor LS


Yves Scholler
SKAN

Isolator Technology Workshop

Live Online Training

30 November - 01 December 2021


Image: Skan AG

Highlights

- Isolator and Associated Technologies
- From the Conceptual Design to the Validated Equipment
- Mock-Up Study
- Process Development of Isolator Decontamination
- Troubleshooting in Isolator Technology
- Glove Integrity Testing
- Sterility Testing in Isolators
- Aseptic / Toxic Isolators
- New regulatory requirements and trends
- Case studies from Merck and Sanofi

Including Live-Online Workshops

Programme

Objectives

Why should you attend this Live Online Training?

- 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
- In various virtual live workshops you can see how the theory is put directly into practice and
- You have the opportunity to discuss your questions directly with experts

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 / decontamination 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" and the expected revision of EU GMP Guide Annex 1.

Target Audience

This ECA Live Online Training 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

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

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

Programme

Regulatory Requirements for Isolators for Aseptic Use

- Regulatory bodies
- US laws and regulations
- European laws and regulations
- Guidelines
- Basic Isolator definitions

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

A virtual factory tour at SKAN shows you actual isolators in different stages of the manufacturing process

Case Study Merck: New Aseptic Filling Building: A Quality by Design Approach

- Presentation of the project
- Business case construction
- Compliance requirements
- QBD approach and implementation
- Product Tech Transfer strategy
- ASTME2500 qualification and validation strategy

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

Workshop

Qualification 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 Integrity Testing

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

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

Workshop: 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

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)

Case Study / Workshop: Troubleshooting at Customer Site

- Description of the situation
- What kind of investigation is expected?
- Corrective Action Preventive Action (CAPA)

A Look into Rapid Microbial Contamination Detection in Cell containing Samples

- Current challenges of conventional methodologies
- Beta Testing of Celsis Adapt™ system at Boehringer Ingelheim and Labor LS
- Technology features and perspectives for the pharmaceutical industry

Speakers

Dr Patricia Desmaris, Merck Group
Pharmacist specialized in biotechnology, expert in Aseptic Processes, F&F, Isolator Technology and CGMPs Compliance. Currently managing a team in charge of all the equipment (compounding, Aseptic filling, washing and sterilization, stopper processing) for a new aseptic filling building from design to qualification/validation.

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.

Johannes Oberdörfer, Boehringer Ingelheim Pharma GmbH & Co.KG
Johannes studied at the University for Applied Sciences in Bingen. He joined Boehringer 2005 as Biological Technician. After positions as Expert Analytical Scientist, responsible for Potency assays and Head of Sample Management he is in his current position as Lead Scientist responsible for Rapid Microbiology Methods.

Benoît Ramond, Sanofi SA, France
Since 2004 he is microbiology expert in Sanofi group. In his function he has 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.

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Reservation Form (Please complete in full)

Isolator Technology Workshop
Live Online Training from 30 November - 01 December 2021

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)

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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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.

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 of the Live Online Training

Tuesday, 30 November 2021
09.00 h – 17.00 h
Wednesday, 1 December 2021
09.00 h – 17.00 h

All times mentioned are CET.

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The fee is payable in advance after receipt of invoice.

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 will be made available to you prior to the Live Online Training as PDF files. 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.

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