ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers


Ruth Barensteiner
Janssen Pharmaceuticals


Kevin Gadient
Emergent


Winnie Hagen Madsen
Novo Nordisk A/S


Dr Daniel Müller
Local Government of Baden Württemberg


Youwen Pan
WuXi Biologics


Hoang Phan
Genentech


Ute Schleyer
Vetter Pharma-Fertigung


Dr Christian Siegmund
F. Hoffmann-La Roche


Dr Thomas Thurn
Janssen Cilag

Robotic Isolators – Challenges and Modern Monitoring Systems

A Part of the European Microbiology Conference 2022

Live Online Training on 05 May 2022


Quelle: Syntegon

Highlights

- Technical Principles of Robotic/Gloveless Isolators
- Challenges of Modern Monitoring
- Implementation Experiences
- Inspectors Point of View
- Perspective and Experience of Recent Inspections

Complete Conference (03-05 May 2022) 3 Tracks: Control of Cell- and Gene-Based Products/ATMP, Trend in Endotoxin and Pyrogen Testing, Robotic Isolators

Objectives

Aseptic production has always been complex and cost-intensive and the risk of contamination high. To minimise the risks, the techniques used have become increasingly sophisticated, from simple cleanrooms, sterile workbenches and RABS to the classic isloators. With the new possibilities of automation, digitalisation and rapid microbiological methods, there are currently even more opportunities to minimise contamination risks and optimise processes. This also, or especially, plays a role in the production of novel therapies with biological starting materials, which often have small batch sizes.

One possible method is the use of modern isolators, without gloves, automated and in combination with modern real time or online monitoring systems. However, when establishing such systems, the user is faced with the challenge that the currently valid regulatory requirements were often oriented towards the previous systems and are difficult to apply across the board for modern systems, either because given limits were derived from the less sensitive systems or because comparability of the results is difficult or impossible to achieve due to the different methodologies.

This workshop will provide an insight into the view of a GMP inspector, an introduction to available techniques and systems, as well as industry experience in implementation and the hurdles that may be encountered in regulatory acceptance.

Background

In the current era, where conferences and seminars are mainly held online and virtually, new approaches and structures are needed to offer participants optimal value and expert input. Therefore, the ECA Academy has decided to offer the European Microbiology Conference 2022, which has been an integral part of the European conference landscape since 2008, in a special topic-focused format. During 2.5 days, 3 topics will be offered, which can be booked individually or in combination.

Target Audience

This workshop is aimed at all those involved in manufacturing, quality assurance and quality control who are concerned with the possibilities of barrier technologies and modern monitoring systems and with the challenges of implementation and the requirements of the authorities for new technologies.

Moderators

Dr Wolfgang Eder
Roche Diagnostics

Axel Schroeder
Concept Heidelberg

Programme

Part 1: Technical Principles and Challenges

Functional principle and background
Christian Siegmund, F. Hoffmann-La Roche

- Zone classifications within the Vanrx SA25
- Horizontal air flow

Challenges in Aseptic Filling
Thomas Thurn, Cilag/JnJ

- Consideration of Robotic Solution in Aseptic Filling
- Aseptic Smart Fill Concept Study

Robotic Fill & Finish
Ute Schleyer, Vetter

- Robotics used for all main activities
- VHP cycle prior to aseptic set-up

Part 2: Challenges and Hurdles – Modern Monitoring in Isolators and Implementation Experiences with Authorities

Monitoring for viables in closed robotic isolators
Winnie Hagen Madsen, Novo Nordisk

- Limitations and possibilities
- Authority expectations
- Use of BioTrak

Process Controls for Gloveless Isolator Systems
Hoang Phan, Roche/Genentech

- Current process controls were designed around cleanroom, RABS, or gloved isolator filling systems
- A new class of gloveless isolator system that have designed out traditional risks should then allow for a different approach to process control

Challenges and requirements during introduction of a continuous monitoring system for viable particles in a new robotic filling line
Ruth Barensteiner, Cilag

- Implementation Strategy
- Example for a continuous monitoring set-up
- Challenges

Health Authority Expectations Regarding Gloveless Isolator Implementation
Kevin Gadient, Emergent

- Process Overview
- Feedback from FDA & Health Canada

Part 3: Personal view and expectations of a GMP Inspector

Dr Daniel Müller, GMP Inspector

- Current regulations for isolators / barrier systems, including EU Annex 1 (revision)
- How far are robotic systems addressed in guidelines?
- Challenges and discussion points

Part 4: CMO Perspective and Experience of Recent Inspections

Youwen Pan, WuXi Biologics

- Experience of recent interactions with inspectors from FDA and China NMPA on Vanrx SA25

Panel Discussions and Q&A with Speakers and Experts

Speakers

Ruth Barensteiner
Janssen Pharmaceuticals

Ruth Barensteiner is working at Janssen Pharmaceutical Discovery, Product Development and Supply as Compliance Manager in the Fill Finish Pilot Plant for the manufacturing and supply of clinical trial material. Ruth has studied Biotechnology at the Technical College in Darmstadt, where she completed as a graduate engineer and has more than 25 years in the pharmaceutical industry, with focus on microbiology and aseptic processing. In her current position she is a subject matter expert for the implementation of new environmental monitoring system for a new gloveless robotic filling line.

Kevin Gadient
Emergent

Kevin Gadient went from aseptic filling in an open Grade A cleanroom to being responsible for the procurement and implementation of a gloveless, robotic isolator. He is the Senior Director of Manufacturing Operations at the Emergent BioSolutions site in Winnipeg, Manitoba, Canada. Kevin is a registered Professional Engineer and holds a Bachelor of Science degree in Chemical Engineering from Queen's University.

Winnie Hagen Madsen
Novo Nordisk A/S

Winnie Hagen Madsen has a master degree in engineering within biotechnology from the Technical University of Denmark. Since 2006 she has worked for Novo Nordisk A/S Denmark, where she has worked with aseptic filling. In the beginning with optimisation of production processes on traditional filling lines placed in a grade A environment and in the later years with installation and validation of isolator filling machines.

Dr Daniel Müller
Local Government of Baden Württemberg, Germany

Daniel Müller studied Pharmacy at the University of Wuerzburg, followed by doctorate. He started working in the pharmaceutical industry in 1998. Among other positions he served as a Qualified Person of large volume parenterals. In 2001 he joined a German inspectorate at Tübingen. Since that time he has been working as a GMP-Inspector with focus on biotechnological active ingredients and sterile drug products.

Youwen Pan
WuXi Biologics

Youwen has more than 20 years of work experience in pharmaceutical microbiology including microbial contamination control in biologics processing, classified clean room/zone environment, sterilization processing, and development of rapid microbial test methods. Before joining WuXi, he worked for Roche/Genentech, Baxter and Fresenius-Kabi. He obtained PhD degree of Microbiology from North Carolina State University.

Hoang Phan
Genentech

Hoang Phan is a Distinguished Engineer at Genentech, and is serving as a Network Technology Lead within Roche. He has over 29 years of experience at Genentech with roles in manufacturing and MSAT, spanning drug substance and drug product. Hoang is currently leading Roche's efforts to introduce a fleet of modular filling systems that will allow for fast deployment, agile production across our network, and effortless technology transfers.

Ute Schleyer
Vetter Pharma-Fertigung

Ute Schleyer studied Biology at the Johann Wolfgang von Goethe-University in Frankfurt. After receiving her Ph.D. Ute spent 4 year in the position of lab supervisor at the Institute of Biotechnology, based in the Research Center Juelich.
In 2007 she joined Vetter as a Manager of Aseptic Production. In 2008, she was promoted to production manager for the manufacture and filling of sterile drug products, which included single-chamber and dual-chamber filling lines. In 2016, Ute Schleyer was appointed Project Manager in the Site & Plant Development department of Vetter. In this position, she is responsible for supporting pharmaceutical engineering projects including V-CRT®.

Dr Christian Siegmund
F. Hoffmann-La Roche

Christian Siegmund studied Pharmacy at the University of Basel. He started working in the pharmaceutical industry in 1999 at Hoffmann-La Roche. He worked in Parenteral Production for over 25 years. Before joining the modular filler project, he acted for almost 10 years as Head of Liquid vial and prefilled syringes filling at the Parenteral Production in Kaiseraugst, Basel.

Dr Thomas Thurn
Janssen Cilag

Thomas Thurn is working at Janssen Pharmaceutical Discovery, Product Development and Supply responsible for process development, manufacturing and supply of clinical trial material. Thomas holds a PhD in Physical Chemistry from Manchester University and has over 20 years experiences in the pharmaceutical industry working in areas of new technologies and product development up to commercialization in clinical and commercial supply chain with experiences from API to final product in solid, semi-solid and in the biologics field.

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Reservation Form (Please complete in full)

European Microbiology Conference, Live Online Conference on 03-05 May 2022

- ☐ **Day 1 (03 May 2022): Microbiological Control of Cell- and Gene-Based Products/ATMPs**
- ☐ **Day 2 (04 May 2022): Endotoxin and Pyrogen Testing – Current Trends**
- ☐ **Day 3 (05 May 2022, Half Day): Robotic Isolators – Challenges and Modern Monitoring Systems**

Title, first name, surname

Department Company

Important: Please indicate your company's VAT ID Number Purchase Order Number, if applicable

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If you cannot attend the conference you have two options:
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2. If you have to cancel entirely we must charge the following processing fees:
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- Cancellation until 1 weeks prior to the conference 50 %
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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.

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Date of the Live Online Training

Thursday, 05 May 2022, 13.30 h - 17.30 h CEST

Technical Requirements

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Fees (per delegate, plus VAT)

1 Day Ticket
ECA Members EUR 890.- | APIC Members EUR 940.-
Non-ECA Members EUR 990.- | EU GMP Inspectorates EUR 495.-

2 Day Ticket
ECA Members EUR 1590.- | APIC Members EUR 1690.-
Non-ECA Members EUR 1790.- | EU GMP Inspectorates EUR 895.-

Half Day Ticket (Day 3)
ECA Members EUR 640.- | APIC Members EUR 665.-
Non-ECA Members EUR 690.- | EU GMP Inspectorates EUR 345.-

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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