



## Speakers



Thomas Bach Nielsen  
Novo Nordisk



Dr Simone Bläsi  
F. Hoffmann-La Roche



Christoph Dumont  
UCB



Thorsten Haefner  
PSM



Maren Jahn  
Vetter Pharma-Fertigung



Kenan Kanmaz  
Metall+Plastic



Didier Meyer  
DMCompliance



Dr. Daniel Müller  
Local GMP Authority of  
Baden Württemberg



Franck Pavan  
GTP Nano



Julian Petersen  
groninger & co.



Dr Ute Schleyer  
Vetter Pharma-Fertigung



Marcel Schulze  
PPT Pharma Process  
Technology



Robert G. Schwarz  
FH Campus Wien



Dr Tim Stöveken  
Merz Therapeutics



Frank Studt  
gempex



Rudolf M. Weiss  
Stäubli Tec-Systems  
GmbH Robotics

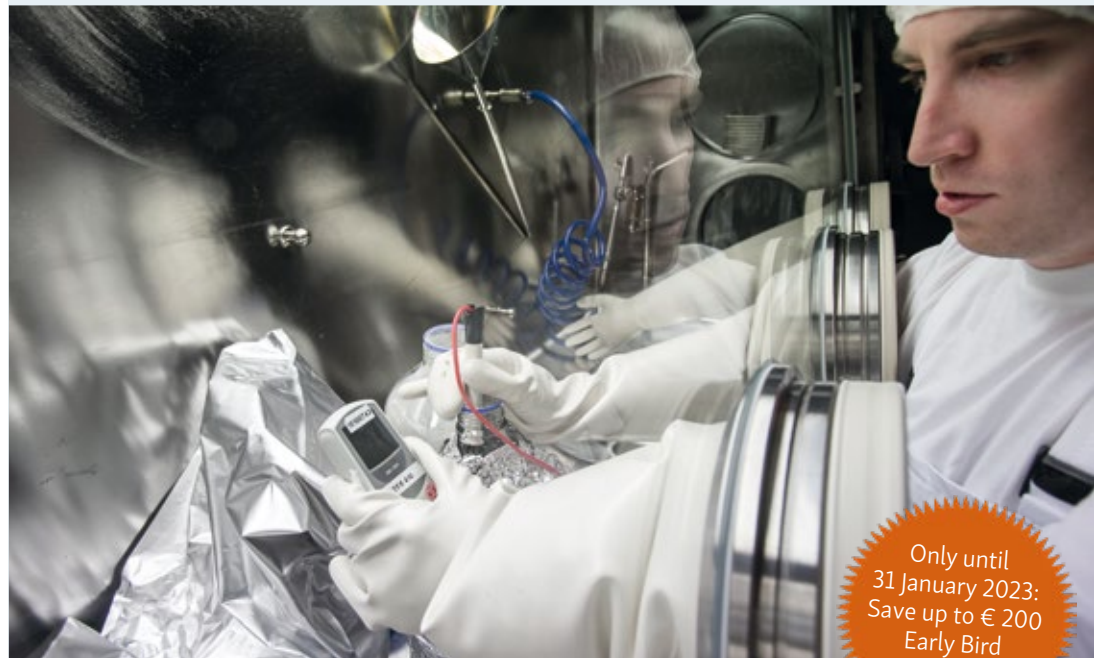


Jörg Zimmermann  
Vetter Pharma-Fertigung

# New Developments in Barrier Systems & Robotics

Part of PharmaCongress 2023

28/29 March 2023 | Wiesbaden, Germany



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## Highlights

- Barrier Systems and the New EU GMP Annex 1 Requirements
- Robotics Technology in Pharmaceutical Manufacturing
- Case studies from:
  - F. Hoffmann-La Roche
  - GTP Nano
  - Merz Therapeutics
  - PSM
  - Novo Nordisk
  - UCB
  - Vetter Pharma-Fertigung



## Objectives

This is why you will benefit from attending this conference:

- Case studies from various pharmaceutical companies deal with the implementation, qualification and operation of Isolator, RABS systems and Robots.
- You will discuss the current state of the art and new technological developments in Barrier Systems and Pharmaceutical Robotics Technology.
- You will get to know first-hand the new EU-GMP Annex 1 requirements on Barrier Systems
- Experts from pharmaceutical companies will share their knowledge regarding operational experience.

## Background

The protection against microbial contamination is the most important point for drugs produced by aseptic processes. Today the regulators require a stricter separation between operators and product in the form of an access barrier.

Two systems are on the market – RABS (Restricted Access Barrier System) and Isolators. But only isolators are referred to by the US FDA as advanced aseptic technology. Another consequence of the separation of operator and production process is the increased introduction of Robot Technology in the aseptic environment.

This conference will focus on current questions of barrier systems and robotics coming from FDA regulations as well as from the revised EU-GMP Annex 1, and it will specifically address the subject from the perspectives of pharmaceutical operators, planners and engineers.

## Target Audience

This event is directed at decision-makers from pharmaceutical production, automation, development and quality assurance/control. It also addresses engineers and planners who need to be well informed about current developments in the field of barrier systems and robotics.

## Moderators

Didier Meyer, DMCompliance  
Frank Studt, gempex

## Programme 28 March 2023

### Retrofitting RABS - Upgrade to V-CRT

*Dr Ute Schleyer, Vetter Pharma-Fertigung*

- After Vetter had already built 4 new clean rooms with V-CRT technology, 2 clean rooms have been added.
- These two clean rooms previously operated as RABS for several years before being upgraded to the V-CRT system.
- Challenges and differences to the newly built cleanrooms to the retrofitted are presented.

### Process Automation in a Small Scale Aseptic Manufacturing Site for Clinical Trial Products

*Dr Tim Stöveken, Merz Therapeutics*

*Marcel Schulze, PPT Pharma Process Technology*

- Presentation of flexible manufacturing concept for sterile liquid products for clinical trials
- Filling of small batches with automation of the most critical processes
- Implementation of Isolator technology into an existing building
- Training and operation concept in a non-routine environment

### Replacement of H<sub>2</sub>O<sub>2</sub> Generator from Existing Vial Filling Line

*Dr Simone Bläsi, F. Hoffmann-La Roche*

*Kenan Kanmaz, Metall+Plastic*

- Project challenge from the first step – timeline
- Production shutdown and realization
- Risk and other key tasks of upgrading
- Results of cycles development with the new H<sub>2</sub>O<sub>2</sub> Generator RG4
- Key features and advanced technologies of RG4 - H<sub>2</sub>O<sub>2</sub> Generator
- DECOpulse® - effective H<sub>2</sub>O<sub>2</sub> Bio-decontamination System

### Barrier Systems and Automation - the Needs and the Potential considering Contamination Control Strategy (CCS)

*Robert G. Schwarz, FH Campus Wien*

- Annex 1 - game-changer for RABS or documented state of the art?
- RABS vs Isolator - the decision prior robotics
- Struggling in updating existing Barrier Systems - are all of us ready for robotics in aseptic processing?

## Benefits of Robotics in a CDMO Environment – A Case Study at the German CDMO PSM GmbH about using gloveless robotic Filling System in the Light of Contamination Control Strategy (CCS)

Julian Petersen, Groninger & Co  
Thorsten Häfner, PSM

- Layouts and processes for using a gloveless robotic filler for high value drugs
- Replacement of manual processes by robots
- Minimizing humans in the aseptic area
- Comparison of traditional technologies with robotic applications

## Barriers & Robotic Isolators in New Annex 1 (2022 version)

Dr Daniel Müller, Local Government, Germany

- Requirements for barriers/ isolators
- Major changes for barriers (version 2008 vs. 2022)
- How far are robotic isolators addressed?
- Challenges, discussion points & GMP inspector's view

## Programme 29 March 2023

### The Use of Robotic Systems in Aseptic Processing and the Pharma-Industry Overall

Jörg Zimmermann, Vetter Pharma-Fertigung

- Automation and Robotics in the pharmaceutical industry
- Robots for cleanrooms: things to consider
- Robotic automation in aseptic processing: implementation examples and outlook
- Use of robotics in compounding, testing and secondary packaging

### Automated Thawing Process: Combining Robotic and Manual Process Steps

Maren Jahn, Vetter Pharma-Fertigung

- Concept: the path from process needs to first ideas
- Self-driving robot for the homogenization of frozen protein solution during thawing
- Technical Challenges: operator safety versus processing time; integration of specific robotic solution in multi-use facility
- Implementation Challenges: Comparison of manual versus automated homogenization process of API bottles; integration in batch documentation; interaction between robot and operator

## Disposable Isolator and Robotic Input, Why Not?

Frank Pavan, GTP Nano

- Introduction of fill and finish activities in grade A
- Use of 6 axes robots outside critical manufacturing area
- Use of Disposable filling Grade A isolator for parenteral manufacturing
- Containment of Highly potent products using Disposable isolator

## Live Demos

### Advanced Technologies of Isolator Systems with Integrated Aseptic Transfer Solutions (RTP) from METALL+PLASTIC & CASTUS

Optima pharma

- Basics, Key features and advanced technologies of Isolator
- Aseptic and High-Potent Concepts
- DECOpulse® - integrated H2O2 Bio-decontamination System
- Transport System MTC & RTP
- Glove Testing System

### According to Annex 1 Revision: Use Software to Check all Barrier System Components that are to be Tested

MK Versuchsanlagen

- Leak test of barrier system
- Change since Annex 1 revision
- Components of the barrier system that are to be tested: gloves, RTP / alpha ports / beta containers, half suits
- One central software with various integration options to map all leak tests
- Efficient processes - maximizing valuable production time

### How Robotics can Support Laboratory in a Very Compact Space

Stäubli

- Highlight the compactness of our robot is to be implemented in small cell in very small area such laboratory or hospital
- Highlight the flexibility provided by our Stäubli Division tool changer that allow manipulating flask, vials, PCR test, in different format with the same robot.
- Automation in hospital is also the response to big sanitary crisis we have faced. We need to anticipate.
- Laboratory employee needs to focus on the high value task. Not on repetitive tasks
- This equipment can be available on aseptic environment

### An Innovative Solution to Reduce Particle Generation in Primary Packaging

Steriline

- Robotic management of vial capping without vibrating parts
- D vision system for robot guidance
- Automatic format change with no mechanical parts
- No Need of stopper alignment

# Speakers

## New Methods to develop Pharma Automation and Robotic Solutions in Warp Speed

Thomas Bach Nielsen, Novo Nordisk

Rudolf M. Weiss, Stäubli Tec-Systems GmbH Robotics

## Fill&Finish Machine for Cell&Gene Therapy: From Requirements to Concept and Realization

Christoph Dumont, UCB

TBN

- Presentation of UCB's requirements and drivers
  - for small batches (1000pcs. - 2R vial)
  - RTU vials in nests, SiO2 vials
  - 100% IPC
  - no product loss (also during the production start)
  - conventional stoppering and aluminum capping
  - compact footprint
  - under Isolator
  - Environmental conditions:
    - Outside surface of the outer bag exposed to the decontamination agent under Grade C
    - Tub debagging under Grade A air supply
    - Tub opening under Grade A
    - Filling & Closing Under Grade A
    - Crimping at least Grade A air Supply
- Presentation of machine concept
  - 3D drawings and movie clips of our robotic design
  - No-Loss-Philosophy: Re-filling, Re-stoppering, Re-capping functionalities

# Speakers



**Thomas Bach Nielsen**  
Novo Nordisk

Thomas has more than 22 years of experience in automation in various positions such as, Automation programmer, Automation engineer and technical project management. Currently, he is the Director and head of Novo Nordisk's Robotics and Operational Technology development and innovation unit.



**Dr Simone Bläsi**  
F. Hoffmann-La Roche

Simone Bläsi has been a validation expert at F. Hoffmann La-Roche in Kaiseraugst Switzerland since 2019.



**Christoph Dumont**  
UCB



**Thorsten Häfner**  
PSM

VP Business Development.



**Maren Jahn**  
Vetter Pharma-Fertigung

Maren completed her master's degree "Master of Science – Life Science Engineering" at Friedrich-Alexander University Erlangen in 2014. Since 2015 she has been working at Vetter Pharma Fertigung as Manager Technology & Process Transfer.



**Kenan Kanmaz**  
Metall+Plastic

Kenan Kanmaz works more than 12 years as technical engineer in the clean room section. Currently he works as Technical Sales Manager for METALL+PLASTIC GmbH since 2016.



**Didier Meyer**  
DMCompliance

Didier worked 7 years with Millipore Europe in various positions of sales, marketing and training. Since 1983 he has worked in the development of isolation technology in the Biopharma industry with La Calhène. Currently he is consultant at DMCompliance.



**Dr Daniel Müller**  
GMP/GDP Inspector, Local Government, Germany

Currently Daniel Müller is head of GMP inspectorate (local competent authority) at Tuebingen, Germany. Since 2001 he has been working as GMDP inspector, conducting national inspections as well as EMA- and overseas inspections.



**Frank Pavan**  
GTP Nano

20 years of experience in CDMO activities for fill and finish in clinical and commercial scale. Consultant for sterile manufacturing of highly potent products.



**Julian Petersen**  
groninger & co

After a short timeout in the semiconductor/metrolology business, Julian returned to the pharmaceutical fill&finish business as a Sales Director responsible for the DACH market. Now leading the Business Development and Product management.



**Dr Ute Schleyer**  
Vetter Pharma-Fertigung

Ute Schleyer, Ph.D., was appointed Project Manager in the Site & Plant Development department of Vetter in 2016. In this position, she is responsible for supporting projects in the field of pharmaceutical technology. Ute joined Vetter in 2007 as Manager of Aseptic Production. She was promoted to the position of Head of Production in 2008 in the area of manufacturing and filling of sterile drug products, which includes various single and dual-chamber filling lines.



**Marcel Schulze**  
**PPT Pharma Process Technology**  
 Since 2021 Marcel Schulze works for PPT. He and his team provide engineering services for sterile manufacturing processes from feasibility studies til start of production.



**Robert G. Schwarz**  
**FH Campus, Vienna**  
 Robert Schwarz, graduate in “Bioprocess Engineering” and “Biotechnological Quality Management”, was responsible for environmental monitoring as well as validation of decontamination systems at Baxter (now Shire). Since 2010 he is working as a lecturer in the field of biotechnology with a focus on validation/qualification, aseptic process methods and cleanroom technology at the University of Applied Sciences Vienna.



**Dr Tim Stöveken**  
**Merz Therapeutics**  
 Since 2008 at Merz in Biotechnology Process Development.



**Frank Studt**  
**gempex**  
 Managing Director



**Rudolf M. Weiss**  
**Stäubli Tec-Systems GmbH Robotics**  
 In October 2020 he started in the senior management at STÄUBLI Robotics and took over the global responsibility for robotic/automation business in pharma and medical devices as Global Head of Pharma and Member of the Global Management Team.



**Jörg Zimmermann**  
**Vetter Pharma-Fertigung**  
 Since November 2019, Jörg Zimmermann is Vice President, Vetter Development Service, External Affairs.

## Congress Keynotes

28 March 2023

### Comprehensive Transformation of DR. KADE's Sites and Supply Chain

*Dr Norbert Marquardt, Dr Kade Health Care*

29 March 2023

### Trends in Aseptic Manufacturing: Questions and demands for Pharma Machine Vendors

*Dr Friedrich Haeefe, formerly Boehringer Ingelheim Pharma*

## PharmaCongress 2023



The guiding theme of the PharmaCongress 2023 on 28/29 March will be „users sharing challenges and solutions in practice“. Therefore, benefit from your colleagues' experience and from the direct information exchange at PharmaCongress & PharmaTechnica 2023.

### The Tracks

As a participant you can switch between any of the tracks any time and also visit the PharmaTechnica Expo with more than 100 international exhibitors.

Conference Tracks	28 Mar	29 Mar
European Aseptic Conference	✓	✓
New Developments in Barrier Systems & Robotics	✓	✓
PUPSIT: Complying with the Main Annex 1 Changes	✓	✓
GMP for Pre-Filled Syringes (PFS)	✓	✓
Pharma 4.0 & Digitalisation	✓	✓
Handling of Highly Active Products	✓	✓
ATMP – Manufacturing, Quality & Safety	✓	✓
PharmaTechnica Expo	✓	✓

Find out more about the other conference tracks on our website [www.pharma-congress.com](http://www.pharma-congress.com).

Reservation Form (Please complete in full)

## New Developments in Barrier Systems & Robotics - Part of PharmaCongress 2023 28/29 March 2023, Wiesbaden, Germany

- Day 1 & 2 (28/29 March 2023)
- Day 1 (28 March 2023)
- Day 2 (29 March 2023)

Yes, I would also like to take part in the Social Event on the evening of 28 March 2023.

Title, first name, surname

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### General terms and conditions

- If you cannot attend the conference you have two options:
- We are happy to welcome a substitute colleague at any time.
  - 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 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!) (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 [http://www.gmp-compliance.org/eca\\_privacy.html](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 Conference

Tuesday, 28 March 2023, 09.00 - 18.00 h  
 Wednesday, 29 March 2023, 09.00 - 17.00 h  
 Registration: 28/29 March 2023, 08.00 - 09.00 h

## Venue

RheinMain CongressCenter (rmcc)  
 Friedrich-Ebert-Allee 1  
 65189 Wiesbaden  
 Phone: +49 (0) 611 / 1729-444  
 veranstaltungsservice-rmcc@wicm.de

## Fees (per delegate, plus VAT)

The one day ticket is available for € 690,- plus VAT (until 31 January 2023 only € 590,- plus VAT), both days for € 1,380 plus VAT (until 31 January 2023 only € 1,180 plus VAT). It includes participation in any conference track of PharmaCongress 2023 on that day(s) and the visit of the PharmaTechnica Expo. In addition, lunch and beverages during the tracks and in breaks as well as the social event on the evening of the first congress day, 28 March is included; please mark if you would like to attend the Social Event.

The fee is payable in advance after receipt of invoice.

## Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms close to the CongressCenter. You will receive a room reservation form when you have registered for the conference. Reservation should be made directly with the hotel. 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](http://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.

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