GMP/FDA Compliant Facilities & Technology

31 May/1 June 2022 | Düsseldorf/Neuss

Image: Boehringer Ingelheim

Highlights

/New and flexible vaccine manufacture
/Large Scale Cell Culture
/Fast track projects during the COVID pandemic
/A modular GMP plant for clinical trials
/Facility requirements and containment for solid drug products
/Usage of new techniques in freeze drying
/Closed systems in CNC ball room
/Mastering spatial constraints in remodelling projects
/Single-use technology for final filling
/Single-use technology in continuous purification processes
/Among others, case studies of
/Boehringer Ingelheim | Roche | IDT Biologika | CSL Behring | Vetter | Novo Nordisk | Merck Healthcare | Merz Pharma

#sharing challenges and solutions in practice

GMP-PHARMA CONGRESS

CONCEPT HEIDELBERG
Pharmaceutical Quality
Training. Conferences. Services.

Supported by

ECA Academy
Your GMP/GDP Information Source

Overview

Benefit from your colleagues' experience and from the direct information exchange at the PharmaCongress 2022 again. The guiding theme from 31 May - 1 June 2022 will be „users sharing challenges and solutions in practice".

The Conferences

As a participant you can switch between any of the conferences any time and also visit the exhibition PharmaTechnica. Fore more details please also see "Fees" below.

Conference	31 May	1 June
▪ GMP/FDA Compliant Facilities & Technology	✓	✓
▪ GMP/FDA Compliance Conference	✓	✓
▪ European Aseptic Conference	✓	
▪ Cost Efficiency in Pharma Manufacturing		✓
Exhibition PharmaTechnica	✓	✓

Exhibition

Parallel to the conferences there will be the exhibition PharmaTechnica. Take advantage of this opportunity to get to know new technologies, products and services at the stands of the exhibitors.

Fees

€ 690,- **for the one day ticket** plus VAT. These one day tickets allow you to follow any conference offered that day (you can also switch between the conferences any time). They include a lunch and beverages during the conferences and in breaks as well as the free visit of the exhibition PharmaTechnica and the social event on the evening of the first congress day. Charges are payable after receipt of invoice. Please note that due to the special fees for the congress, ECA membership discounts are not applicable.

Location

Crowne Plaza Congress Centrum Düsseldorf / Neuss
Rheinallee 1
41460 Neuss
Tel.: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
emailus.neu02@gchhotelgroup.com

Contact

For questions regarding the content of the conference:
Dr Robert Eicher (Operations Director),
Phone +49 (0)6221/84 44 12,
E-Mail: eicher@concept-heidelberg.de.

For questions regarding the organisation of the conference:
Mr Ronny Strohwald (Organisation Manager),
Phone +49 (0) 6221/84 44 51,
E-Mail: strohwald@concept-heidelberg.de.

Please note

Exhibition Visit: The exhibition will also be open to visitors on both days who are not attending the Congress. Please be aware, though, that you will need to register in advance of the free of charge visit. The visit of the exhibition does not entitle you to also attend any of the conferences.

Congress Materials: Please note that there will not be any print-outs at the Congress. Instead you will receive all presentations prior to the Congress as Downloads.

Room Reservations: There will be no room reservations via Concept Heidelberg. Please book your hotel room directly with the reservation form which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice.

General Information

Objective
The focus of this conference is on innovative investment projects and their GMP-compliant, technical realisation.

Background
State-of-the-art greenfield, brownfield and pharmaceutical technology projects will be presented by the “pharmaceutical user” under the motto "Users report for users".
Compliance with GMP requirements is mandatory in these projects, although those are usually described in little detail in guidelines from authorities. Benchmarking with other companies in the pharmaceutical industry is all the more important here in order to derive the current state of the art.

Target Audience
The target group of the conference are specialists and managers from the areas of technology and production, as well as representatives of pharmaceutical plant construction and from engineering companies.

It particularly addresses the departments:
- Production
- Engineering / Technology

Moderator
Dr Johannes Krämer, CSL Behring

Speakers


Volker Glück
Boehringer Ingelheim, Senior Project Manager


Nicole Härdter
Ludwig-Maximilians-Universität München


Dr Charles Heise
Fujifilm, Senior Staff Scientist BioProcess Strategy & Development


John Honey
Roche, Head of Site Engineering at Roche in Penzberg


Lars Hovmand-Lyster
Novo Nordisk, Senior Engineering Specialist


Matthias Klein
CSL Behring, Director Aseptic Filling


Dave Mills
GEMÜ, Key Account Manager Pharma, Food & Biotech


Dr Daniel Minör
IDT Biologika, Senior Manager Production


Steffen Mörler
CSL Behring, Project Excellence Lead


Markus Multhauf
ECA Validation Group


Alois Probst
Roche, Project Engineer


Nicola Rutigliani
Merck, Senior Project Manager


Ilka Rudzio-von Arx
Pharmaplan, Senior Project Manager


Dr Martin Schwab
Vetter Development Services Austria, Site Manager Vetter Development Services Austria GmbH


Dirk Steinhäuser
Glatt Ingenieurtechnik, Vice Head Dresden Engineering Office & BD Manager


Dr Markus Weigandt
Merck Healthcare KGaA, Head Pharmaceutical Technologies


Fred Wulfgramm
Merz Pharma, Head of Engineering Site Dessau


Udara Yapa
WuXi Biologics, *Head of Validation*


Thomas Zlabinger
Boehringer Ingelheim RCV GmbH & Co KG, Qualification Manager

Programme 31 May2022

The LSCC Program

Thomas Zlabinger, Boehringer Ingelheim

- Introducing Boehringer Ingelheim and the LSCC program
- Challenges during the project this sizes
- Deep dive: Commissioning and Qualification strategies

Boehringer Ingelheim in Vienna, Austria has opened its LSCC building (Large Scale Cell Culture) in October 2021 to further strengthen its biopharmaceutical product portfolio. To date, the LSCC is the largest single investment the company has ever made.

IDT Biologika: Design & Implementation of new flexible (modular) Vaccine Production Facility

Dr Daniel Minör, IDT Biologika
Dirk Steinhäuser, Glatt Ingenieurtechnik

IDT Biologika has extended its biotech CMO capacity for vaccines at its Dessau site in Germany with a new, very flexible biotech facility. The case study will provide an overview on the project development from initiation phase, via Concept Design and all Engineering phases, fast-track modular building construction, implementation of HVAC, cleanrooms, biotech equipment for upstream and downstream processing, media and buffer systems and further necessary periphery. Specific requirements for a multi-purpose vaccine production facility will be outlined. Further key points are:

- Production of virus vaccines, including cancer vaccines
- Biosafety level 2 and cleanroom class B design, implementation and operation
- Attention points of single-use equipment and application
- Fast track modular building using concrete steel prefab systems
- Supply chain management for single use material in pandemic environment

Merz Pharma: Investment in Dessau

Fred Wulfgramm, Merz Pharma

CSL Behring: Challenges due to limited Space in the existing Building during Construction Phase

Matthias Klein, CSL Behring
Steffen Mörler, CSL Behring

The ILC-H69 (Increase Lyophilization capacity – building H69) project involves the installation of two new freeze dryers with automatic vial loading system and connection to existing filling line. The special challenges of this project are the extremely limited space in the existing building and the continuation of filling operations during the construction phase. These were mastered with the use of new planning tools.

- 3D Planning
- Laserscan
- Virtual Reality visualization
- Feasibility Study for large component intake

Microwave-assisted freeze-drying of Biologicals

Nicole Härdter, Ludwig-Maximilians-Universität München

- Basic principles of microwave-assisted freeze-drying
- Experimental design
- Critical quality attributes of the lyophilizates
- Stability studies

Vetter Pharma: Integration of an existing pharmaceutical Manufacturing Site into Vetter's Development Services

Dr Martin Schwab, Site Manager Vetter Development Services Austria

- Site acquisition
- Technical and regulatory assessment
- Strategic approach
- Technical adaptions
- Process optimization

In July 2020 an acquisition contract has been signed by Vetter's general management. This contract absorbed the former commercial and clinical manufacturing site in Rankweil, which was planned, built and operated until Q4 2019 by Rentschler, into Vetter's company structure. Aim of this acquisition was to support Vetter's growing clinical manufacturing business and to establish Rankweil as an additional dedicated clinical manufacturing site - analogous to the clinical manufacturing site in Skokie, USA. For this buildup, including several technical and structural adaptions, an ambitious project has been established with its main milestone, the inspection of the Austrian authorities, planned and accomplished less than 1.5 years after the signature of the acquisition contract.

Novo Nordisk: Closed Systems in CNC Ballroom, A Risk Based Approach

Lars Hovmand-Lyster, Novo Nordisk

- Harmonization and evaluation of appropriate room classification requirements across the biopharmaceutical industry
- A risk based approach to assigning appropriate room classification to operations during facility design
- Enabling pharmaceutical industry to move operations to a more flexible facility whilst reducing both operational and capital costs
- Impact of closed systems and ballroom design on facility design, construction and qualification
- Ultimately increasing speed to market and reducing cost of goods to patient
- For closed systems increasing room classification has no increase in product safety and in reality has a negative impact

Programme 1 June 2022

Merck's new modular GMP Plant for clinical DP Manufacturing

Dr Markus Weigandt, Merck Healthcare

- Overview of Merck's modular approach to cover the Drug Product GMP supply of the early healthcare pipeline
- Products possible up to OEB5
- Manufacture of orals solid dosage forms and parenterals
- Small technical and operational footprint : flexible setup enables a broad technology base
- Qualification strategy
- Lessons learned


Image: Merck

Boehringer Ingelheim: New solid Launch Facility for Containment

Volker Glück, Boehringer Ingelheim
Ilka Rudzio-von Arx, Pharmaplan


Image: Boehringer Ingelheim/Pharmaplan

In this presentation the new solid launch facility of Boehringer Ingelheim in Ingelheim for the production of launch products with OEB Level 4 with containment technology will be shown.

- Overview of main data of the project
- Containment strategy
- Layout considerations for OEB Level 4
- Solutions for containment

Implementation of cold WFI systems in Europe

Markus Multhauf, ECA Validation Group

- Current technical developments
- Regulatory issues

Roche: CAPEX Project Delivery for What Patients Need Now

John Honey, Roche
Alois Probst, Roche


Image: Roche

The COVID-19 pandemic triggered a significant demand for Diagnostics Operations. Several "Fast Track" projects were initiated to install additional capacity in order to meet the immediate demand. The classical milestone approach to project execution would not deliver capacity in time so alternative strategies were employed. Just in time planning, overlapping of project phases, transparent and collaborative communication supporting funding approval, long lead item ordering at risk, etc.

Road from Design, Commissioning, Qualification to Process Validation for Fast tracked Projects

Udara Yapa, WuXi Biologics

Overview of common pitfalls that happens during fast tracked projects and potential solutions to overcome these pitfalls. Following stages will be explored:

- Purchasing and negotiation
- Design Qualification
- Commissioning and Qualification
- Handover to the user
- Time loss between end of OQ till start of PV
- Constraints during transition from PV to a routine manufacturing

Aseptic Sterile Filtration using Single Use and Isolator Technologies

Nicola Rutigliani, Merck

- Project: facility and equipment pre-requisites, qualification and implementation of SUS
- Risk identification when using SUT and mitigation strategy
- SU integrity test at the point of use (method development & qualification)

FUJIFILM Diosynth Biotechnologies CDMO: Multifunctional Single-Use Purification System for connected and integrated Continuous Processing

Dave Mills, GEMÜ
Dr Charles Heise, Fujifilm

- Tangential Flow Filtration
- Protein A affinity chromatography
- Viral Inactivation
- Cation and anion exchange chromatography
- Viral Filtration
- Ultrafiltration/Diafiltration

Easy Registration

Registration Form:
CONCEPT HEIDELBERG
Rischerstraße 8
69123 Heidelberg

Registration Form:
(06221) 84 44 34

E-Mail:
info@concept-heidelberg.de

Internet:
www.pharma-congress.com

Date
Tuesday, 31 May 2022, 09.00 – 18.00 h
Wednesday, 1 June 2022, 09.00 – 17.00 h
(Registration: Monday, 30 May 2022, 19.00 – 20.00 h,
Tuesday, 31 May 2022, 08.00 – 09.00 h and
Wednesday, 1 June 2022, 08:00 – 09.00 h)

Venue
Crowne Plaza Düsseldorf / Neuss
Rheinallee 1
D-41460 Neuss, Germany
Phone.: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
E-Mail: emailus.neu02@gchhotelgroup.com

On site, we will implement the necessary and required hygiene measures in close co-operation with the hotel.

Fee
EUR 690.- per delegate and day plus VAT (EUR 1,380.- for both days)

The conference fee is payable in advance after receipt of invoice and includes lunch on that day as well as beverages during the event and during breaks. It also includes the Social Event on the evening of the first congress day (31 May 2022).
Your registration also entitles you to participate in all other Pharma Congress conferences on either day of your registration. For the other conferences on both days please visit www.pharma-congress.com.

Registration
Via the reservation form below, by e-mail or by fax message. Or you register online at www.pharma-congress.com

PLEASE NOTE
Please note that there will not be any print-outs at the Congress. Instead you will receive all presentations prior to the Congress as Downloads.

Please further note that there will be no room reservations via Concept Heidelberg. Please book your hotel room directly with the reservation form which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice.

Organisation & Contact
CONCEPT HEIDELBERG - on behalf of the ECA Academy
P.O. Box 10 17 64
D-69007 Heidelberg
Telefon 0 62 21/84 44-0
Telefax 0 62 21/84 44 34
E-Mail: info@concept-heidelberg.de
www.gmp-navigator.com

For questions regarding content:
Dr Robert Eicher (Operations Director) at +49-6221/84 44 12, or per e-mail at eicher@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager) at +49-6221/84 44 51, or per e-mail at strohwald@concept-heidelberg.de.

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

GMP/FDA Compliant Facilities & Technology (31 May-1 June 2022)

+49 6221 84 44 34

Part of the PharmaCongress Production & Technology 2022
Düsseldorf/Neuss, Germany, 31 May - 1 June 2022

I register for (Please complete in full):

☐ Day 1 (31 May 2022) ☐ Day 2 (1 June 2022) ☐ Both days (31 May & 1 June 2022 – 1.380,- €)

☐ I would also like to participate in the Social Event on 31 May 2022

☐ I want to pay by credit card VISA MasterCard AMERICAN EXPRESS

☐ Mr ☐ Ms ☐ Mx ☐ Dr

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Please indicate the Purchase Order Number, if applicable

Street / P.O. Box

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 %,
☐ 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 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)!
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.

WH/17052022