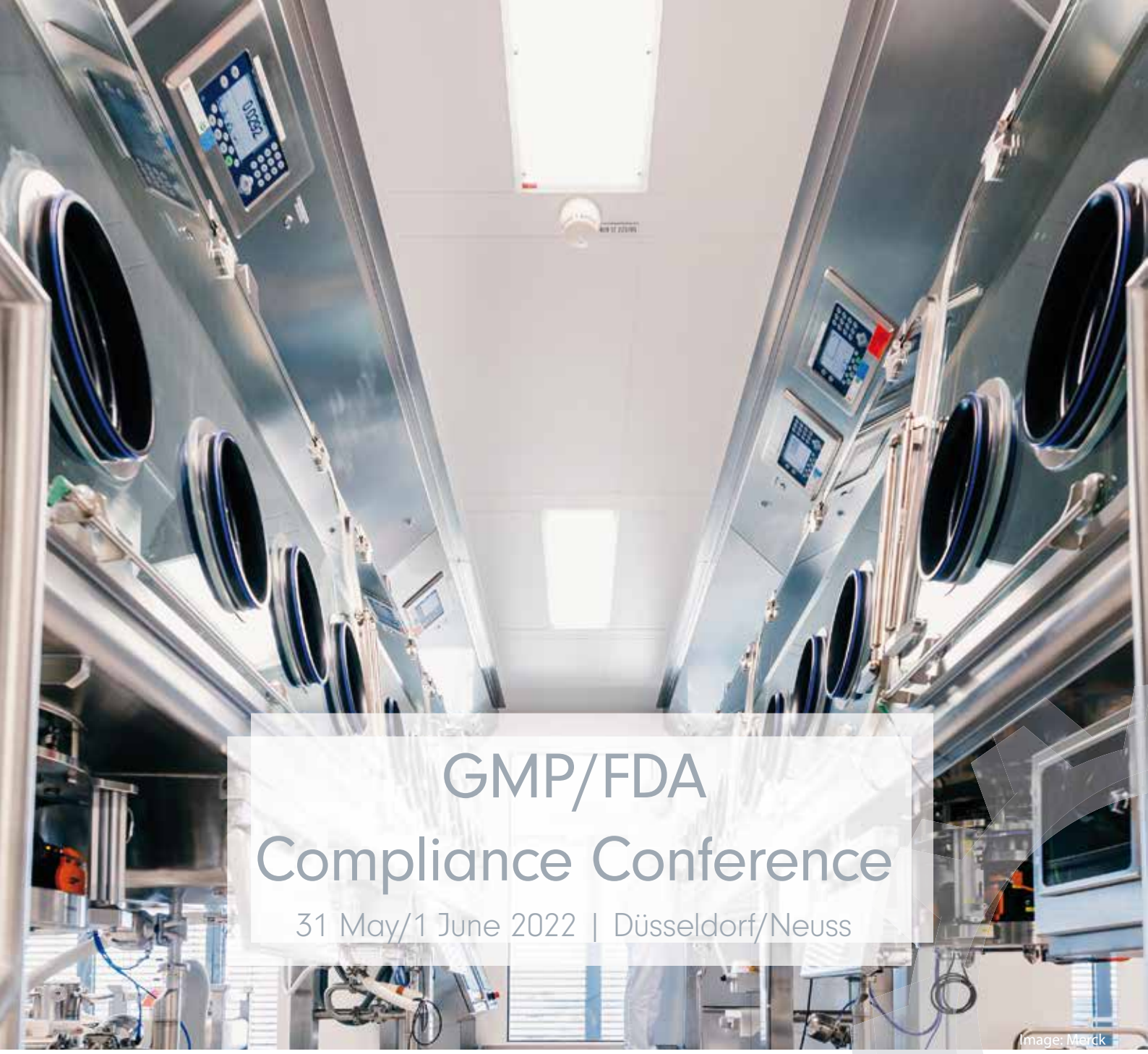

GMP/FDA Compliance Conference

31 May/1 June 2022 | Düsseldorf/Neuss

Image: Merck

Highlights

/Compliance trends and their impact to pharmaceutical manufacturing
/COVID-19-pandemic and compliance trends
/Current status of the EU GMP Annex 1 Revision
/Case studies from:
/Accord Healthcare | Bipso | Boehringer Ingelheim Pharma | Merck | MSD AH Danube Biotech | Novartis Pharma | Vetter Pharma-Fertigung

#sharing challenges and solutions in practice

GMP-PHARMA CONGRESS

CONCEPT HEIDELBERG
Pharmaceutical Quality
Training. Conferences. Services.

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ECA Academy
Your GMP/GDP Information Source

Overview

Benefit from your colleagues' experience and from the direct information exchange at the Pharma Congress 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

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Phone +49 (0)6221/84 44 41,
E-Mail: mangel@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

Reasons to attend this conference: You will receive an overview of current regulatory developments in the area of pharmaceutical production with a focus on:

- EU GMP Guide Annex 1 revision
- Data integrity
- USP trends
- Risk management

Background

Even during the pandemic, the further development of GMP does not stand still. GMP requirements from regulatory guidelines have an influence on pharmaceutical engineering and pharmaceutical technologies. Examples from pharmaceutical practice show possibilities for implementation. In addition, it will be discussed how GMP compliance can be maintained in times of the pandemic.

Target Audience

The event is directed at specialists from the pharmaceutical industry as well as at engineers and planners who have to deal with current aseptic technologies in clean areas in their daily practice.
It particularly addresses the departments:

- Production
- Quality assurance
- Engineering / Technology

Moderator

Jörg Zimmermann, Vetter Pharma-Fertigung
Gert Moelgaard, Moelgaard Consulting

Speakers

Dr Hans-Joachim Anders
Novartis Pharma Stein AG, Unit Head Microbiological Quality Control

Dr Simone Biel
Merck KGaA, Senior Regulatory Consultant Life Science | Quality and Regulatory Management

Dr Michael Eakins
Eakins & Associates, USP Expert Committee member

Christian Gavranovic
PPT Pharma Process Technology GmbH, Head of Quality and Compliance

Dr Brigitte Gübitz
VTU Engineering GmbH

Dr Stephan Heck
Bipso GmbH, Director Quality

Christoph Holzmann
MSD AH Danube Biotech GmbH

Dr Philip Hörsch
Vetter Pharma-Fertigung GmbH & Co. KG, Director QA - Validation/Risk Management/Trending

Dr Jean-Denis Mallet
ECA, former head of the French Inspection Department AFSSAPS

Gert Moelgaard
Moelgaard Consulting, Lyngby, Denmark

Dr Daniel Müller
Local GMP Authority of Baden Württemberg, Head of GMP Inspectorate

Balasubramanian Ramaiah
Accord Healthcare, Senior Manager Quality / Responsible Person

Luigi Scaffidi
Boehringer Ingelheim Pharma GmbH & Co. KG

Robert G. Schwarz
GXP-TrainCon e.U., Founder and Managing Director; Member of the ECA Contamination Control Strategy Task Force

Jörg Zimmermann
Vetter Pharma-Fertigung GmbH & Co. KG, Vice President Vetter Development Service, External Affairs

Programme 31 May2022

Experience from COVID-19-Pandemic- a GMDP-Inspector's View

Dr Daniel Müller, Local GMP Authority of Baden Württemberg

- Challenges & options for GMDP-surveillance
- GMDP-Inspections
- Marketing authorisation licensing agencies
- On-site inspections, distant assessments or hybrid approach
- Experience during last 2 years of pandemic situation

GMP Compliance Trends during COVID-19 Out-break

Balasubramanian Ramaiah, Accord Healthcare

- Do Covid-19 GMP flexibilities compromise the compliance?
- How the NCA monitor the GxP compliance?
- NCA road maps to GMP inspection reliance
- Reliance of remote vs physical inspections
- Inspection finding trends during Covid-19 outbreak

From Risk Analyses to Traceability Matrix 4.0

Christoph Holzmann, MSD AH Danube Biotech
Dr Brigitte Gübitz, VTU Engineering

- Integrated commissioning and qualification – requirements and regulations
- FMEA - the centerpiece of a successful iC&Q approach
- Traceability right from the beginning - integration of user requirements into risk assessments
- Leveraging approach – how to link mitigating actions with commissioning procedures and qualification tests
- Automated risk assessments to create C&Q documents electronically
- Hot to use a life-cycle FMEA to track changes during a C&Q project

The ECA Good Practice Guide for Suppliers and Users on integrated Qualification and Validation

Gert Moelgaard, Moelgaard Consulting

- Introduction to the guide
- The role of a good supplier partner for effective qualification projects
- Equipment categories as tool for qualification planning
- Remote testing with web based computer tools
- Case stories from successful qualification projects

Update on USP's Bioreactivity, Extractables and Glass Containers Packaging

Dr Michael Eakins, Eakins & Associates

- Bioreactivity
  - Deletion of outdated methods in <87> and <88> and addition of genotoxicity methods to <87>
  - Deletion of the plastic classification system of Classes in <88>
  - Moving sensitization methods from <1184> to <88>
  - Expand the scope of <1031> to encompass plastic materials of construction for pharmaceutical packaging/delivery systems
  - Add a risk-based approach to biocompatibility evaluation in <1031>
- Extractables & Leachables
  - Revise and update <1663> and <1664> in line with current thinking
- Glass Containers
  - Incorporate new materials of construction
  - Update key quality tests
  - Revise spectral transmission test

Review of Online Water Monitoring Analyzers (OWBA) and their potential Application

Dr Hans-Joachim Anders, Novartis Pharma Stein

- Available methods and their measurement principles
- Possible applications of OWBA for quality control
- Evaluation study results for Aqu@Sense
- Speedbumps regarding implementation of OWBA

Ensuring Data Integrity in the daily Practice of Pharmaceutical Manufacturing

Dr Philip Hörsch, Vetter Pharma-Fertigung

- Handling of recipes and settings in manufacturing
- Role of in-process-controls
- Definition of quality-/decision-relevant data
- Examples of manufacturing processes and their data and audit trail review procedures
- Paper-/electronic hybrid situations and their impact on data review and audit trail review procedures

Programme 1 June 2022

Update EU GMP Annex 1

Dr Daniel Müller, Local GMP Authority of Baden Württemberg

- Update on Annex 1-Revision process
- Comparison old & new version
- Important changes, serious improvements
- Points of discussion

Current Views on aseptic Processing from the Perspective of the FDA: Report from a recent Panel Discussion

Jörg Zimmermann, Vetter Pharma-Fertigung

- Panelists included Rick Friedman, Brooke Higgins, Robert Sausville, Alonza Cruse, Thomas Arista and more
- FDA thinking on Annex 1
- Learnings from remote assessments and data requests
- Auditing in times of COVID
- Regulations for ATMPs and their interpretation

Airflow Visualization / Aseptic Process Simulation

Luigi Scaffidi, Boehringer Ingelheim Pharma
Christian Gavranovic, PPT Pharma Process Technology

- Airflow Visualization
  - Guideline
  - Life Cycle / Technique
  - Link to APS
- Aseptic Process Simulation

Sterile Filtration – How to Keep Flexibility and Regulatory Compliance

Dr Simone Biel, Merck

- Filter inside or outside the isolator?
- Redundant filtration – the extra piece of mind?
- PUPSIT required – but exceptions allowed?
- Post-approval change of a filter – critical or non-critical?
- Multiple use of a filter?
- Filter as part of a ready to use single-use system – how to ensure integrity downstream the filter?

Quality Assurance for Contrast Media – Parametric Release & New Annex 1

Dr Stephan Heck, Bipso

- Overview of contrast media and mechanisms of action (for X-ray examinations and MRI)
- Quality requirements for sterile production: terminal sterilized vs. aseptic production
- Parametric Release – Possibility to increase quality and productivity in sterile production
- New Annex 1 – Contamination Control Strategy

CCS (Contamination Control Strategy): Is it really a new Tool?

Dr Jean Denis Mallet, ECA

- Introducing the concept of "Contamination Control Strategy" as a powerful tool to ensure the quality (sterility), safety (sterility) and efficacy of product
- A list of different components that form the CCS and analyse the link / relationship from one to another
- In this aspect it can be accepted that CCS is 'simply' a structuration of what the more performing companies already do

How to implement a CCS according to Annex 1 (“A Guide to the Guide”)

Robert G. Schwarz, GXP-TrainCon e.U.

- ECA’s Guide on “How to Develop and Document a Contamination Control Strategy”
- Implementation from the scratch (for newbies in GMP)
- Putting together the pieces (for the ambitious advanced in GMP)

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
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For questions regarding reservation, hotel, organisation etc.:
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If the bill-to-address deviates from the specification to the right, please fill out here:

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Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

GMP/FDA Compliance Conference (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

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.

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