

GMP – Green or Good Manufacturing Practice?

19 March 2024

Part of PharmaCongress 2024

19/20 March 2024

Wiesbaden, Germany

Highlights

- Sustainability and GMP Compliance – does it fit?
- Green GMP and Sustainability – Sustainability and Green GMP – what it stands for and what it is
- Case Study: Sustainable and Energy-Efficient New Construction
- Case Studies: Sustainability Projects – with Significant Energy savings
- Reducing the Carbon and Water Footprint

Speakers

Henning Austermann | Siegfried, Germany

Dr Andrea Bauer | ABC&Q, Germany

Markus Burkert | Syntegon, Germany

Manuel André Deuringer | Lonza, Switzerland

Lenz Kunath | Merck Healthcare, Germany

Susana Lima | BIAL Portela, Portugal

Dr Jean Denis Mallet | Pharmaplan, France

Ana Cláudia Pinho | BIAL Portela, Portugal

Dr Johannes Reich | Microcoat Biotechnologie, Germany

Alistair Wotherspoon | CRB, Switzerland



This conference is part of PharmaCongress 2024



Academy
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Information Source



OBJECTIVES

This conference track will take a closer look at and discuss the possibilities of sustainability, environmental thinking and energy saving also under GMP conditions. The extent to which regulatory requirements, quality demands and modern sustainability requirements fit together will also be a topic of discussion. Case studies will be used to present practical implementations and highlight improvement measures.

BACKGROUND

In the past, compliance with quality requirements and safety aspects in the manufacture of drugs, active ingredients, etc. was often the primary focus. Environmental aspects, energy costs, water consumption and the like were usually not at the top of the priority list. This has changed in recent years - under the influence

of climate change, rising energy prices, increased transport costs and scarcity of raw materials. Buzzwords like Sustainability or Green GMP are heard more and more often. On the one hand because of the increasing environmental problems and on the other hand because of the rapidly rising costs for energy, water and raw materials. The challenge is often how to combine the requirements of GMP and sustainability.

TARGET AUDIENCE

This conference track is aimed at all persons in the field of manufacturing, facility management, quality assurance and quality control who have to deal with the problems of sustainability aspects under the regulation of GMP.

PROGRAMME 19 March 2024

Sustainability and GMP – Contradictive or supportive? How can Sustainability Aspects be built in GMP Requirements

Dr Andrea Bauer, *ABC&Q*

- Expectations of stakeholders
- Embedding sustainability in entire product life cycle
- Supporting and contradicting expectations and requirements

Does Sustainability stand only for Green GMP?

Ana Cláudia Pinho, *BIAL Portela*

Susana Lima, *BIAL Portela*

- What does Sustainability Mean – Environment Saving? Green?
- Other Aspects
 - Social responsibility
 - Economic viability
 - Ethical considerations

Sustainable and Energy-Efficient Planning and Construction of a Laboratory and Production Facility

Dr Johannes Reich, *Microcoat Biotechnologie*

- Planning of a new Laboratory and Manufacturing Complex
- Solar and water - energy generation and storage
- Heating and cooling - modern possibility of sustainability
- Pros, cons and pitfalls
- Costs and ROI

Reading the EU-GMP Guide with green Glasses

Dr Jean-Denis Mallet, *Former head of the French Inspection Department AFSSAPS, Pharmaplan*

- The Green target
- Type of actions that really be deemed Green
- Reading the guide with Green Glasses : the main promising points
- How much Green action will be impacting the marketing authorization dossier ?
- Conclusion

Sustainability – HVAC Optimization Program at Merck Healthcare KGaA with significant Energy Savings

Lenz Kunath, *Merck Healthcare*

- Challenge “regulated” air change rates, use other criteria to determine room cleanliness
- Reduce permanent air change rates
- Reduce air change rates during non-productive times
- Challenges executing the program

How to reduce Carbon & Water Footprint in clean Utility Systems

Alistair Wotherspoon, *CRB*

Manuel André Deuringer, *Lonza*

- Reducing the carbon burden of aseptic products is an uphill battle for manufacturers still latching on to WFI by distillation
- In 2017, the European Pharmacopoeia joined the majority of pharmacopoeias around the world allowing for alternative methods of generating WFI – methods far less demanding on energy and water than that of distillation
- It’s time to reevaluate the WFI systems
- Industry is poised to make the move to benefit the environment and find resiliency against energy uncertainty
- User case from an ongoing project at Lonza

Sustainability in Pharma – how a Company can achieve CO₂ net zero Goal

Henning Austermann, *Siegfried*

Markus Burkert, *Syntegon*

- Siegfried's goal of climate neutrality
- Projects and activities - from green electricity to district steam and heating
- CO₂ analysis and optimization of machine park
- Further prospects and potentials, e.g. sustainable raw materials

SPEAKERS



Henning Austermann

Siegfried, Germany

Henning Austermann studied mechanical engineering and economics. He worked for DTG and Benteler before joining Siegfried in 2021. There he is Head of Engineering.



Dr Andrea Bauer

Andrea Bauer Consulting Quality (ABC&Q), Germany

Dr Andrea Bauer is an independent consultant. She has 25+ years of experience in the pharmaceutical and medical device industry.



Markus Burkert

Syntegon, Germany

Markus Burkert has a degree in industrial engineering. In January 2023 he joined Syntegon as a product manager for sustainable pharmaceutical filling machines.



Manuel André Deuringer

Lonza, Switzerland

Manuel André Deuringer, Associate Director Clean Utilities Engineering at Lonza, is a global subject matter expert for Design Standardization, Engineering and Sustainability of Clean and Process Utilities with 15 years of experience.



Lenz Kunath

Merck Healthcare KGaA, Germany

Lenz Kunath joined Merck 1991 as project leader and became Director Site Account Engineer in 2000.



Susana Lima

BIAL - Portela & C^o, S.A. Portugal

Susana has a Master's degree in Environment Engineering and 10 years of experience in the field. She is working in BIAL within the environmental management department and recently completed training in Circular Economy and Sustainability Reporting.



Dr Jean Denis Mallet

Pharmaplan, France

He was previously the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps=ANSM). Now he is member of the ECA advisory board and works for NNE Pharmaplan.



Ana Claudia Pinho

BIAL - Portela & C^o, S.A. Portugal

As previously the Senior Manager of QA at BIAL and now the Senior Manager of Sustainability Ana is challenged to keep higher standards of GMP without compromising the company's sustainability for the next century.



Dr Johannes Reich

MicroCoat Biotechnologie GmbH, Germany

Johannes Reich studied marketing and chemistry and obtained his doctorate in Regensburg. He has been General Manager at Microcoat Biotechnology in Bernried since 2016.



Alistair Wotherspoon

CRB, Switzerland

Alistair Wotherspoon is a Senior Process Utilities Engineer with more than 15 years of experience.

The guiding theme of the GMP PharmaCongress 2024 on 19/20 March will be „users sharing challenges and solutions in practice“. Therefore, benefit from your colleagues' experience and from the direct information exchange at the GMP PharmaCongress & GMP PharmaTechnica 2024.

The GMP PharmaCongress Conference Tracks

As a participant you can switch between any of the **11 conference tracks** any time and also visit the PharmaTechnica Expo with more than 110 international exhibitors.

| The GMP PharmaCongress Conference Tracks | 19 March 2024 | 20 March 2024 |
|--------------------------------------------------------------|---------------|---------------|
| Non-Sterile Products – Challenges in Manufacturing & Quality | ✓ | n.a. |
| GMP – Green or Good Manufacturing Practice? | ✓ | n.a. |
| Packaging/Packaging Materials – Challenges & Solutions | n.a. | ✓ |
| European Aseptic Conference – Technology | ✓ | ✓ |
| Trends in Barrier Systems & Robotics | ✓ | ✓ |
| Modern Cleanroom Technology | ✓ | ✓ |
| Digitalisation & Artificial Intelligence | ✓ | ✓ |
| GMP for Pre-Filled Syringes (PFS) | ✓ | ✓ |
| Lyophilization – Modern Techniques & New Requirements | ✓ | ✓ |
| ATMPs – Hurdles & Achievements in Quality and Safety | ✓ | ✓ |
| Vaccines – Advantages & Challenges in Manufacturing | ✓ | ✓ |
| GMP PharmaTechnica Expo | ✓ | ✓ |

Keynote on 19 March 2024

The CEPI Project – 40 Countries – 1 Billion Euros for Vaccines

Dr Guido Dietrich, CEPI

Do you know the worldwide importance of CEPI? And why is this so important for everyone working in pharmaceutical production? Our first keynote will address a very important new development. More than 40 countries, several non-governmental organizations and the European Commission are involved in the Coalition for Epidemic Preparedness Innovations (CEPI).

What is the goal?


The goal of CEPI is to develop, produce and distribute a vaccine as quickly as possible in the event of the next global pandemic, i.e. within 100 days.

What is the current budget?

For the first 5 years alone, a budget of one billion euros has been made available.

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

Congress Dates

Tuesday, 19 March 2024, 09.00 - 18.00 h
Wednesday 20 March 2024, 09.00 - 17.00 h
Registration

Tuesday & Wednesday, 19/20 March 2024, 08.00 - 09.00 h

Fees

The one day ticket is available for € 690,- plus VAT, both days for € 1,380.- plus VAT. It includes participation in any track on that day 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, 19 March is included; please mark if you would like to attend the Social Event. The fee is payable in advance after receipt of invoice.

Venue

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

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.

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.
CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone: +49 (0) 62 21 / 84 44-0 | Fax: +49 (0) 62 21 / 84 44 34
info@concept-heidelberg.de | www.concept-heidelberg.de

For questions regarding content please contact:
Axel H. Schroeder (Operations Director) at
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For questions regarding organisation please contact:
Mr Ronny Strohwald (Organisation Manager) at
+49 (0) 62 21 / 84 44 51, or at strohwald@concept-heidelberg.de

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

Reservation Form (Please complete in full)

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- Day 1 & 2 (19/20 March 2024)
 Day 1 (19 March 2024)
 Day 2 (20 March 2024)
 Yes, I would also like to take part in the Social Event on the evening of 19 March 2024.

Mr Ms Mx Dr

First name, Surname

Company

Department

Important: Please indicate your company's VAT ID Number

P.O. 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 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). 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.