Vaccines – Advantages & Challenges in Manufacturing

Part of PharmaCongress 2024

19/20 March 2024
Wiesbaden, Germany

Highlights

- Quality and Regulatory Strategies
- Development of Vaccines
- Batch release
- Authority perspectives like USP and more
- Case Study: Cleaning of Lipid Nanoparticles (LNP)

Speakers

Dr Alexander Bachmann | Pharmaceutical Consultancy Dr Bachmann, Germany

Petra Falb | AGES, Austrian Agency for Health and Food Safety

Dr Sabine Hauck | Leukocare, Germany

James Humphrey | Croda Pharma, UK

Faye Litherland | Blue Sky Process Engineering, UK

Dr Natalia Markova | Malvern Panalytical, Sweden

Cecilia Pierobon | STERIS Life Sciences, Germany

Nikhil Rautela | USP, Italy

Dr Frank Sielaff | Hessian State Office of Health and Care, Germany

Dr Mohamad Toutounji | Molgenium, Germany

Dr Andrea Traube | KyooBe Tech, Germany

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GMP-PHARMA CONGRESS

This conference is part of PharmaCongress 2024

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OBJECTIVES

The development and production of vaccines places high demands on the manufacturing pharmaceutical industry. The special requirements for handling and safety with living organisms require measures that go beyond the requirements of classical drug production. This conference track is aimed at all those who develop, manufacture, release vaccines and deal with regulatory issues. Experienced speakers from the field of vaccines will explain the current requirements, share their knowledge of new innovative achievements, report on their experiences and implementation in the company.

BACKGROUND

"Vaccines are expected to be very safe" is one of the headlines in the presentation by CBER's Vaccine safety team. At the same time, many vaccines are being developed and new vaccines are still needed for diseases for which no vaccine is currently available, and production technologies need to be improved to produce high-quality and, above all, patient-safe product. This has led to the emergence of new technologies, approaches and guidelines. Through Corona, we have realized the importance of rapid development with subject matter expertise, as well as then manufacturing to the latest technology and requirements. Regulatory hur-

PROGRAMME 19 March 2024

Global Progress in Vaccine Development: Regulatory Considerations and Scientific Advances

Dr Mohamad Toutounji, *Molgenium*

- Evolution of Global Vaccine Regulations
- Challenges and Opportunities in Vaccine Access
- The Future of Vaccine Research and Development
- Implementing Vaccination Programs Worldwide

Modern Vaccines – Perspective from the Regulatory Authority

Petra Falb, *AGES – Austrian Agency for Health and Food Safety*

- Changing regulatory Requirements for latest Technologies
- Regulatory Challenges – from conventional Antigens to Platforms
- User-related Technology Examples – RNA Vaccines / DNA Vaccines / Vector Vaccines

Added Value by Advance Formulations for Vaccines?

Dr Sabine Hauck, *Leukocare*

- Selection of smart methods to assess stability during formulation development
- Advanced formulations - case studies
- Potential of stability prediction

Low-Energy-Electron Irradiation – a potential Game Changer for the Development of Vaccines and Cell Therapies

Dr Andrea Traube, *KyooBe Tech*

- Explanation of low-energy electron irradiation (LEEI)
- Advantages compared to conventional methods
- Application in cell therapy and development of vaccines

Resolving Facility Design Conflicts between Biocontainment & Good Manufacturing Practices for Vaccines Manufacture

Faye Litherland, *Blue Sky Process Engineering*

- Facility location and layout
- Heating, Ventilation and Air Conditioning (HVAC)
- Construction methodology
- Utility supply

The Search for efficacious and sustainable Alternatives to Triton™ X-100 in Therapeutics

James Humphrey, *Croda Pharma*

- An overview of the technical and regulatory challenges of finding suitable alternatives to Triton™ X-100
- Utilising structural characteristic and performance relationships to identify appropriate candidates to replace Triton™ X-100 in therapeutics
- Demonstrating the application performance of Triton™ X-100 alternatives for vaccine, biotherapeutic protein and gene therapy applications

dles, batch release, audits and purification are a few of the many issues that can complicate the supply and production of vaccines. The applications of vaccines seem limitless, but the implementation often fails. The typical questions often come up:

- What are the official requirements, that I have to implement?
- How can I implement this cost-effectively and as quickly as possible?
- How can I produce permanently with consistent quality and still improve my process?

TARGET AUDIENCE

This conference is aimed at all persons who

- are involved in the development and manufacturing of vaccines
- Responsible persons from quality assurance and control
- are responsible for microbiological or analytical testing
- audit vaccine manufactures
- deal with authorisations

PROGRAMME 20 March 2024

Batch Release of Vaccines

Dr Alexander Bachmann, *Pharmaceutical Consultancy Dr Bachmann*

- Batch release of IMP vaccines
- Batch release of authorized vaccines

Modern Vaccines – GMP Inspector's View

Dr Frank Sielaff, *Hessian State Office Of Health and Care, Darmstadt, Germany*

- Regulatory Guidelines
- Specific Aspects for modern Vaccines
- GMP-Inspections in Vaccine Production

Considerations for Cleaning Lipid Nanoparticles

Cecilia Pierobon, *STERIS Life Sciences*

- Application and advantages of Lipid Nanoparticles (LNP)
- Hurdles with cleaning of LNP
- Case Study: General cleaning recommendation based on laboratory and field testing

USP Approach to mRNA and Viral Vector Vaccines

Nikhil Rautela, *USP*

- mRNA and Viral Vector Draft Guideline updates
- Toolkit
- Other vaccine resources at USP

mRNA as API and as Part of LNP Structure

Dr Natalia Markova, *Malvern Panalytical*

- Developability challenge with nucleic acid-based drugs
- Light-scattering and calorimetric techniques as fit-for-purpose analytics
- Informing on structure-function relationship

SPEAKERS

Dr Alexander Bachmann
Pharmaceutical Consultancy Dr Bachmann, Germany
Dr Alexander Bachmann studied chemistry and biochemistry. After his PhD, he worked in various areas in the pharmaceutical industry (R&D, regulatory affairs, quality department, management). Since 2010, he has been working as a consultant in the areas of tech transfer/manufacturing, regulatory affairs, quality and QP for clinical trial samples and market goods.

Petra Falb
AGES, Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH, Austria
Petra Falb studied at Veterinary University Vienna (Austria). From 1998 to 2001 she worked as scientist at the Institute for Virology and later at the Institute for pathology. 2001-2003 she was self-employed as veterinary surgeon. In 2003 she joined the AGES with responsibilities in quality assessment of human and veterinary vaccines (national, decentralised and centralized procedures). Until 2016 her focus was on viral vaccines.
In 2017, she took over new responsibilities for veterinary vaccines.

Dr Sabine Hauck
Leukocare AG, Germany
Sabine Hauck is Executive Vice President Corporate Development at Munich-based biotech company Leukocare AG. She has 20+ years of experience in the biotech industry, in which she held various positions in pharmaceutical development, quality assurance and regulatory affairs. Her experience spans from small molecules to cell therapies and includes a variety of dosage forms. In the current position, Sabine is responsible for digitalization activities at Leukocare AG as well as for Business Process Management and Quality Management. In this role, she supports the ongoing digital transformation of the organization related to the algorithm-based formulation development approach at Leukocare.

James Humphrey
Croda Pharma, UK
James has over 16 years' experience focusing on the formulation and surfactant sector. A chemist by training, at Croda James initially lead the new surfactant and formulation development teams, focusing on formulation science to develop novel surfactants in the cosmetic business, before moving to the pharmaceutical sector 10 years ago to focus on understanding and developing old and new excipients. James takes particular interest on the role of the excipient type and quality on the stability in both small and large drug molecule formulations, along with their translation into bioprocessing applications.

Faye Litherland
Blue Sky Process Engineering Ltd, UK
Faye Litherland has over 25 years of experience in the pharmaceutical industry and is a Chartered Engineer, Chartered Scientist and Fellow of the Institution of Chemical Engineers. She has been involved with the design, peer review, troubleshooting and as an expert witness for multiple biological containment laboratories and manufacturing facilities, at all containment levels, for governments and corporations around the globe.

Dr Natalia Markova
Malvern Panalytical, Sweden
Natalia Markova has a degree in Civil Engineering and a PhD in Physical Chemistry from University of Lund, Sweden. During the last 20 years Natalia has worked on core teams of drug discovery campaigns and biopharmaceutical development projects as Senior Scientist at Pharmacia-Biovitrum in Stockholm and Head of Biophysics at the Structural Genomics Consortium, Karolinska Institute. Prior to joining Malvern Panalytical in 2014 Natalia held a global position of Senior Customer Relation Manager at GE Healthcare Life Sciences.

Cecilia Pierobon
STERIS Life Sciences, Germany
Cecilia Pierobon currently holds the position of Technical Services Manager at STERIS Life Sciences and is based in Germany. In this position, she provides technical support on cleaning validation and cleaning chemistries application and validation. Over her four years of experience in the industry she has worked in the qualification of pharmaceutical equipment for production and laboratory environments, as part of the Quality GMP Compliance Team and as Project Manager in Supply Chain packaging serialization.

Nikhil Rautela
USP, Italy
Nikhil Rautela (MSc., M. Phil) joined USP in July 2021. He has an experience of 13 years ranging from academia to R&D across Drug Discovery at AstraZeneca, Immunotherapy at a university spin off and Stem Cell and Diagnostic proteins in a mid-sized company, prior to joining USP. He is a senior scientific affairs manager for biologics at USP where his primarily role is to engage with stakeholders to advocate for the quality of USP science supporting biologics as well as peptides and oligonucleotides in the EMEA region.

Dr Frank Sielaff
Hessian State Office of Health and Care, Darmstadt, Germany
GMP Inspector at the competent authority of Hessen with the focus on inspection of drug manufacturers and laboratories in Germany and countries outside of the EU. Before joining the GMP inspectorate Dr Sielaff was several years employed in the pharmaceutical industry as Head of Quality Control and as Qualified Person.

Dr Mohamad Toutounji
Molgenium, Germany
Dr Mohamad Toutounji has 10 years of experience in ATMP and has worked in various positions in R&D, CMC, Manufacturing at Molgenium, Sanofi and GE Healthcare during these years. He is also the CEO and founder of Molgenium.

Dr Andrea Traube
KyooBe Tech GmbH, Germany
CEO of KyooBe Tech, a highly innovative subsidiary of the Bausch + Ströbel Group focussing on the development and commercialisation of new manufacturing technologies. Prior to joining KyooBe, I spent over 20 years in the cell therapy and cell culture automation field specializing on the transfer of manual cell culture processes into automation.

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 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.

In the Live Demo Area in the PharmaTechnica Expo hall you will benefit from the exhibitors' demonstrations – presenting their latest technology, products and services. Take advantage of these live performances – and get to feel and experience their products. For a list of all companies exhibiting at PharmaTechnica, please see the exhibitor list and plan on the website at **www.pharma-congress.com**.

Exhibitor	Stand	Live Demo
boTec	A 7	TBN
MKVersuchsanlagen	A 12	TBN
Ellab	A 16	TBN
Bausch & Ströbel	A 33	OMNIA - Boost your processes and step closer to your pharmaceutical plant of the future.
PHARMAPLAN	A 37	Accelerated Design Decisions enabled by Digital Twins
Quascenta Pte	B 6	Using an Intelligent Lifecycle-Based Solution for Streamlined Product Tracking, Design Optimization, Collaboration, and Reporting
ZETA	B 12	TBN
IWT / Tecniplast	B 15	High pressure cleaning in pharmaceutical production. Advantages, challenges, sustainability and savings
MBV	B 20	TBN
Emerson Automation Solutions	B 22	TBN
Atec Steritec	B 28	Safe & Sterile Transfer with Minimal Operator Intervention
REA Elektronik	B 29	Experts in Printing and Code Verification of pharmaceutical and medical-device packaging (f.e.UDI/MDR)
Friedrich Sailer	B 31	Shining Solutions: Live Demo of Cutting-Edge Stainless Stell Cleanroom Equipment
Merck	B 32	Annex 1's "Specific Risks Associated with Single-Use Systems"
Particle Measuring Systems	C 7	Facility Monitoring Systems
Yokogawa	C 9	Flow Imaging using FlowCam for High Performance Products to warrant constant excellent Quality

Easy Registration

Registration Form:
CONCEPT HEIDELBERG
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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

Only until 31 December 2023: Save up to € 200 Early Bird Discount

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.
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Reservation Form (Please complete in full)

Vaccines – Advantages & Challenges in Manufacturing

Part of PharmaCongress 2024

19/20 March 2024, Wiesbaden, Germany

☐ 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

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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 %.

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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.
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