Packaging/ Packaging Materials – Challenges & Solutions

20 March 2024

With a view on the implications of the New EU GMP Annex 1!

Part of PharmaCongress 2024
19/20 March 2024
Wiesbaden, Germany

Highlights

- Primary and Secondary Packaging
- Regulatory Challenges
- Packaging Challenges in Aseptic / Sterile Manufacturing
- Microbiological Control
- Automated Text & Code Verification
- Distribution Testing

Speakers

Jyotsna Agnihotry | Flavine Europe, Germany

Dr Carsten Börger | Valicare, Germany

Sergio Cuevas Luján | Boehringer Ingelheim, Spain

Dr Marcel Goverde | MGP Consulting, Switzerland

Frank Hessler | Schlafender Hase, Germany

Pirkko Lahti | Orion, Finland

Mahboobeh Rastegar | GfPS, Germany

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GMP-PHARMA CONGRESS

This conference is part of PharmaCongress 2024

ECA Academy
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GMP–PHARMA CONGRESS

PACKAGING/PACKAGING MATERIALS – CHALLENGES & SOLUTIONS

Image: GEA

OBJECTIVES

In this conference you will learn which requirements apply for packaging material and pre-sterilized material (e.g., ready-to-use, ready-to-sterilize). You will get to know relevant GMP aspects for packaging materials (e.g., vials, stoppers) that influence the quality of the final product. In addition, practice-oriented presentations and case studies will guide you through the relevant requirements on qualification / validation, and controls for packaging materials, including text control.

BACKGROUND

Currently there is a growing demand in the development of packaging materials (e.g. ready-to-fill, ready-to-use, sterile clean filling) for several enhanced Biotech applications. However, new GMP requirements for the sterile packaging material apply with the revised EU GMP Annex 1. In addition, there are various other requirements like testing on E&Ls, distribution testing and text and code control (e.g., Data Matrix codes required for serialization purposes).
This event will therefore deal with the current discussions and trends in the packaging operations and packaging materials:

- Regulatory Challenges & GMP requirements
- Primary and Secondary Packaging
- Text and Code Control
- Packaging Challenges in Aseptic / Sterile Manufacturing
- Microbiological Control
- Distribution Testing

The presentations will be provided in a practice-oriented way from the different viewpoints of suppliers of packaging materials / devices / services, and the pharmaceutical industry.

TARGET AUDIENCE

This event is designed for employees working in the pharmaceutical industry (including drug device combination products), for suppliers of packaging materials & devices and to all who have to deal with the manufacture, control and release of packaging materials. The key areas are

- Sterile Production
- Packaging material / Medical Devices
- Manufacturing / Processing / Assembling
- Quality Control
- Quality Assurance

MODERATOR

Dr Marcel Goverde, *MGP Consulting*

PROGRAMME 20 March 2024

Primary and Secondary Packaging of Drug Substances

Jyotsna Agnihotry, *Flavine Europe*

- Primary and secondary packaging in the Biopharmaceutical industry
- Types of primary packaging
- Single Use Systems (SUS)
- Secondary packaging for Biopharmaceuticals
- Packaging of Biopharmaceuticals for safe storage and shipping (e.g., correct packaging to enable efficient filling, freezing, and transportation)

Regulatory Challenges in Injection's Primary Packaging Materials

Pirkko Lahti, *Orion*

Regulatory demands for

- QC testing (routine, development)
- Extractables studies
- Leachables studies

Packaging Materials Challenges in Aseptic / Sterile Manufacturing

Sergio Cuevas Luján, *Boehringer Ingelheim*

- Packaging materials for aseptic manufacturing: a complex packaging for a complex process
- Safety, efficiency, sustainability in packaging design and packaging materials for aseptic processes
- Packaging materials validation for aseptic manufacturing
- New trends in packaging materials for aseptic manufacturing

Microbiological Control of Packaging Materials

Dr Marcel Goverde, *MGP Consulting*

- Regulatory Expectations
- Microbiological Specifications
- Testing Methods

Development and Validation of a Cloud-based System for Automated Text Verification

Dr Carsten Börger, *Valicare*

Frank Hessler, *Schlafender Hase*

- User requirements for automated text verification for leaflets and graphical artworks
- Good documentation in software development
- Comparison of internal software validation for release versus software validation of a COTS-software
- Delimitation of duties in cloud-based system

Distribution Testing: How to make sure, the Product makes it to the Destination?

Mahboobeh Rastegar, *GfPS*

- The significance of distribution testing and commonly applied standards
- Potential hazards on the transport field
- How to interpret the test results to optimize the packaging
- Improving the protecting function of the secondary packaging
- Subsequent testing on the primary packaging

SPEAKERS

Jyotsna Agnihotry
Flavine Europe, Germany
Jyotsna is currently Head of QA and Regulatory Affairs with over 10 years of experience in Quality Assurance, Quality Control, Training & Development, Pharmacovigilance processes and Regulatory compliance & Audits including Medical Devices.

Dr Carsten Börger
Valicare, Germany
Carsten is currently Senior GMP Project Manager. He has been working for the last 10 years in GMP regulated industries with a strong focus on qualification and validation. He has a focus on computer system validation and managed over 20 projects in this field.

Sergio Cuevas Luján
Boehringer Ingelheim, Spain
Sergio is currently Packaging Materials Engineer at BI. Previously he worked in the same position for Sanofi and as Packaging Development Supervisor for Novartis. He is specialized in packaging materials for aseptic processing.

Dr Marcel Goverde
MGP Consulting, Switzerland
Marcel worked at Roche in the microbiological Quality Control department from 2002 to 2010. From 2010-2011 he served as an expert for microbiology at Novartis Pharma. Since 2011 he is running his own business for consulting, training, project and deviation management. He is one of the Swiss experts in the EDQM Group 1 (Microbiological Methods and Statistical Analysis).

Frank Hessler
Schlafender Hase, Germany
Frank is the Managing Director at Schlafender Hase. He co-founded the company in 2001 and was initially responsible for overseeing the development of the Text Verification Tool (TVT) and future applications.

Pirkko Lahti
Orion, Finland
Pirkko is currently Senior Development Manager. She has 30 years of experience in pharma and in primary packaging materials (e.g. injections, nasals, ophthalmics).

Mahboobeh Rastegar
GfPS, Germany
Mahboobeh is specialized in testing of medical products packaging under the requirements of DIN EN ISO 11607. The scope of her expertise covers stability and performance testing as well as integrity testing.

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

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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69007 Heidelberg, Germany
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For questions regarding content please contact:
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For questions regarding organisation please contact:
Mr Ronny Strohwald (Organisation Manager) at
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Packaging/Packaging Materials – Challenges & Solutions | 20 March 2024

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

First name, Surname

Company

Department

Important: Please indicate your company's VAT ID Number | P.O. Number (if applicable)

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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.

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