Non-Sterile Products

Challenges in Manufacturing & Quality
19 March 2024

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

Highlights

- Fully Automated and DoE-Based Development of an Oral Solid Dosage Form
- Improvement of Production with SPC, Cp and CpK
- Self Inspection
- Grid-Line Approach for the Identification of Sampling Points
- Risk Assessment
- Case of Burkholderia cepacia Complex in non-sterile Manufacturing

Speakers

Pranvera Apostoli | Profarma, Albania

Dr Thomas Brinz | Syntegon, Germany

Eni Bushi | Profarma, Albania

Dr Tony Cundell | Microbiological Consulting, USA

Rashid Idd Kihwelo | Kairuki Pharmaceuticals, Tanzania

Dr Marcel Goverde | MGP Consulting, Switzerland

GMP–PHARMA CONGRESS

This conference is part of PharmaCongress 2024

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OBJECTIVES

This year, the first part of the conference track will deal with topics such as automation, statistical process control or self-inspection, and the second part will deal with cleaning validation and microbiological issues. Current and modern approaches for identifying sampling points in the non-sterile area (grid-line approach) will be presented, and topics such as risk mitigation versus microbial testing will also be discussed.

BACKGROUND

Even though the focus today is strongly on the new Annex 1 and the various sterile drugs, non-sterile drugs still represent the most common dosage form, especially tablets with a share of more than 50%. Solids in particular often represent cost-effective dosage forms. They have good stability and open up adjustable options for active ingredient release.

But the various forms of non-sterile drugs also face a number of challenges in manufacturing, quality assurance and quality control. Continuous processing, procurement of production equipment and validation issues related to manufacturing play a role as well as modern validatable purification or microbial requirements e.g. regarding modern risk assessment in bioburden or Burkholderia cepacia complex. Questions of monitoring are also of interest again and again.

TARGET AUDIENCE

This conference track is aimed at all persons in the field of manufacturing, quality assurance and quality control who have to deal with the problems of the non-sterile manufacture of medicinal products or their active and starting materials.

PROGRAMME 19 March 2024

Fully Automated and DoE-Based Development of an Oral Solid Dosage Form

Dr Thomas Brinz, *Syntegon*

- Planning of all trials using Design-of-Experiments
- Automated execution of all experiments and analysis of the results
- How to reach Based on the automation of all development steps a high throughput and short development time

Use and Implementation of SIXsigma and SPC (Statistical Process Control) Cp and CpK to improve our Routine Production Process throughout finding the Problems

Pranvera Apostoli, *Profarma*

- Capture of CPP values as part of APR (Annual Product Review) values for 300 generics - captured for final product and process steps
- Use of SPC, IMR and trend charts
- Analysis of Cp and CpK values and assessment of stability
- Root Cause Analysis in Cases of Instability

Self Inspection in Non-Sterile Manufacturing

Speaker invited

- Why Self Inspection - regulatory background
- Planning a Self Inspection
- Performing a Self Inspection

Cleaning Validation in Pharmaceutical Manufacturing Industry

Eni Bushi, *Profarma*

- Regulatory requirements for cleaning validation
- Cleaning validation program
- Sampling procedure
- Establishment of limits

Modern Approach for Identifying Sampling Points in the Non-Sterile Area (grid-line Approach)

Dr Marcel Goverde, *MGP Consulting*

- FMEA or HACCP or Risk Assessment?
- Can a gridline approach also be used for non-sterile areas?
- Application in practice

Bioburden Control in Non-sterile Drug Substance and Product Manufacturing – Risk Mitigation versus Microbial Testing

Dr Tony Cundell, *Microbiological Consulting*

- Pros and cons of risk mitigation or microbiological testing compiled - with view on microbial quality of pharmaceutical ingredient, formulation, manufacturing process, physicochemical properties, packaging, dosage and recipients of a drug product
- The types of microbiological compendial tests, sampling limitation and suitability for microbial enumeration and unacceptable microorganisms
- Case Study: The shortage of infant formula in the U.S. in 2022 due to a product recall for Cronobacter sakazakii

A Case of *Burkholderia cepacia* Complex in Non-Sterile Manufacturing; Challenges in Isolation, Identification and Product Recalls

Rashid Idd Kihwelo, *Kairuki Pharmaceuticals*

- What is Burkholderia cepacia Complex (Bcc)
- Taxonomy and diversity of BcBcc contamination in non-sterile manufacturing
- Challenges in isolation, Identification and the new USP chapter <60>
- Product recalls of non-sterile products and measures to be taken to prevent Bcc contamination

SPEAKERS

Pranvera Apostoli
Profarma, Albania
Pranvera received a MsC in Pharmacy primary from Faculty of Pharmacy, University of Tirana, Albania in 2012 and secondly nostrified from Charles University, Czechia in 2020. After two years as community pharmacist, she joined Profarma in 2015, as a part of the Drug Regulatory Affairs and PhV department. Following she joined the QA Department, mainly dealing with the managing of Annual Product Review and Validations. Additionally she was involved in upgrading the production processes until it reaching the EU GMP level.

Dr Thomas Brinz
Syntegon, Germany
Thomas Brinz studied chemistry in Ulm. He then joined Robert Bosch GmbH in 1995 as a Senior Scientist and later became Director PharmaServices at Bosch Packaging, now Syntegon. He is currently Director Pharma Services Waiblingen at Syntegon.

Eni Bushi
Profarma, Albania
Eni Bushi has more than 5 years of experience in Quality Assurance Department of Profarma. She is in charge of Process Validation, Cleaning Validation and Risk Assessment. She also works in the University of Medicine Tirana as an assistant of pharmaceutical technology.

Dr Tony Cundell
Microbiological Consulting, LLC, USA
Tony worked for over 30 years as microbiologist at the director level in product development and quality organizations in large pharmaceutical companies. Long-term member of the USP Microbiology Expert Committee. Published over 100 articles and book chapters. Currently he is working as an industry consultant.

Rashid Idd Kihwelo
Kairuki Pharmaceuticals, Tanzania
Rashid has a bachelor degree in Microbiology from the University of Dar es Salaam. After first experiences in pharmaceutical microbiology from Tanzania Medicine and Medical Devices Authority (TMDA) he joined Kairuki in quality control microbiology laboratory as Senior Quality Microbiologist.

Dr Marcel Goverde
MGP Consulting, Switzerland
Marcel Goverde studied Biology at the University of Basel. From 2002 to 2010 he was leading the QC lab for non-sterile products and the lab for research & development of microbiological methods at F. Hoffmann-La Roche Ltd in Basel. From 2010-2011 he worked as microbiological expert at Novartis. In 2011 he started his own company for consulting, training and project management in microbiology.

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.
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GERMANY

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)

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City | Zip Code

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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 %.

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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.
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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