GMP for Pre-Filled Syringes (PFS)

Development, Manufacturing, Control

Part of PharmaCongress 2024

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

19/20 March 2024
Wiesbaden, Germany

Highlights

- Basics & Regulatory Overview
- Pre-fillable Syringes Design and Requirements
- Fill-Finish & Assembly Processes
- Process Simulation / Validation
- Visual Inspection & Container Closure Integrity
- Contamination Control Strategy
- MDR - Ensuring Compliance for Syringe based Combination Products
- GMP issues in Inspections
- Case Studies

Speakers

Maria Luisa Bernuzzi | MesaLabs, France

Jean-François Decoster | UCB, Belgium

Katharina Golly | Novartis, Switzerland

Dr Bernhard Illes | Microcoat Biotechnologie, Germany

Christa Jansen-Otten | West, Germany

Dr Daniel Müller | Local GMP Authority of Baden Württemberg, Germany

Jinesh Sadalge | Novartis, Austria

Dr Helen Sauter | Vetter Pharma-Fertigung, Germany

Dr Max Scheible | Vetter Pharma-Fertigung, Germany

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GMP-PHARMA CONGRESS

This conference is part of PharmaCongress 2024

ECA Academy
Your GMP/GDP Information Source

GMP FOR PRE-FILLED SYRINGES (PFS)

OBJECTIVES

In this conference you will learn which requirements for pre-fillable syringes are defined by the regulations. You get to know all aspects of the manufacture of pre-fillable syringes that influence the filling process and the quality of the final product. In addition, practice-oriented case studies will guide you through the relevant production processes, simulations and controls for pre-filled syringes.

BACKGROUND

Currently there is a growing demand in the development of pre-fillable syringes (e.g. ready-to-fill, ready-to-use, sterile clean filling) for several enhanced Biotech applications (i.e. for the final product, the Pre-filled Syringe). However, new GMP requirements, also for the sterile packaging material (e.g. regarding validation of the sterilization procedure for the syringe), apply with the revised **EU GMP Annex 1 entitled "Manufacture of Sterile Medicinal Products"**.

This event will therefore deal with the current discussions and trends in the manufacture of pre-filled syringes:

- GMP requirements for pre-fillable syringes / devices
- PFS Design & Safety Systems
- Alternatives to glass
- GMP Requirements for personnel, cleanrooms, equipment & facilities
- Processing of pre-filled syringes
- Auto-injector Assembling

PROGRAMME 19 March 2024

Regulatory Overview, Annex 1 Impact and Inspection experience

Dr Daniel Müller, *Local GMP Authority of Baden-Württemberg, Germany*

- Regulatory framework (EU), impact for pre-filled syringes
- Impact of new Annex 1
- Inspection experience

Contamination Control Strategy

Dr Helen Sauter, *Vetter Pharma-Fertigung*

Practical experiences

- CCS – a new Annex 1 requirement
- Case Study: CCS implementation
- Risk based approach for control point identification

Medical Device Regulations - Understanding the Impacts and ensuring Compliance for Syringe-based Combination Products

Christa Jansen-Otten, *West*

- Navigating the EU MDR Regulations requirements
- Advantages of platforming on prefillable syringes
- Case example of technology being applied by the market for platform applications
- Needs of suppliers for supportive documentation

PFS made from Glass or Polymer

Katharina Golly, *Novartis*

- Materials
- Manufacturing
- Sterilization methods
- Design
- Pros and Cons

PFS and Needle Safety Systems

Katharina Golly, *Novartis*

Jinesh Sadalge, *Novartis*

- Regulatory Requirements
- Active vs. Passive Systems
- Design Considerations
- Examples

Validation of a Steam Sterilization Process for a Pre-Filled Syringe

Maria Luisa Bernuzzi, *MesaLabs*

- Challenges in steam sterilization of a PFS and its biological validation
- How to manage a heat sensitive load
- Bioburden/biological indicators approach, D value determination and the correct choice of biological indicators
- Validating the specific cycle

- Contamination Control Strategy
- Observations during GMP inspections

The presentations will be provided in a practice-oriented way from the different viewpoints of authorities, suppliers of packaging materials / devices / services (including sterilization activities), 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 prefilled syringes.

They key areas are

- Sterile Production
- Packaging material / Device development
- Manufacturing / Processing / Assembling
- Quality Control
- Quality Assurance

MODERATOR

Dr Andrea Kühn-Hebecker, *CONCEPT HEIDELBERG*

PROGRAMME 20 March 2024

Container Closure Integrity

Jean-François Decoster, *UCB*

- Requirements for CCIT
- Method development and validation

Process Simulation / Media Fill

Dr Helen Sauter, *Vetter Pharma-Fertigung*

- Media Fill Design
- Worst-case parameters & requirements
- Validation of processes with Media Fills
- Trends with regards to Media Fills

Visual Inspection

Jean-François Decoster, *UCB*

- Requirements
- Method development and validation
- AQL testing
- Automated vs. semi-automated vs. manual inspection

Automated Visual Inspection: Process and Transfer

Dr Max Scheible, *Vetter Pharma-Fertigung*

- Automated Visual Inspection (AVI) as an alternative to MVI
- State-of-the-art technologies for a robust and reproducible process
- Qualification & Transfer

Endotoxin Detection in Pre-Filled Syringes: Challenges during Method Development and Validation

Dr Bernhard Illes, *Microcoat Biotechnologie*

- Introduction to Endotoxin testing and endotoxin masking (Low Endotoxin Recovery (LER))
- General approach for development and validation of endotoxin detection methods
- Considerations and challenges for method development and validation for PFS
- Case studies for method development and validation for GMP release testing

SPEAKERS

Maria Luisa Bernuzzi
MesaLabs, France
Maria is working as Product and Application Engineer for MesaLabs. She has deep knowledge and experience in validations of steam, dry heat sterilization/ depyrogenation and hydrogen peroxide decontamination to guarantee the microbiological quality of the product.

Jean-François Decoster
UCB, Belgium
Jean-François holds a Master Degree in Chemical Engineering from the Brussels Industrial Superior School. He joined UCB in 2005 where he took increasing responsibilities in Primary Packaging Development. Since 2010, he has been the Head of Primary Packaging Development for UCB. In 2022, he moved to the Global Quality organization of UCB, where he is now in charge of several strategic projects, including Annex 1 implementation.

Katharina Golly
Novartis, Switzerland
Katharina is Senior Expert Engineering and began her professional career at Schott. Among other things, she was responsible for the development of silicone-based coatings for prefilled glass syringes. In 2015, she moved to Novartis as a packaging expert and supported ophthalmic PFS projects before becoming the technical lead for vials & kits.

Dr Bernhard Illes
Microcoat Biotechnologie GmbH, Germany
Bernhard joined Microcoat as a project manager in 2021 and is in charge of endotoxin service projects with a focus on LER, mitigation, method development and validation.

Christa Jansen-Otten
West, Germany
Christa is currently Director of Technical Product Development at West Pharmaceutical Services Inc. She has worked within the pharmaceutical industry for more than 20 years and gained experience as QA Manager in one of the world's leading pharmaceutical companies in sterile filling and packaging.

Dr Daniel Müller
GMP/GDP Inspector, Local Government, Germany
Daniel is currently head of the GMP Inspectorate at the local competent authority (GMP inspectorate) in Tuebingen, Germany. Since 2001 he has been working as GMDP inspector, conducting national inspections as well as EMA and overseas inspections. Before joining the authority, Dr Müller was working in the pharmaceutical industry, last serving as Qualified Person for sterile drug products.

Jinesh Sadalge
Novartis, Austria
Jinesh is a Senior Expert Engineering and started career as a Validation Engineer at Barry Plastics (Formerly known as REXAM) in 2012. There he was responsible for the validation of injection molding, assembly lines and test methods. Before joining Novartis, he worked with Biocon and Medtronic as Design Quality Engineering for Pen injectors, Auto injectors and Spinal cord stimulators. In 2020, he changed as a Device Manager to Novartis and working on Needle Safety Devices projects before taking the Delivery System lead for Syringe and Safety system in 2023.

Dr Helen Sauter
Vetter Pharma-Fertigung, Germany
Helen received her Ph. D. in microbiology at the University of Stuttgart-Hohenheim. She has been working for Vetter since 2013. Currently she holds the position of Director QA – Sterility Assurance/Lab Operation/Training systems.

Dr Max Scheible
Vetter Pharma-Fertigung, Germany
Max made his PhD in physics at the Technical University Munich in 2014, specializing on DNA nanotechnology. Afterwards he worked as a post-doc at the Technical University Braunschweig and co-founded an EXIST-based company in the field of microscopy. In 2018 he joined Vetter as part of the Development Service. Since then he is responsible for process development and process qualification as well as the implementation of new AVI products.

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
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.

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

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 organisation please contact:
Mr Ronny Strohwald (Organisation Manager) at
+49 (0) 62 21 / 84 44 51, or at strohwald@concept-heidelberg.de

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

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Fax +49 (0) 62 21/84 44 34
D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

GMP for Pre-Filled Syringes (PFS)

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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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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