ECA Academy
Your GMP/GDP Information Source

Speakers


Markus Busch
Vetter Pharma-Fertigung


Jean-François Decoster
UCB


Radek Fialka
Oncomed


Manuel Grund
Roche Diagnostics


Susanne Hall
Vetter Pharma-Fertigung


Peter Huonker
Lonza


Horst Koller
HK Packaging


Dr Daniel Müller
Local Government, Germany


Dr Helen Sauter
Vetter Pharma-Fertigung


Klaus Ullherr
Syntegon

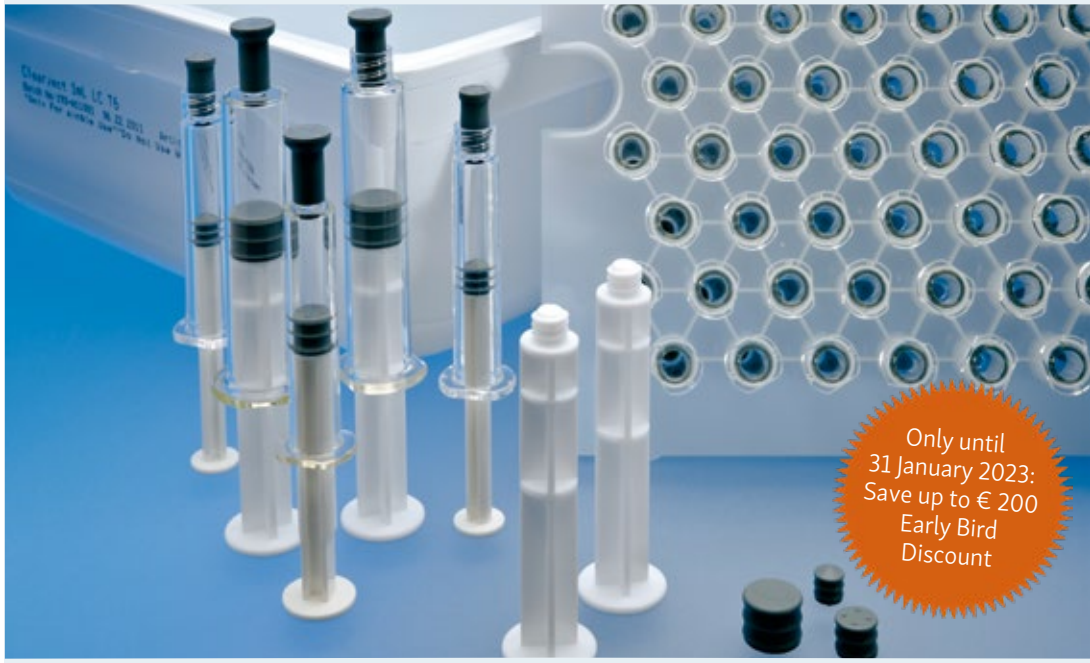

Iwan Tresch
FischerSöhne

GMP for Pre-Filled Syringes (PFS)

Development, Manufacturing & Control

Part of PharmaCongress 2023

28/29 March 2023 | Wiesbaden, Germany



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

Highlights

- Basics & Regulatory Overview
- Pre-fillable Syringes Design and Requirements
- Fill-Finish & Assembly Processes
- Process Simulation / Validation
- Visual Inspection & Container Closure Integrity
- Sterile Secondary Packaging
- GMP issues in Inspections
- Case Studies

GMP–PHARMA CONGRESS

This conference is part of PharmaCongress 2023

Objectives

In this course 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), will 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
- Sterile secondary packaging
- 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

Programme

Regulatory Overview, Annex 1 Impact and Inspection Experience

Dr Daniel Müller, Local Government, Germany

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

PFS made from Glass or Polymer

Horst Koller, HK Packaging

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

PFS and Needle Safety Systems

Horst Koller, HK Packaging

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

Tubs and Nests

Iwan Tresch, FischerSöhne

- Production process with its challenges from the raw material until a "RTU-Tub" ready to fill
- Requirements according to ISO 11040 – 7
- Further developments on Tubs and Nests

Fill-Finish Processes for prefilled Syringes

Markus Busch, Vetter Pharma-Fertigung

- Technology Overview
- Bulk syringes
- Pre-sterilized syringes

Device Assembling and Control Processes for Auto Injectors

Susanne Hall, Vetter Pharma-Fertigung

- What do you have to think about before selecting a device
- Impact of the Primary packaging material
- Assembling and Final Packaging
- Scale up process
- Inline Controls, Function and Release Tests

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

Silicone-free Primary Packaging Materials in Filling & Stopper Process Development – Challenges & Opportunities
Manuel Grund, Roche Diagnostics

- Glass vs. COP - what are the differences?
- Viscous solution, high-speed filling and vacuum
- Process-technical requirements for NC vacuum stoppering
- Helium leakage testing

High speed Syringe Filling Line for Oncological Drugs – Challenges & Solutions
Radek Fialka, Oncomed
Klaus Ullherr, Syntegon

- Project setup
- Choice of filling line and isolator
- Learnings from the mock-up study
- Integration into the building
- Strategy for filling toxic drugs
- Special challenges when filling toxic drug into syringes
- Use of NTT (No-Touch-Transfer) with fully automatic bag opening for inner and outer bag

Sterile Secondary Packaging: Case Study
Peter Huonker, Lonza

- Basic Process Overview
- Components
- Assembly
- EO Sterilization

Congress Keynotes

28 March 2023
Comprehensive Transformation of DR. KADE's Sites and Supply Chain
Dr Norbert Marquardt, Dr Kade Health Care

29 March 2023
Trends in Aseptic Manufacturing: Questions and demands for Pharma Machine Vendors
Dr Friedrich Haefele, formerly Boehringer Ingelheim Pharma

Speakers

Markus Busch
Vetter Pharma-Fertigung, Germany

Markus has been working at Vetter since November 2017 as Manager Technology & Process Transfer in the area of aseptic process transfers. Before that, he worked in the Manufacturing Science and Technology department of the downstream division for Boehringer-Ingelheim. He graduated with a Master of Science in Chemical Engineering and Process Engineering from the KIT in 2015.

Jean-François Decoster
UCB, Belgium

Jean-François holds a Master Degree in Chemical Engineering from the Brussels Industrial Superior School. After 5 years of experience with Eli Lilly & Co in Packaging Development, 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. Currently he is Director & Head of Devices & Delivery Systems Science.

Radek Fialka
Oncomed, Czech Republic

Radek Fialka worked in many roles in pharmaceutical operations in PLIVA/Barr/TEVA Group acting in the field of aseptic HPAPI injectables, HPAPI production, and OSD forms. In 2010 he was one of the founders of Oncomed, a CDMO member of medac Group. Currently he is Board of Directors Member and leads the project of a new HPAPI isolator high-speed pre-filled syringe line implementation. He is a member of ISPE and is active in local Czech Associations of Pharma Companies and regional Life Science initiatives.

Manuel Grund
Roche Diagnostics, Germany

Manuel started his work at Roche in 2016. He initially took a leadership role in the cGMP-regulated parenteral production of PFS. From 2018 to 2021, Manuel supervised the aseptic DP production of several biologics and small molecules in glass vials on a Lyo liquid line as MSAT officer. Since 2021, he has been developing and validating formulation and fill-

ing processes in silicone-free COP primary packaging for tray fillers as a process engineer for Parenteral Launches.

Susanne Hall
Vetter Pharma-Fertigung, Germany
Susanne originally started at Vetter in 1993 in Packaging QC including conducting of supplier audits. After holding several positions in Development Services, Packaging Development & Primary Packaging Development, she is currently Director Secondary Packaging & AVI Projects.

Peter Huonker
Lonza, Switzerland
Peter was a Microbiology Lab Supervisor at Zimmer GmbH, and Head of Quality Management at Früh Verpackungstechnik AG. Among other things, he was responsible for sterilization processes, Environmental Monitoring, internal and external audits for medical products and packaging processes. Since January 2023, he has been Head Microbiology DPS at Lonza.

Horst Koller
HK Packaging, Switzerland
Prior to becoming a consultant, Horst worked for Abbott Diagnostic and SCHOTT Pharmaceutical Packaging with a total of more than 20 years industry experience. His consulting company is focusing on Technical, Regulatory and QM Support around Primary and Secondary Packaging Systems including Medical Devices. He is an active member within the technical ISO Committees TC76 and TC84 as well as an active speaker on international conferences.

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.

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.

Klaus Ullherr
Syntegon, Germany
Klaus has a degree in electrical engineering. In March 2000 he joined Robert Bosch GmbH, Packaging Technology, Product Division Pharma Liquid, now Syntegon Technology. Since 2002 he is product manager for the business fields syringes and RTU containers with global product responsibility. He is a well-known speaker and trainer covering trends and solutions for fill/finish equipment especially for PFS and other pre-sterilized containers.

Iwan Tresch
FischerSöhne, Switzerland
Iwan is a plastics technologist holding a mechanical engineer degree. Currently he is CEO of FischerSöhne AG. Previously he worked for B. Braun Medical, Gerresheimer Küssnacht Schweiz AG. He has over 25years of industry experience in the main fields of the plastic converting industry according to ISO 13485, GMP, and clean room production requirements.

PharmaCongress 2023

GMP–PHARMA CONGRESS

The guiding theme of the PharmaCongress 2023 on 28/29 March will be „users sharing challenges and solutions in practice". Therefore, benefit from your colleagues' experience and from the direct information exchange at PharmaCongress & PharmaTechnica 2023.

The Tracks

As a participant you can switch between any of the tracks any time and also visit the PharmaTechnica Expo with more than 100 international exhibitors.

Conference Tracks	28 Mar	29 Mar
European Aseptic Conference	✓	✓
New Developments in Barrier Systems & Robotics	✓	✓
PUPSIT: Complying with the Main Annex 1 Changes	✓	✓
GMP for Pre-Filled Syringes (PFS)	✓	✓
Pharma 4.0 & Digitalisation	✓	✓
Handling of Highly Active Products	✓	✓
ATMP – Manufacturing, Quality, Safety	✓	✓
PharmaTechnica Expo	✓	✓

Find out more about the other conference tracks on our website www.pharma-congress.com.

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

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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

GMP for Pre-Filled Syringes (PFS) - Part of PharmaCongress 2023, 28/29 March 2023, Wiesbaden, Germany

☐ **Day 1 & 2 (28/29 March 2023)**
☐ **Day 1 (28 March 2023)**
☐ **Day 2 (29 March 2023)**

☐ **Yes, I would also like to take part in the Social Event on the evening of 28 March 2023.**

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

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 HEIDELBERGwill 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.

Date of the Conference
Tuesday, 28 March 2023, 09.00 - 18.00 h
Wednesday, 29 March 2023, 09.00 - 17.00 h
Registration: 28/29 March 2023, 08.00 - 09.00 h

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

Fees (per delegate, plus VAT)
The one day ticket is available for € 690,- plus VAT (until 31 January 2023 only € 590,- plus VAT), both days for € 1,380 plus VAT (until 31 January 2023 only € 1,180 plus VAT). It includes participation in any conference track of PharmaCongress 2023 on that day(s) 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, 28 March is included; please mark if you would like to attend the Social Event.

The fee is payable in advance after receipt of invoice.

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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