

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



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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

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 par-enteral 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 25 years of industry experience in the main fields of the plastic converting industry according to ISO 13485, GMP, and clean room production requirements.

PharmaCongress 2023



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.

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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

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- Cancellation until 2 weeks prior to the conference 25 %,
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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.
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German law shall apply. Court of jurisdiction is Heidelberg.

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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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