



## Speakers



Markus Busch  
Vetter, Germany



Jean-François Decoster  
UCB, Belgium



Susanne Hall  
Vetter, Germany



Peter Huonker  
FRÜH, Switzerland



Horst Koller  
HK Packaging, Switzerland



Dr Bettina Rietz-Wolf  
GMP Inspector for EMA and  
local Government, Germany



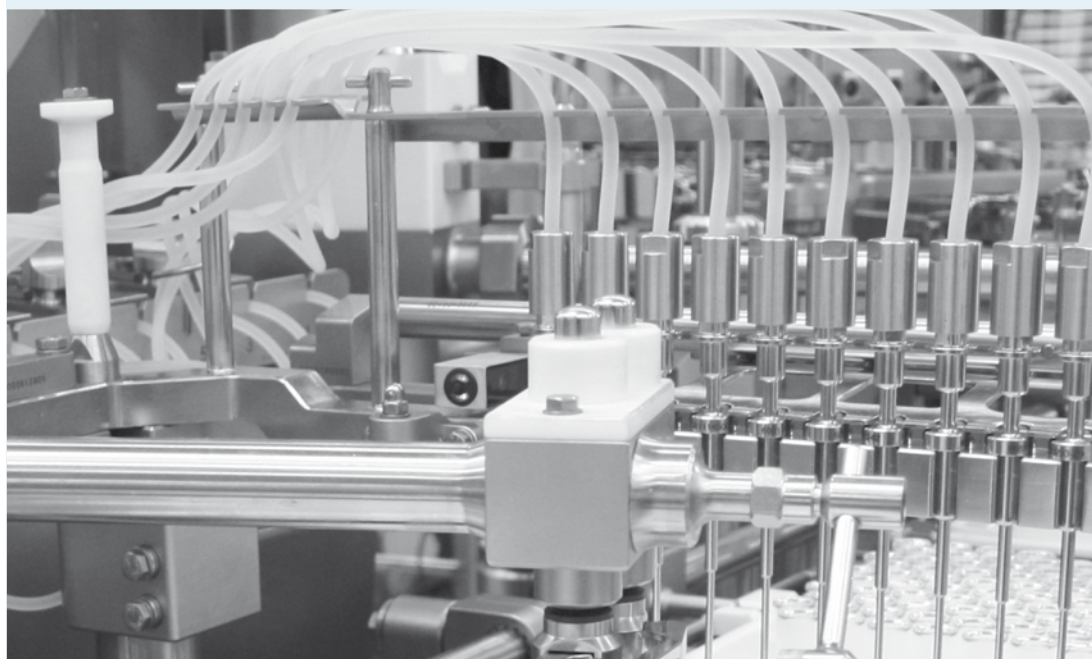
Dr Helen Sauter  
Vetter, Germany

# GMP for Pre-Filled Syringes (PFS)

Development, Manufacturing & Control



Live Online Training on 3/4 May 2022



## Highlights

- Basics & Regulatory Overview
- Personnel, Equipment & Facilities
- Pre-fillable Syringes Design and Requirements
- Fill-Finish & Assembly Processes
- Process Simulation
- Visual Inspection & Container Closure Integrity
- Sterile Secondary Packaging
- GMP issues in Inspections

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

## Objectives

In this live online course you will learn which requirements for pre-fillable syringes as a packaging material 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 videos and 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 upcoming revised **EU GMP Annex 1 entitled "Manufacture of Sterile 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 (e.g. via videos) from the different viewpoints of authorities, suppliers of packaging materials / devices / services (including sterilization activities), and the pharmaceutical industry.

## Target Audience

This online 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 Day 1



Provisional timetable, the actual schedule may vary depending on the situation.

09.00 – 09.15 h Welcome / Introduction

09.15 – 11.00 h

Basics & Regulatory Overview /  
GMP Issues in Inspections

- Applicable regulations and guidance
- The new Annex 1
- Personnel:
  - Qualification & disqualification
  - Training
  - Protective clothing
  - Gowning and gowning validation
  - Personnel Monitoring

11.00 – 11.15 h Short Break

11.15 – 12.15 h

PFS made from Glass or Polymer

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



12.15 – 12.45 h  
Q&A Session 1

12.45 – 13.45 h Break

13.45 – 14.45 h

PFS and Needle Safety Systems

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

14.45 – 15.45 h

Fill-Finish Processes for Prefilled Syringes

- Bulk and pre-sterilized
- RABS and isolators
- Annex 1

15.45 – 16.00 h Short Break

16.00 – 16.45 h

Pen-and Auto Injector Assembly Processes

- Assembly processes of the syringes into injection devices (auto-injectors, safety systems, etc.)



16.45 – 17.15 h  
Q&A Session 2

## Programme Day 2

09.00 – 09.45 h

### Container Closure Integrity

- Requirements for CCIT
- Method development and validation

09.45 – 10.45 h

### Process Simulation / Media Fill

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

10.45 – 11.00 h Break

11.00 – 11.45 h

### Visual Inspection

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



11.45 – 12.30 h

### Sterile Secondary Packaging: Case Study

- Sterile secondary packaging of PFS
- Validation of sterilization methods



12.30 – 13.00 h

### Q&A Session 3

## Your Benefits

### Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training...“  
This is why you receive an acknowledged participant certificate, which lists the contents of the Live Online Training in detail and with which you document your training.



### This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This Live Online Training is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at [www.gmp-certification.org](http://www.gmp-certification.org)

## Speakers



### Markus Busch, Vetter, 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.



### Susanne Hall, Vetter, 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 Head of the Department Secondary Packaging & AVI Projects.



### Peter Huonker, FRÜH, Switzerland

Peter was a Microbiology Lab Supervisor at Zimmer GmbH, responsible for sterilization processes, among other things. Since the beginning of 2018, he has been Head of Quality Management at Früh Verpackungstechnik AG. Among other things, he is responsible for deviations, complaints, CAPA, Change Control, Environmental Monitoring, internal and external audits for medical products and packaging processes.



### 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 Bettina Rietz-Wolf, GMP Inspector for EMA and local Government, Germany

Bettina is a pharmacist and GMP Inspector for the District Government of Baden-Württemberg and the EMA and performs GMP inspections worldwide. She was head of the German expert group EFG3 “Manufacturing of sterile products” at the ZLG.



### Dr Helen Sauter, Vetter, 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.

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Reservation Form (Please complete in full)



GMP for Pre-Filled Syringes (PFS) - Development, Manufacturing & Control  
Live Online Training on 3/4 May 2022

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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  2. If you have to cancel entirely we must charge the following processing fees:
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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. 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 January 2012). German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training

Tuesday, 3 May 2022, 09.00h – approx. 17.15 h  
Wednesday, 4 May 2022, 09.00h – 13.00 h  
All times mentioned are CEST.

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At <https://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,690  
APIC Members € 1,790  
Non-ECA Members € 1,890  
EU GMP Inspectorates € 945

The conference fee is payable in advance after receipt of invoice. VAT is reclaimable.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at [www.gmp-compliance.org/recordings](http://www.gmp-compliance.org/recordings). These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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