ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Packaging Manager

Speakers

Markus Busch
Vetter, Germany

Jean-François Decoster
UCB, Belgium

Susanne Hall
Vetter, Germany

Peter Huonker
FRÜH, Switzerland

Horst Koller
HK Packaging, Switzerland

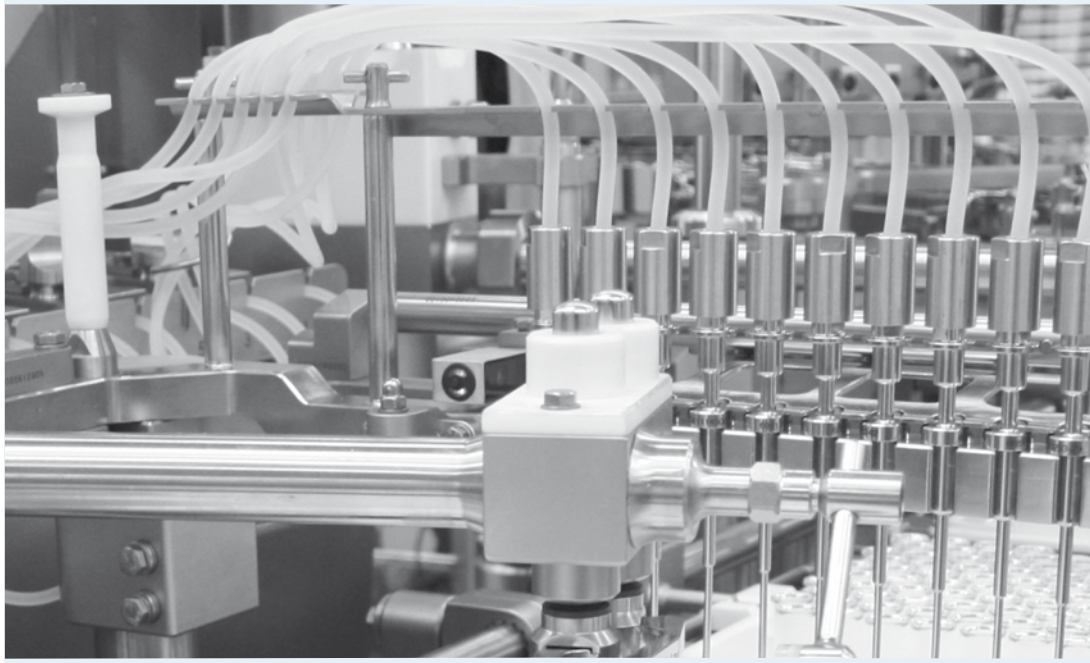
Dr Bettina Rietz-Wolf
GMP Inspector for EMA and local Government, Germany

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!

Programme

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.


CERTIFICATE

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 appropiate 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

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.

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

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week 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 January 2012).
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 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.

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.

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. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Conference language

The official conference language will be English.

Organisation and Contact

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Andrea Kühn-Hebecker (Operations Director) at
+49(0)62 21/84 44 35,
or at kuehn@concept-heidelberg.de.

For questions regarding organisation please contact:
Ms Sarah Schmidt (Organisation Manager) at
+49(0)62 21/84 44 16,
or at s.schmidt@concept-heidelberg.de.

PE/08122021