ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Packaging Manager

Speakers

Markus Heinz
Syntegon

Dr Rainer Kahlich
GMP/GDP Inspector

Dr Ana Kuschel
West Pharmaceutical Services

Sergio Cuevas Luján
Boehringer Ingelheim

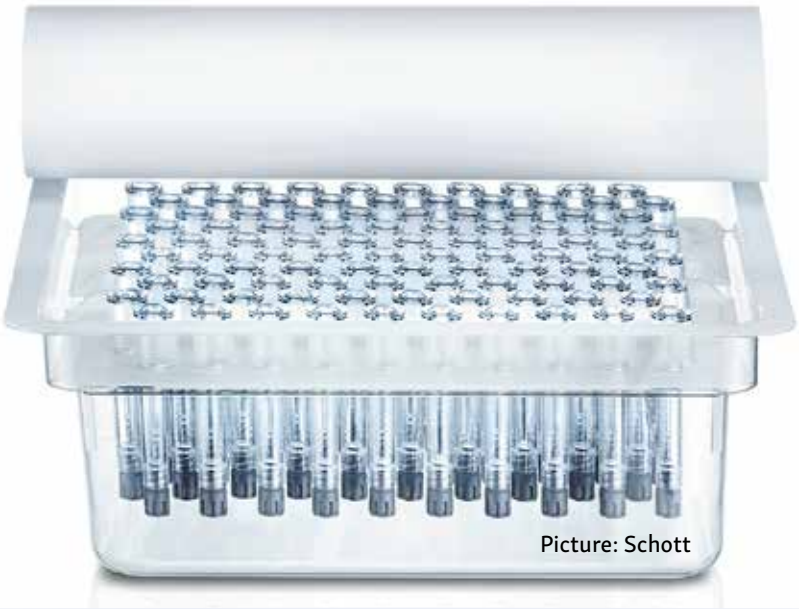
Aaron Mertens
STERIS

Dr Wenzel Novak
Gerresheimer

GMP Pre-Sterilized Packaging Material

Requirements and Challenges for RTU / RTS Products

Live Online Training on 14 November 2024



Picture: Schott

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

Highlights

- Implications of the New EU GMP Annex 1
- How to Select a Sterilization Method
- Packaging Design and Management of Pre-sterilized Packaging Material
- How to Validate a Sterilization Process
- A Suppliers' Perspective
- Decontamination of Pre-Sterilized Vials

Objectives

In this live online course, you will learn which requirements apply for pre-sterilized packaging material (e.g., ready-to-use, ready-to-sterilize). You get to know all aspects of the GMP manufacture of pre-sterilized products (e.g., vials, stoppers) that influence the the quality of the final product. In addition, practice-oriented presentations and case studies will guide you through the relevant requirements on qualification / validation, and controls for pre-sterilized materials, including impact of the new EU GMP Annex 1.

Background

Currently there is a growing demand in the development of pre-sterilized packaging materials (e.g. ready-to-sterilize, ready-to-use) for several enhanced Biotech applications. However, new GMP requirements for the sterile packaging material (e.g. regarding validation of the sterilization procedure) apply with the revised **EU GMP Annex 1 entitled "Manufacture of Sterile Medicinal Products"**, which provides guidance on the approaches to sterilization of products, equipment and packaging components. All sterilization processes should be validated.

Annex 1, Scope: The manufacture of sterile products covers a wide range of sterile product types (active substance, excipient, **primary packaging material** and finished dosage form).

This event will therefore deal with the current discussions and trends in the manufacture of GMP pre-sterilized packaging materials:

- GMP requirements for sterilization of packaging materials / devices
- Selection of a suitable sterilization method
- Critical process parameters (CPPs) that should be considered in qualification and / or routine processing
- Validation strategy
- Requirements for suppliers

Validated loading patterns should be established for all sterilization processes and load patterns should be subject to periodic revalidation. Maximum and minimum loads should also be considered as part of the overall load validation strategy. The validity of the sterilizing process should be reviewed and verified at scheduled intervals based on risk.

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 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 packaging materials for aseptic processing. They key areas are

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

Programme

GMP Aspects / Implications of the New Annex 1

- Regulatory expectations
- What´s new in Annex 1? (relevant aspects for packaging materials)
- Requirements for supplier qualification of pre-sterilized packaging material manufacturers
- Issues in inspections

Selection of a Sterilization Method

- Type of Packaging Materials
- Different Sterilization Methods
- EtO-Alternatives
- Pros and Cons

Packaging Design and Management of Pre-sterilized Packaging Material

- Design Aspects – What need to be considered?
- How to handle packaging materials for aseptic processing

Q&A Session 1

Validation of a Sterilization Procedure

- Critical Process Parameters (CPPs)
- Validation Strategy
- Validation of loading patterns
- Revalidation

A Suppliers' Perspective on EU GMP Annex I Requirements

- Revised EU GMP Annex I: Strong focus on primary packaging materials
- Appropriate primary packaging components and adequate primary packaging material selection
- How can this support pharmaceutical companies in complying with the respective requirements laid out in EU GMP Annex I?

Decontamination of Pre-Sterilized Containers (including Case Study)

- What is the ideal process for transferring ready-to-use (RTU) vials into the fill & finish area of an isolator?
- Effects of Vaporized Hydrogen Peroxide (VHP) on pre-sterilized glass and plastic vials
- VHP as a technology for proper outer decontamination of RTU packaging material

Q&A Session 2

Speakers

Markus Heinz
Syntegon, Germany
Markus Heinz is Global Product Manager at Syntegon Technology where he is responsible for all vial fill finish machines and applications. He holds a bachelor degree in business engineering and a master degree in international management. He´s within the Syntegon group (formerly Bosch Packaging division) since 2008. He has a strong background in dosing and closing technologies of sterile and aseptic liquid and powder dosage forms.

Dr Rainer Kahlich
GMP/GDP Inspector, Local Government of Baden-Württemberg, Germany
Dr Rainer Kahlich is pharmacist and GMP/GDP Inspector for the Local Government in Germany and the EMA and performs GMP/GDP-inspections worldwide.

Dr Ana Kuschel
West Pharmaceutical Services, Germany
As Principal Scientific Affairs Europe, Ana is providing technical support relating to West's packaging components and delivery systems for injectable drugs and healthcare products, as well as bridging scientific information through industry outreach. This is complementing her previous role as Manager Material Development, where she worked on both existing and new rubber formulations. Ana holds a PhD in macromolecular chemistry and is an active member of the ISO TC 76.

Sergio Cuevas Luján
Boehringer Ingelheim, Spain
Sergio is currently Packaging Materials Engineer at BI. Previously he worked in the same position for Sanofi and as Packaging Development Supervisor for Novartis. He is specialized in packaging materials for aseptic processing.

Aaron Mertens
STERIS, USA
Aaron is currently Senior Technical Service Manager at STERIS Corporation. In this role, he has responsibility for providing global technical support primarily for Critical Environments Products (i.e. environmental sanitizers, disinfectants, sporicides), Sterility Assurance Products (i.e. biological and chemical indicators), and Barrier Products Solutions (i.e. sterilization wrapping), application and validation.

Dr Wenzel Novak, Gerresheimer, Germany
Wenzel is currently Global Senior Director Business Development at Gerresheimer (including syringes, vials and cartridges). Previously he was in charge of project management. As head of production for pre-sterilized syringes, he designed the manufacturing area, built up the process and quality systems and operated the start-up phase of production. In between, he took role as Chief-Innovation-Officer at a pharmaceutical equipment supplier, developing new methods for sterilization and filling processes.

Your Benefit

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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 seminar in detail and with which you document your training.

This could be of interest for you

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
- APIs (ICH Q7)
- Medicinal Products
- Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

Why not online? GMP/GDP Training Courses/ Conferences, Webinars and E-Learning

Take advantage of the wide range of „on demand" training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course. Find out more at https://www.gmp-elearning.com and https://www.gmp-compliance.org/recordings.

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GERMANY

Reservation Form (Please complete in full)

GMP Pre-Sterilized Packaging Material
Live Online Training on 14 November 2024

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 https://www.gmp-compliance.org/privacy-policy). 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
Thursday, 14 November 2024, 09.00 – 17.15 h CET

Technical Requirements
We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 € 1,090
APIC Members € 1,140
Non-ECA Members € 1,190
EU GMP Inspectorates € 595
The conference fee is payable in advance after receipt of invoice.

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.

Conference language
The official conference language will be English.

You cannot attend the Live Event?
We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this Live Online Training.

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