ECA Academy
Your GMP/GDP Information Source

Speakers


Dr Simone Biel
Merck


Vincent Delferriere
GSK


Manuel Grund
Roche Diagnostics


Dr Philip Hörsch
Vetter Pharma-Fertigung


Guillaume Lesage
Merck


Matthias Schaar
Novartis Pharma Stein


Dr Florian Witte
Boehringer Ingelheim Pharma

PUPSIT: Complying with the Main Annex 1 Changes

Part of PharmaCongress 2023

28/29 March 2023 | Wiesbaden, Germany

Image: Merck

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Highlights

- Current EU Annex 1 requirement on PUPSIT
- Technical Requirements to implement PUPSIT
- What inspectors expect?
- Case studies from:
  - Boehringer Ingelheim Pharma
  - GSK
  - Merck
  - Novartis
  - Roche Diagnostics
  - Vetter Pharma-Fertigung

GMP–PHARMA CONGRESS

This conference is part of PharmaCongress 2023

Programme

Objectives

Reasons to attend this conference:

- You learn why PUPSIT found its way into the revised EU GMP Annex 1
- Inspectors discuss what they expect from the implementation of PUPSIT in pharmaceutical companies
- Pharmaceutical companies present their strategy for PUPSIT implementation in case studies

Background

PUPSIT is one of the most intensely and controversially discussed topics in the revised EU GMP Annex 1. But why do we have this intense discussion. Do the expectations of the regulatory authorities regarding the safety of sterile filtration differ from the practice in pharmaceutical companies? If so, why? Does PUPSIT now have to be implemented 100% in every case or where are there exceptions. If so, how must these be justified? Several case studies from pharmaceutical companies focus on the companies' specific strategies for implementing the current PUPSIT requirements.

Target Audience

The event is directed at specialists from the pharmaceutical industry as well as at engineers and planners who have to deal with sterile filtration and especially PUPSIT in their daily practice.
It particularly addresses the departments:

- Production
- Quality assurance
- Engineering / Technology

Moderator

Dr Simone Biel, Merck

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

Programme 28 March 2023

PUPSIT, or Not to PUPSIT....?
Dr Sione Biel, Merck

Since the first draft of the new Annex 1 was published, the pre-use post-sterilization integrity test (PUPSIT) of a sterile filter was one of the most discussed topics related to the Annex 1 revision.

- How to interpret the Annex 1 PUPSIT clause?
- Why is it a debate?
- And what is the industry's answer on PUPSIT?

Practical Aspects of Pupsit Implementation
Guillaume Lesage, Merck

- Intricated with PUPSIT are several technical challenges related to the preparation of filtration systems:
- Dry leak testing, flushing dynamics, Integrity test selection and dilution/drying challenges.
- Filtration assembly characterization insights
- Filter integrity test limits specific to single-use assembly

Case Study Boehringer Ingelheim Pharma: PUPSIT Risk Assessment: The Impact of Equipment Design
Dr Florain Witte, Boehringer Ingelheim Pharma

- Case study Boehringer Ingelheim
- PDA risk-based approach
- Holistic risk assessment including equipment design

PUPSIT – Annex 1 - Application of Risk Management
Dr Philip Hörsch, Vetter Pharma-Fertigung

- Risk Assessment for PUPSIT and Considerations of Associated Risks in Established Processes
- Risks of flaw masking and filter damage
- Product and process evaluations
- Risk-Benefit analysis

Case Study Novartis Pharma: PUPSIT – YES or NO?
Matthias Schaar, Novartis Pharma Stein

- What does Pre-use Post sterilization integrity testing (PUPSIT) mean?
- What do the guidelines say?
- What are the challenges, benefits and disadvantages for implementation?
- So, what to do?

Case Study GSK: PUPSIT - From Design to Implementation
Vincent Delferriere, GSK

- Regulatory environment around PUPSIT
- Design of Single Use Solution (from Generic to custom)
- Technical Implementation challenges
- Extractable approach
- Automation equipment
- Supply challenges

Programme 29 March 2023

Case Study Roche Diagnostics: Pre-Use Post Sterilisation Integrity Testing (PUPSIT) in the Revised Annex 1 - Friend or Foe of the Pharmaceutical Entrepreneur?
Manuel Grund, Roche Diagnostics

- Everything was better in the past... or was it? - An overview of the regulatory changes
- PUPSIT and its scientific raison d'être
- The process and the product - Which aspects play a major role?
- Quality Risk Management in application

Live Demos

Annex 1 and Sterile Filtration – how to keep Flexibility and Regulatory Compliance
Merck

- We will showcase „gold standard" and fault designed with live explanation what is not optimize in the design while implementing PUPSIT in SU FF assemblies

Palltronic® Flowstar V Integrity Test Instrument – Taking Filter Integrity Testing to the Next Level
Pall

- Taking filter integrity testing to next level with Flowstar V
- Installation, programming and test execution
- Data integrity (ALCOA Plus) and 21 CFR Part 11 compliance
- Automation and network integration
- Data Management System

Podium Discussion on PUPSIT

Speakers

Dr Simone Biel
Merck
Simone Biel is a Senior Regulatory Consultant and provides regulatory expertise to our customers and internal stakeholders with a focus on Single-Use Technology and filtration.

Vincent Delferriere
GSK
Vincent is working in 11 years in the Global MSAT organization of GSK Vaccines. For the last 8 years, I lead global Single Use project in the life cycle area (POFF – PUPSIT), managing our suppliers, as well as developing new (micro) technology in collaboration with our Technical R&D teams.

Manuel Grund
Roche Diagnostics
Since 2021, he has been developing and validating preparation and filling processes in silicone-free COP primary packaging for tray fillers as a process engineer for Parenteral Launches

Dr Philip Hörsch
Vetter Pharma-Fertigung
Between 2004 and 2015 as Project Manager Microbiology, Team and Site Manager Quality Operations at Vetter. Since 2015 Director Quality Assurance for (Process-) Validation, Risk Management, Trending, IT-Systems, IPC/Visual Inspection Systems and Specification Management Packaging Materials.

Guillaume Lesage
Merck
During his 26 years of experience in filtration & separation technologies deployed in the pharmaceutical industry, he has been involved in many projects for design, sterilization, validation, troubleshooting of critical filtration systems used in aseptic processing.

Matthias Schaar
Novartis Pharma Stein
Matthias started his career in Novartis Stein, Switzerland in the Microbiological Department. Now he is supporting the sterile production more specialized with sterilization processes such as sterile filtration with the implementation of new products.

Dr Florian Witte
Boehringer Ingelheim Pharma
Since 2021 he is heading the quality assurance unit for device development.

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GERMANY

Reservation Form (Please complete in full)

PUPSIT: Complying with the Main Annex 1 Changes - 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

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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 %.

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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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