ECA Academy
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Speakers

Dr Philip Hörsch
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PUPSIT in Practice

Live Online Training on 06 November 2025

Highlights

- Practical solution proposals
- Experience reports from inspections to implement regulatory requirements
- Application of risk-based approaches for integrating PUPSIT into existing cleanrooms

Regulatory Expectations & Implementation

Objective

This seminar aims to provide participants with a comprehensive understanding of the regulatory requirements and practical challenges associated with Pre-Use Post Sterilisation Integrity Testing (PUPSIT). The focus is on the requirements of Annex 1 of the EU GMP guidelines, and the resulting expectations of the relevant authorities and auditors. By the end of the training, participants should be able to correctly interpret regulatory requirements, make appropriate decisions based on risk assessments, and develop specific implementation strategies for their company.

Background

PUPSIT is not a simple system to implement. Many companies face technical, spatial and organisational challenges. Existing systems in particular are often not easily adapted for PUPSIT implementation. While some manufacturers have already successfully implemented PUPSIT, others are still struggling or need to create a well-founded risk analysis to justify an alternative approach or the avoidance of PUPSIT altogether.

To understand the relevance and complexity of this topic, it is essential to look at the regulatory background. The revised Annex 1 of the EU Guidelines for Good Manufacturing Practice (GMP), which came into force in 2023, introduced significantly more detailed and stringent requirements for the manufacture of sterile medicinal products. One of the key additions is the reinforced expectation that PUPSIT should be performed unless a scientifically justified and documented risk assessment can be provided as to why it is not feasible or necessary.

PUPSIT is a critical quality assurance step in sterile filtration processes. It involves performing an integrity test on the sterilising-grade filter after sterilisation but before use. This ensures that the filter has not been damaged during sterilisation (e.g., by heat or pressure) and will function as intended when product is passed through it. The purpose is to confirm the filter's integrity before it comes into contact with the product, thus minimizing the risk of contamination and ensuring product sterility.

Despite its importance from a regulatory and patient safety standpoint, the implementation of PUPSIT in practice can be complex. Many systems in aseptic production environments were not designed with PUPSIT in mind. Significant redesigns, investment and operational adjustments are often required to adjust these systems to allow for reliable and validated PUPSIT procedures. Furthermore, space limitations in cleanrooms, the need for additional equipment, and changes to SOPs and training programs all add to the burden.

This seminar will address these issues from multiple perspectives. It begins with an overview of the regulatory framework and the expectations that inspectors bring to audits regarding PUPSIT and Annex 1 compliance. It then moves on to practical aspects, discussing how companies can approach implementation, what challenges they may face, and how to navigate them.

Finally, it presents a structured, risk-based methodology for evaluating whether PUPSIT is required and how to integrate it into existing processes if needed. By combining regulatory insight, practical guidance, and risk-based thinking, the program provides valuable orientation for decision-makers in pharmaceutical manufacturing who are faced with the critical question: "PUPSIT – yes or no?"

Target Audience

This seminar is aimed at pharmaceutical industry specialists and managers who work in aseptic manufacturing and quality control, and who have either already introduced PUPSIT or still have to implement it. The program is relevant for people with the following background:

- Employees from the Quality Assurance and Quality Control (QA/QC) departments
- Production managers and production engineers
- Validation and qualification managers
- Project managers and technology managers
- Auditors and inspection preparation teams

Moderator

Clemens Mundo, Concept Heidelberg

Programme

Sterile Filtration – PUPSIT and Regulatory Requirements Beyond
(Frank Sielaff)

- Requirements of Annex 1
- Expectations on PUPSIT
- Experiences from inspections

Practice Considerations for PUPSIT Decision
(Matthias Schaar)

- 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?

PUPSIT - Application of Risk Management
(Philip Hörsch)

- Considerations and risk evaluation when discussing PUPSIT
- Important aspects when implementing PUPSIT in existing clean rooms
- Roll-out considerations

Speakers

Dr Philip Hörsch
Vetter Pharma
Director QA Process Performance & System Compliance

Responsible for the topics Process Validation and Continued Process Verification, Process & Quality System Trending, Combination Products, Quality Risk Management, IT-/QM-Systems, System Compliance and Data Integrity.

Matthias Schaar
Novartis
Technical Steward Microbiology

Matthias Schaar has been working for Novartis in Switzerland since 2007. He began building up his knowledge in microbiological quality assurance and quality control. He supported the production of sterile medicinal products with aseptic process validation, environmental control and sterilisation processes. Currently, his main focus is on supporting the validation team and routine manufacturing in the context of sterile filter validation and its application.

Dr Frank Sielaff
Regional Authority Darmstadt, Germany
GMP Inspector

GMP Inspector at the Regierungspräsidium Darmstadt with the focus on inspection of drug manufacturers and laboratories in Germany and countries outside of the EU. Before joining the GMP inspectorate Frank was several years employed in the pharmaceutical industry as Head of Quality Control and as Qualified Person.

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Reservation Form (Please complete in full)

PUPSIT in Practice
Live Online Training on 06 November 2025

Title, first name, surname

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Date of the Live Online Training
Thursday, 06 November 2025, 09.00 h – 12.30 h (CET)

Technical Requirements
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Fees (per delegate, plus VAT)
ECA Members € 590
APIC Members € 640
Non-ECA Members € 690
EU GMP Inspectorates € 345
The conference fee is payable in advance after receipt of invoice.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22490.

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.

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 seminar in detail and with which you document your training.

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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