



Dear Sir, Madam,

Sterile Filtration is becoming more and more important in the Biopharmaceutical production processes together with Single Use Technology to increase the security level of the final products and, consequently, to the patient protection.

In the meantime, Regulatory bodies are continuously upgrading the standards to adapt them to the technical evolution.

To discuss this important topics sharing knowledge and views of the different perspectives **Masterfilter GmbH** (Germany) and **Lab Analysis Process Pharma** (Italy) are organising a seminar on the **24th September 2025** in which we invite you to participate.

How to increase the safety level in the production of sterile medicines: design and validation of filtration systems integrated in traditional and single-use technology.

The goal of this seminar is to share our advice and recommendations on the development, qualification and maintenance of filtration system validation, the integration of particle pre-filtration and bioburden reduction stages, and PUPSIT management. It will be held by Masterfilter GmbH (www.masterfilter.com) and its partner Labanalysis Process Pharma s.r.l. (www.labanalysis.it), the specialists in filtration solutions, to discuss technical and regulatory aspects and future developments.

We will also be able to discuss your practical cases and any questions you may have on the subject.

In order to better organise this seminar, we would be grateful if you could indicate your intention to attend via the attached seminar registration.

Who is this seminar for?

- Quality Area Management
- Qualification and Validation Managers
- Engineering Managers
- Production Management



How to increase the safety level in the production of sterile medicines: design and validation of filtration systems integrated in traditional and single-use technology.

Seminar Agenda

9:30 – 10.00 Welcome of participants and distribution of seminar documentation

10:00 - First Session:

International Regulatory Context – Requirements for Filtration Systems from Regulatory Bodies and Global Quality Associations (PDA, EMA, EU Annex 1, ISO 13408-2, and US-FDA guideline on aseptic processing)

11.15 – 11.30 - Coffee Break

- Filtration System: Traditional technology approach
- Process Validation Studies: a complete overview
- Q & A

12.30 to 13.30 - Lunch Break

13.30 - Second Session:

- Single Use: most common applications
- Validation approach to Single Use Systems

14.45 to 15.00 Coffee Break

- Future Regulatory Trends
- EU-Annex 1 revision contents – PUPSIT, Redundant filtration, CCS and Filtration System
- Q&A and Seminar wrap-up

16:30 - End of Seminar

SEMINAR REGISTRATION

Topic: **How to increase the safety level in the production of sterile medicines: design and validation of filtration systems integrated in traditional and single-use technology**

Date: **24th September 2025**

Location: **Best Western Plus IO Hotel, Graf-Zeppelin-Str. 2, 65824 Schwalbach**

Participant fee: **200 Euro including lunch, coffee breaks and seminar documentation and certificate**

Participant

Salutation: Mr. Mrs.

First Name: Last Name:

Function:

Email:

Company Name:

Zip: City:

Billing Address

Company Name:

Street:

Zip: City:

Email:

Order number:

City, Date

Signature

Please send the completed and signed registration to:
Masterfilter GmbH, Kapellenstr. 9, 85622 Feldkirchen, Germany
Fax.: 089 2885 8788, Email: info@masterfilter.com

After we receiving your registration, we will send out the conformation and invoice. The registration deadline is the 10th of August 2025. The number of participants is limited to 30 in total.

