

Three Hidden Risks of Microglass HEPA Filters: It's Worth a Closer Look.

Some Leaks Are Harder to See Than Others. So Are the Risks They Can Cause.

HEPA leaks affect every step in the pharmaceutical process, from construction and production to federal compliance, unplanned downtime, and equipment failure. It's a major part of any company's reputation, financial bottom line, and, ultimately, patient safety.

Using HEPA filters with microglass media, even as a part of a Standard Operating Procedure, can lead to decreased production time, increased repair time, and increased energy consumption, not to mention FDA 483 Warning Letters and potentially disastrous recalls. Are you keeping your eye on the risks that are harder to see? And if not, have you considered the consequences?

Unscheduled Downtime:

Would It Surprise You if a Weaker Filter Also Increased Your Risk?

The pharmaceutical industry estimates that 77% of production downtime can be attributed to failures of equipment and environmental problems.* This downtime can be caused by HEPA filters failing. Traditional HEPA filters typically fail because of the poor mechanical strength of the media, a failure due to physical contact or degradation from caustic chemicals. The actions required when these failures occur include replacing the HEPA filter, certifying the installation, investigating potentially contaminated products, and generating a risk assessment report.

The poor durability and low tensile strength of microglass leads to media degradation when exposed to cleanroom chemicals. What's more, high pressure drops and media offgassing result in higher energy costs and lower air quality.

Fragile fiberglass media can lead to unplanned and costly situations, including the need for replacement filters, labor for installation, FDA 483's, and even recalls.

The costs and issues associated with using microglass may be viewed as a cost of doing business, but the ultimate risks are often unrecognized. It has been reported that 1% to 3% of microglass filters are discovered to have leaks during each round of testing. When leaks are found, just the documentation and meetings required in the investigation process alone are expensive, not to mention backup stock for filter replacement.

A company's reputation can also be damaged by these leaks. Publicly posted warning letters are brand killers for pharma, biotech, and medical device companies. And reputation damage from public fear will increase these concerns exponentially. Competitor leverage, loss of business, stockholder confidence—these are just some of the ways that leaks affect your bottom line.



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*Pharmaceutical Manufacturing Magazine (2004)

FDA Testing Guidance

2x a year
Critical Areas
(ISO 5; Class A and B)

1x a year
Non-Critical
Areas
(ISO 7 and 8)

Excessive PAO Testing:

Twice the Testing Offers Twice the Reliability. Right?

Microglass may be PAO compatible, but it is also fragile. Very fragile. This fragility means that any interaction with this media entails a greater risk of damage—which CAN mean more testing, which WILL mean more risk of failure. That's a risk you just can't take.

HEPA filter testing has had a long and complex history. But the FDA requires this regular testing. It is an integral part of any cleanroom protocol. In fact, filters utilizing microglass require more testing than any other media. Microglass requires more testing because it is more fragile. It requires more testing because it can't be trusted to keep your cleanroom safe.

Obviously, it is critical that filter integrity is maintained throughout the entire manufacturing and testing process. Even though overcertification may seem like a solution, it is actually just another leak waiting to happen. Testing is a key part of any cleanroom validation, but every test includes specific risks.

Although additional testing may be appropriate when air quality is found to be unacceptable, testing less may mean testing *smart*. Over testing may make you feel better about leaks in microglass filters, but it won't make the filters any better or stronger.

Overcertification

Overcertification in non-critical environments can cause significant problems for pharmaceutical production, such as additional costs for certification services, longer shutdown time, and greater exposure to damage, gel liquefaction, and leakage. However, while the FDA requires critical room leak testing twice a year, non-critical rooms only require the test once a year. But many companies still test twice a year due to the fragile nature of microglass and their well-founded concerns and fears associated with it.

Gel Degradation

Extra testing may help to find leaks, but there are inherent risks associated with these tests. One of the lesser-known risks is gel degradation. PAO can and does affect these gels. And the ensuing gel liquefaction can dramatically compromise cleanroom processes, in addition to damaging the filter itself and causing devastating cleanroom damage. Contamination and premature replacement, along with associated costs and concerns, not to mention lost production time, could cost millions of dollars. Testing only as required will improve the integrity of your filters, the performance of your cleanrooms, and your bottom line.

Financial Impact:

Do You Understand the Cost of Every Leak You Experience?

Maintaining filter integrity is a challenge for every cleanroom operation, and because of this, you need to understand the significant impact of inferior microglass media on your business.

The FDA has increased emphasis on enforcement and validation. While compliance may be expensive, it is nothing compared to the catastrophic expense of warnings, recalls, and unplanned downtime. What does that really mean? Is the continuous use of microglass worth the risk?

The status quo, a misplaced belief that this old media is sufficient, is a recipe for disaster. How could any faith remain in something that could properly be called “outdated”?

There is very little discussion in the pharma industry as a whole about what’s really going on here. Your competitors could also be listening to manufacturers about a product that will work “good enough” to keep them in business. The truth is, it may not. This provides a great opportunity for a competitive advantage, as well as protecting your reputation and improving your financial fundamentals.

Hidden Costs of Microglass HEPA Filters

We’re calling the costs of microglass use in cleanrooms “hidden,” but with every day that passes it becomes more and more apparent that the cost to individual companies and the pharma industry is staggering.

Let’s take a look at what it costs you EVERY TIME a microglass HEPA filter leaks. These are not theoretical numbers. These are the hard facts about this media and the price you’re paying for continuing with this outmoded technology.

Here is what you need to know:

The time it takes to address a filter leak:

Five to ten minutes planned time for an experienced team to scan a filter

At least **two labor hours** unplanned downtime to remove, replace, and retest a leaking filter

Loss from a single microglass HEPA filter leak:

\$250,000+ hr. (two hours of unplanned downtime)

\$20,000 (documentation and meetings)

\$520,000+ Total cost for a single microglass HEPA filter leak

\$3,000 to \$20,000 Documentation costs associated with a single filter leak

1% - 3% of microglass HEPA filters are discovered to have leaks during each round of testing.

100 filters x 3% leak rate:

3 filters x \$20,000 per filter (documentation and meetings with a single leak)

Cost: \$60,000 (per round of semi-annual leak testing)

OR

\$120,000/yr Total Annual Cost

It should be obvious at this point that a closer look at the use of microglass HEPA filters exposes the disturbing financial risks and extraordinary damage to reputations associated with its use. These expenses will continue to compound in future years. Microglass is unlikely to find a “fix” for its fragility. This fragility is inherent within the media itself. Add to that the fact that HEPA filters cannot be repaired inside critical areas and have to be replaced. Doesn’t it make sense to do it right the first time, for your company and for a public that depends on your end product?

Microglass HEPA Filtration: More That You Need to Know

Microglass HEPA filters pose an enormous risk to your process environment. The air filters used inside your HVAC system have a dramatic impact on the total cost of ownership, the labor resources required to support the systems, product quality, and most importantly, patient safety.

What's more, minimizing the hidden risks and costs associated with successfully operating pharmaceutical cleanrooms requires a continual review and updating of your Standard Operating Procedures, particularly the selection, installation, and maintenance of your filters.

There are other, better pharma-grade HEPA media options that are superior to microglass. These options will operate not only at a validated state with respect to installation and operation—but at an improved state. Before you choose your next HEPA filter, make sure you know what you're buying and what the actual cost in time, performance, and ownership will be.

There are choices in cleanroom filtration. Make certain you know what they are. Because the wrong decision could be a damaging one.

What to look for in HEPA Filters

This checklist will help you decide on the right HEPA filter for your cleanrooms.

Durability	<ul style="list-style-type: none"> • Highest level of mechanical strength for resistance to damage and failure rate • Chemically inert to reduce media degradation in highly corrosive environments • Water resistance to extend the life of the filter
Performance	<ul style="list-style-type: none"> • High PAO holding capacity for better performance and reliability • Low to zero offgassing of chemical components for higher quality clean air • Lowest available pressure drop to reduce energy consumption
Total Cost of Ownership	<ul style="list-style-type: none"> • Clearly understand all of the operational risks associated with your filter selection • Invest in a technology that will give you the greatest impact with minimal effort • Choose a company that provides professional guidance to reduce spending, decrease risk, and save time

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