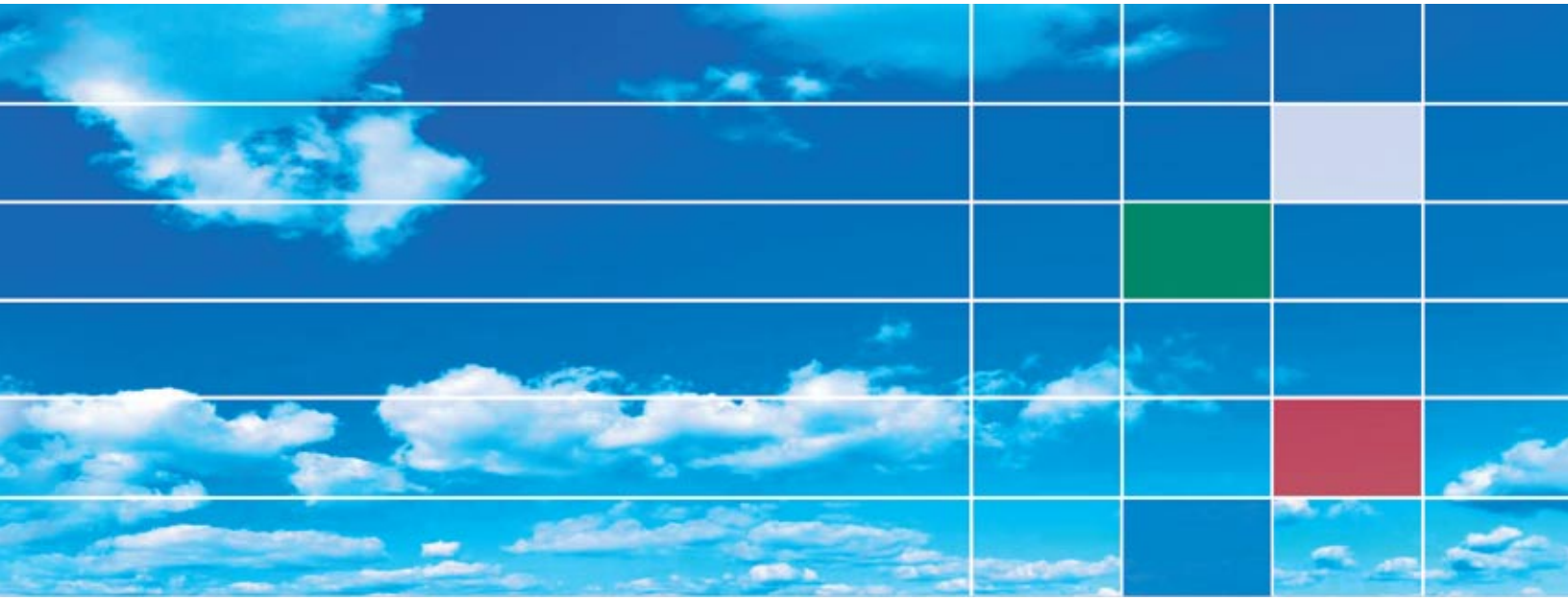
Maximizing Contamination Control With Vacuum Technology



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Cleanrooms, as well as any modular environment where attempts are made to keep airborne contaminants, temperature, relative humidity, differential pressure, static electricity and other factors under strict control, come in many shapes and sizes. Whether discussing hard- or softwalled or any of the other types of cleanroom, one thing is certain – it is virtually impossible to construct and maintain a completely contaminant-free environment, as long as personnel are working in it. There is no perfectly clean cleanroom; there are only levels of acceptable cleanliness.

For the 50 or so years that cleanrooms have been in use, a steady debate has centered on the best ways to keep them clean, and regulatory and advisory agencies have weighed in on the proper and acceptable maintenance of cleanrooms.

In November 2001, the outdated U.S. Federal Standard 209E (FS209E), which has regulated cleanroom operations since 1963, was replaced with a new, stricter set of regulations set forth by the International Organization for Standardization (ISO). Specifically, ISO's standard ISO 14644-1 now defines the criteria that cleanrooms must meet in order for pharmaceutical manufacturers to stay on top in today's increasingly competitive market. To date, ISO 14644-1 has been adopted by the United States, the European Union, and across much of the industrialized world.

As they work to meet ISO's demanding criteria, now is the ideal time for pharmaceutical manufacturers to turn a serious eye inward to evaluate and improve their housekeeping regimens. The risks associated with failing to do so affect a company's operational efficiency, employee health concerns and, ultimately, the bottom line.

Three key approaches work together to ensure a properly maintained cleanroom environment:

- Prevent contaminants from entering the cleanroom
- Clean more efficiently using proven techniques
- Train personnel to ensure good working habits

Quality and Cost Controls

Of course, new regulations and tighter standards often equate to an increased cost and expanded array of confusing choices.

There are clear costs associated with a comprehensive cleanroom maintenance program, represented by labor, equipment and consumable products, with the first representing the largest component. Hidden costs that are difficult to quantify, such as replacing inferior cleaning equipment, utilizing improper procedures, and failing to recognize safety concerns, also affect the bottom line.

Pharmaceutical manufacturers need to control issues where they can by choosing better quality equipment, developing proper procedures and investing in employee education and training. Through these interrelated actions, manufacturers maximize the productivity and profitability of their cleanroom operations.

So what exactly is achieved by maintaining cleanrooms to such high standards?

First, we need to realize that contamination reflects the presence of any foreign substance that can undermine or have a detrimental impact upon whatever you are working on. Relating mostly to particulate matter, contamination falls into three main categories:

- Airborne contamination – carried and moved by aircurrents
- Fluid contamination – generated or dispersed by fluids, whether in machinery or elsewhere.
- Transfer contamination – picked up (often by personnel) and carried to critical areas.

Obviously, the very act of cleaning itself can be a major source of contamination, and this reality has led to an expansion in the availability of products and services utilized by cleanroom technicians and contamination control specialists.

In cleaning, contamination control specialists must consider:

• How particulates are created in a clean environment

• How to prevent them from entering the cleanroom

• What the best methods are for removing dust and debris

• What cleaning supplies and equipment are best for their application

Optimal Cleaning Efficiency

Every square inch of a cleanroom should ideally be as clean as possible. There are multiple surfaces to be considered in a cleaning regimen. Ceiling panels, lighting units, HEPA (high-effeciency particulate air) filtration units, sprinkler heads, walls, glass surfaces, process equipment, piping systems, floors and manufacturing equipment should all be decontaminated regularly.

Even the ambient air must be monitored and maintained at proper levels. HEPA-filtered ventilation systems assisted by preventative measures help manufacturers limit airborne contamination.

Investing in Quality Equipment

Cleaning with both a HEPA-filtered vacuum and traditional wipe-down methods are standard in most cleanrooms. Yet, vacuuming is often the most efficient method because particles are retained inside the machine with little chance of being exhausted into the atmosphere (provided the vacuum has a HEPA-filtered exhaust stream). Vacuuming also eliminates the fiber particles swabs and wipers may leave behind.

Measurements taken in one cleanroom setting found that a dusting system using disposable cloths polluted the space twice as much as a system using a HEPA-filtered vacuum cleaner.

So, what should a cleanroom vacuum include? To safeguard a pharmaceutical facility against multiple sources of contamination, particle size must be taken into account. Any vacuum cleaner used in a cleanroom must be HEPA-filtered to ensure that 99.97 percent of all particles down to and including 0.3 microns are collected and retained. For even smaller particulates, an ULPA (ultralow penetration air) -filtered model is necessary to collect and retain particles down to 0.12 microns.

In addition, it is absolutely critical that the HEPA filter be installed after the motor for it to properly filter the exhaust stream. The motor's commutator and carbon brushes generate dust, and if the exhaust stream is not filtered, that dust will simply be released back into the environment.

However, not all HEPA filtration systems are created equal. For peak operating efficiency, a vacuum should have a multi-stage, graduated filtration system, which uses a series of progressively finer filters to trap and retain particles as they move through the vacuum.

This multi-stage system protects the HEPA filters from blockage and excessive wear and tear, maintaining peak performance.

Ideally, a vacuum's filtration system should use oversized filters, which slow airflow action across the larger surface areas and optimize the air-to-cloth ratio. This allows the vacuum to easily collect large volumes of debris over extended periods of time – while once again minimizing maintenance.

The Basics of Vacuum Filtration

There are four primary factors that affect filtration: particle size, air speed, filter media and running time.

• Particle size – The smaller the particle, the more difficult it is to filter. As particles become airborne, they align themselves with the flow of the air stream, making it easier to penetrate filter media that is too porous. It is this factor that makes a series of graduated filters a critical vacuum component; even tiny particles that make it through the first few layers of filtration will be stopped by the finest filters, ultimately the HEPA or ULPA.

• Air speed – Velocity, or air speed, refers to the pace at which particles move through the hose and into the vacuum cleaner. The faster the particles travel, the deeper they will penetrate into the filter media. A particle traveling at a high

speed may build up enough force to go through the pores of the filter material; however, a particle traveling at a slower speed will be caught on or between the fibers (or weave) of the media. A HEPA-filtered vacuum cleaner with a cyclone or paper-bag filtration stage slows the air down as it enters the machine, preventing particles from gathering too much velocity and enabling the other filters to operate at peak efficiency.

• Filter media – Filtering efficiency is affected by the relationship between the surface area of the filter media and the volume of air trying to pass through it. This relationship is known as the "air-to-cloth" (ATC) ratio; the lower the ATC ratio, the more efficient the filtration system.

The ATC ratio is largely determined by the size of the filter: the larger the filter area, the more efficiently the vacuum can filter debris because there is a larger space in which to trap particles, and consequently less frequent filter clogging. Therefore, the optimum ATC condition is a slow airflow through a large filter.

• Running time – As the vacuum operates, debris will build up on the surface of a filter and embed itself into the filter material, clogging the filter (also known as "blinding" or "loading"). A certain amount of loading is good for the filter; it improves efficiency by making it harder for the particles to penetrate the filter. However, when the filter becomes completely clogged, vacuum suction is reduced and performance suffers. Filters with a low ATC ratio, i.e., with a larger surface area, can operate for longer periods of time without clogging, enabling workers to maintain maximum suction and vacuum performance.

Besides having an exceptional filtration system, any vacuum used in a cleanroom environment should be constructed of non-particle-generating materials. Nonporous, stainless steel vacuums – equipped with smooth hoses and attachments – enable personnel to quickly wipe down and decontaminate equipment for faster, simpler sanitization and validation. Additionally, a vacuum must be specially packaged to prevent contaminants from entering the cleanroom environment when first delivered.

Reducing Contaminants From Within and Without

In pharmaceutical cleanrooms, almost all airborne particles, including invisible ones, are considered contaminants. The human eye can only see particles larger than about 55 microns in diameter, which is about one-third to one-half the diameter of a human hair. Particles smaller than 10 microns can be breathed in and lead to adverse health effects. These small particles make up more than 99 percent of the seven million particles taken in with every breath.

Before any cleaning or maintenance program begins, it's necessary to minimize the presence of contaminants. Three major particle generators exist in typical pharmaceutical cleanrooms: materials, equipment and personnel.

Materials

Cleanroom consumables, such as gloves, masks, wipers, swabs, hairnets, booties, HEPA filters, and tacky mats, have the potential to do major damage. For example, if employees do not decontaminate their gloves before entering the cleanroom, everything they touch may be contaminated.

Equipment

Particles have a tendency to settle on equipment and machinery, which creates a unique cleaning challenge. The vibration of this equipment – whether dedusters, pill packaging machines or other equipment – is often enough to cause a breakdown of particles, which then circulate in the ambient air.

Personnel

The particles generated by people are the most common cleanroom contaminants. They are also among the hardest to control. Cleanroom gowns and other garments are designed to limit human contamination due to skin, hair and clothing particles, but it is impossible to regulate uncontrollable, particle-generating actions like sneezing and coughing. In fact, the typical working person generates approximately one million organic airborne particles greater than 0.5 microns per minute.

Maximizing Operations Through Employee Education

The human component cannot be ignored when evaluating the challenges of a comprehensive contamination control program in pharmaceutical cleanrooms. All personnel should be educated on the finer points of cleanroom operation and maintenance, as well as the large role they play, through a combination of video-based training, on-the-job demonstrations, and one-on-one instruction with management. The key is to focus not only on what they have to do, but why. If employees truly understand the critical implications of following specific procedures, they will be more likely to follow them.

Issues to be included in a comprehensive training program:

- Personal hygiene habits
- Proper gowning techniques
- Knowledge of particle behavior
- Understanding of cleanroom protocols
- Instruction in cleaning procedures

Again, as labor costs represent the greatest component in a cleaning program, the cost savings to be realized through maximizing labor efficiencies is critical. By choosing superior equipment and implementing clear, consistent practices, employees will be more productive and operations will be more profitable.

Conclusion

By investing in cleanroom technology, pharmaceutical processing and manufacturing companies are also making a commitment to maintaining the highest standards of contamination control. But without understanding the major components of a comprehensive cleaning program – materials, equipment and personnel – manufacturers will be challenged to implement an efficient and cost-effective system for contamination control.

Maximizing efficiencies and controlling costs in a contamination control program are realized through investments not only in employee education and training but through researching and investing in quality cleaning materials and equipment. The selection of a high-efficiency industrial vacuum that has the filtration capabilities to preserve the integrity of the product and protect the health and safety of personnel is one of the most critical and cost-effective elements.

Four Things to Consider When Selecting a Cleanroom Vacuum

The HEPA- and ULPA-filtered vacuum cleaners that are used in cleanrooms should contain a number of features for peak operating efficiency and to ensure "absolute" levels of air purity. These include:

- Multi-stage, graduated filtration system – uses a series of progressively finer filters to trap and retain particles as they move through the vacuum. The largest particles are captured first by coarser filters; smaller particles are then caught and retained by the finer HEPA or ULPA filters.

- Oversized main filter – slows airflow across the larger surface area and optimizes the air-to-cloth ratio. This allows the vacuum to easily collect large volumes of debris over extended periods of time with minimal maintenance and without filter clogging.

- Simple, smooth construction – prevents contamination by the vacuum, which should be constructed of a non-particle-generating material such as non-porous stainless steel. Hoses and attachments should also be smooth for fast, simple sanitization and validation.

- Filtered exhaust stream – for optimal efficiency, the vacuum's HEPA/ULPA filter should be installed after the motor. The motor's commutator and carbon brushes generate dust; a HEPA/ULPA filter located after the motor filters the exhaust stream and prevents dust from being released into the environment.

Vacuum Tip: Don't forget to take spill response into account when purchasing a vacuum. At least one of your vacuums should be capable of both wet and dry collection.

About Nilfisk Industrial Vacuums

Nilfisk Industrial Vacuums, also known as Nilfisk-Advance America, Inc,. is one of the largest providers of cleaning equipment in North America. From its Morgantown, PA headquarters, Nilfisk Industrial Vacuums supports three brands of industrial vacuum cleaners: Nilfisk, Nilfisk ALTO and Nilfisk CFM. Equipped with exceptionally efficient filtration systems and user-friendly features, the company's vacuums play a critical role in thousands of manufacturing facilities and industrial processes across North America. Supported by a direct sales force and extensive dealer network, Nilfisk Industrial Vacuums have solved a variety of cleaning challenges, including combustible dust, general maintenance, overhead cleaning, abatement, process integration, laboratory/cleanroom control, and more. For more information, visit www.pharmaceuticalvacuum.com.