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Eight Key Considerations in Selecting a Powered Air-Purifying Respirator (PAPR) System for Pharmaceuticals Manufacturing

As pharmaceutical and biopharmaceutical manufacturers respond to demands for increased quality, security and regulatory overview, pressure to elevate productivity and address key employee environmental health and safety issues is mounting. One of the biggest issues is protecting personnel and the environment from exposure to potent active pharmaceutical ingredients (APIs).

Sentinel Clear XE™ PAPR hood and blower by ILC Dover (photo courtesy of Pharmatek)

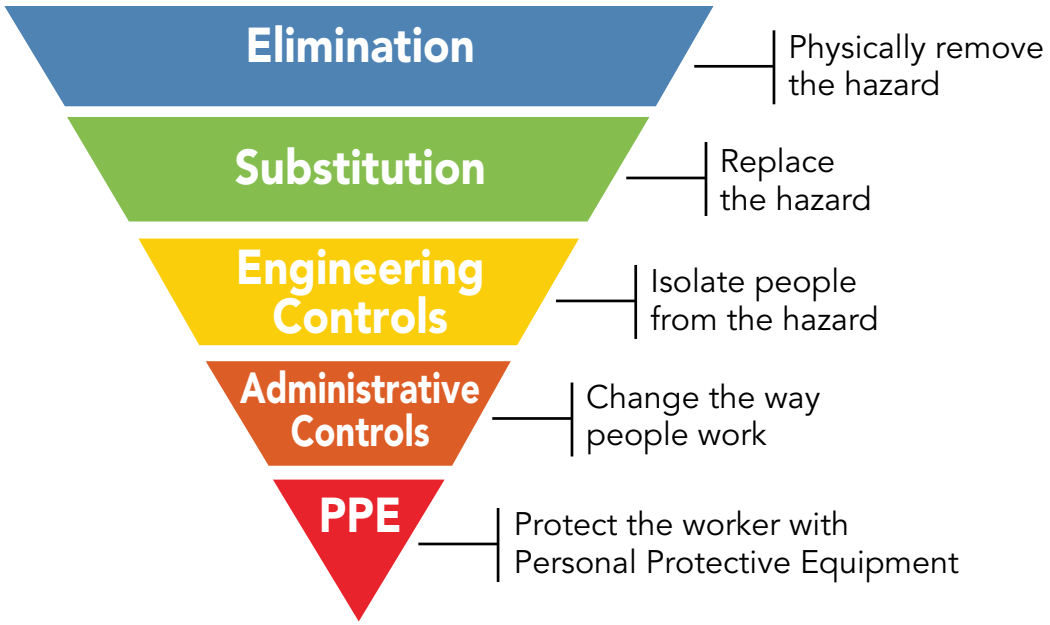
INTRODUCTION

As pharmaceutical and biopharmaceutical manufacturers respond to demands for increased quality, security and regulatory overview, pressure to elevate productivity and address key employee environmental health and safety issues is mounting. One of the biggest issues is protecting personnel and the environment from exposure to potent active pharmaceutical ingredients (APIs). Although potency is not universally defined, there are some generally accepted guidelines. A potent compound may include an API with the following characteristics:

- a therapeutic dose ≤ 10 mg;
- an Occupational Exposure Limit (OEL) of ≤ 10 µg/m3 as an eight-hour time-weighted average (8-hr TWA);
- carcinogenicity, genotoxicity, mutagenicity, teratogenicity, or reproductive toxicant potential at low doses; or
- a novel compound with unknown potency/toxicity(1)

HIERARCHY OF HAZARD CONTROLS

Most pharmaceutical and biopharmaceutical companies follow a traditional hierarchy of hazard controls to handle high potency compounds. This hierarchy places engineering controls at the equipment level first, followed by secondary or administrative controls and then, finally, personal protective equipment (PPE). An example of this tiered hierarchy for handling a potent compound can be found in the table below.



For certain types of compounds, PPE may be the primary control option in a manufacturing operation. Either way, as a first or last line of defense, PPE is a critical element of a comprehensive Environment, Health and Safety (EHS) program.

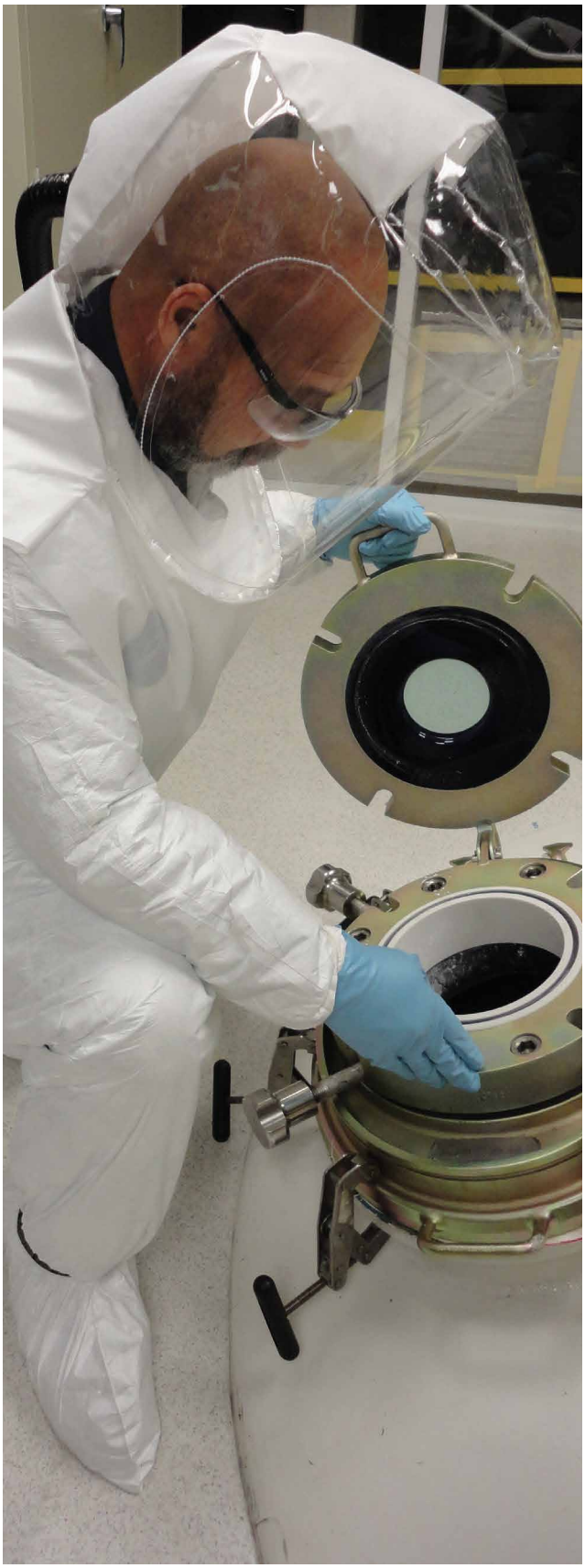
THE ROLE OF POWERED AIR-PURIFYING RESPIRATORS

Powered air-purifying respirators, or PAPRs, are the industry standard for respiratory protection in pharmaceutical production operations. They use a battery-powered blower to pull ambient air through air-purifying elements (filters) before the air is made available for breathing. They come in a variety of styles — half mask, full facepiece and helmets/hoods — but not all styles deliver the same levels of comfort or allow the same range in motion.

Academic articles about the effects of respirators on human performance are not abundant, but new research is beginning to emerge. A number of studies, in both healthcare and pharmaceutical environments, have identified the most important attributes of respirator protection. They must:

- Offer a wide and clear field of view with optically clear lenses
- Reduce blower noise to facilitate communication during wear
- Minimize weight demands on the user
- Reduce carbon dioxide levels during exhalation
- Enable reliable testing of air flow and filter life
- Provide a cooling air flow and minimize breathing resistance
- Integrate into protective clothing systems. (2)

PROTECTING WORKERS AND SUPPORTING PRODUCTIVITY THROUGH RELIABLE, EFFICIENT AND ERGONOMICALLY DESIGNED RESPIRATORY PROTECTION



Loose-fitting PAPR systems exhibit most, if not all, of the features described above. They not only help protect workers from airborne particles, potent drug compounds and hazardous chemical entities, but they also offer excellent visibility, comfort and functionality, contributing to a higher level of worker productivity.

While PAPRs for use in pharmaceutical and biopharmaceutical operations are required to meet EN 12941 certification standards, including protection levels, airflow and filtration performance, differences in other areas of design and functionality may provide an improved level of worker protection and personal comfort.

This white paper explores eight such considerations in detail (many correlated to the attributes described above) and could be helpful to EHS managers and supervisors looking to select a PAPR system for their particular application. They include:

1. Ease of Donning and No Fit-Testing Requirement
2. Larger Field of View
3. Enhanced Psychomotor Performance
4. Hood Design to Maximize Cooling Effects
5. Better Blower/Battery Weight Ratios
6. Long Battery Life
7. Blower/Battery Connections
8. Optimized Acoustic Properties for Improved Communication

The overall content should help you become more knowledgeable and better able to discuss the capabilities and limitations of various PAPR systems with suppliers before choosing a particular PAPR. We also invite you to include ILC Dover on your supplier consideration list.

1 *RESPIRATORS THAT ARE EASY TO DON AND DO NOT REQUIRE FIT-TESTING REDUCE WORKER STRESS AND RESPIRATORY PROTECTION ADMINISTRATIVE TIME.*

Respirators can be classified as tight-fitting or loose-fitting. Tight-fitting respirators, which include half-mask and full-facepiece designs, require a tight seal to work properly. Clearly, the size and shape of the user can affect respirator fit and, as a result, the quality of the seal. The presence of facial hair and glasses can also interfere with a proper fit.

As a result, qualitative and quantitative testing is necessary to ensure that the facepieces of tight-fitting respirators fit the user's face. Unfortunately, fit-testing procedures can cost time, money and human resources. For certain large facilities with thousands of employees, this can become a significant administrative burden.

Moreover, recent human performance research (3) has shown that fit-testing should be considered more broadly to include physical, physiological and psychological measures. Discomfort and poor fitting were cited as common reasons for not wearing respirators in operational environments. But ease of donning is equally important — respirators that are easy to don reduce worker stress and anxiety because they promote end-user confidence. They also promote productivity and decrease administrative costs by getting workers to their assigned tasks faster.

Loose-fitting respirators, such as helmet and hood systems, do not need to be fit-tested, making them attractive solutions for pharmaceutical manufacturers. The Sentinel Clear XE™ PAPR system from ILC Dover features inner and outer bibs for easy donning while still delivering superior personal protection. The Sentinel Clear XE™'s unique skirt/exhaust system inflates the suit to deliver improved protection and comfort.

2 *RESPIRATORS THAT OFFER AN UNOBSTRUCTED FIELD OF VIEW MAY IMPROVE PRODUCTIVITY AND SAFETY.*

There are a number of measures that can indicate the quality of an observer's vision. Visual acuity — the sharpness of vision — is measured by a person's ability to identify letters or numbers on a standardized eye chart from a specific viewing distance. Visual range refers to the distance at which a given standard object can be seen with the unaided eye. And field of view is the extent of the observable world that is seen at any given moment — a measure that can be affected greatly when an external apparatus, such glasses, goggles or PAPRs, are placed on an observer.

A number of studies have evaluated the impact of respirators, especially tight-fitting respirators, on vision. For example, researchers have reported that, among all visual abilities, respirator use can affect the visual range the most. Respirators were also found to worsen visual acuity by three-quarters on Snellen chart lines. (3) This effect can be intensified during physical activity, because full-face respirators can shake and pull on the face, leading to an erosion of visual acuity. (4)

Of course, in pharmaceutical manufacturing operations, hooded respirator systems are more common, which means many of the visual acuity challenges of tight-fitting respirators are eliminated. Even with hoods; however, an observer's field of view can be affected. In fact, some sources list limited visual field as a significant logisitcal disadvantage of hooded systems. (5)

Field of view may be impacted by internal suspension systems within some hoods, such as headbands and other support structures and mechanisms. Hooded PAPR systems that are held aloft by positive air pressure require no such components and do not interfere with vision or become uncomfortable during use.

The visual field for humans with normal eyesight and healthy eyes is typically just under 180° horizontally, so a 180° field of view for a protective hood would seem to make sense. And that is a reasonable minimum target to allow the user to feel comfortable in the hood. With that field of view, a user with their head up and eyes straight ahead would have the same view as without the hood. At the same time, a vertical field of view may be equally important, and PAPRs should be evaluated based on how much they limit the downward vertical field of view. (6)

However, additional factors must be considered in providing full and comfortable visual acuity for those who have to perform a variety of work functions while wearing the hood. For instance, in a hood with a 180° field of view, visualizing an object outside that range would require rotating the head. But if the hood were to have a larger field of view, say 300°– 320°, it would be possible for the user to move his or her eyes only — a glance — to check an object on a table or a readout on a laboratory instrument. This would allow a much more natural work posture and procedure. This is one of the

primary reasons ILC Dover offers its Sentinel Clear XE™ Hood with a full 320° field of view.

Although some research indicates that visual acuity has little to no effect on performance of intense physical activity (4), qualitatively, a more natural and ergonomic work environment may also help to reduce worker fatigue and eye strain.

When choosing a PAPR system, one should choose from hoods that are EN-certified, such as ILC Dover's Sentinel Clear™ Hood. Also, a hood that securely attaches to protective suits will reduce its movement while employees perform work actions. Hoods with double bibs are especially advantageous. These allow the wearer to tuck the inner bib under the suit's neck opening and still have an outer bib overlapping the shoulder. When used in this configuration, the Sentinel Clear XE system is certified to TH3 levels of protection.

3 *LOOSE-FITTING RESPIRATORS CAN REDUCE PSYCHOMOTOR DEFICITS THAT ACCOMPANY WEARING RESPIRATORS FOR EXTENDED PERIODS.*

The impact of respirators on psychomotor ability has been studied less extensively and with more inconclusive results. Still, it's worth considering how respirator design might affect performance on difficult tasks requiring significant dexterity.

The classic study in this area was conducted in 1991 by Zimmerman, who evaluated the effects of three different types of respirators (dust mask, rubber half-mask with HEPA cartridges and a full facepiece airline respirator with supplied air) on task performance (7). Psychomotor ability was evaluated by reaction time, finger dexterity, arm-hand steadiness, and grip strength of participants. Speed and accuracy were measured in each test. The study concluded that full-face respirators may decrease movement time by up to 12% and the steadiness of arm-hand movements by 31%.

Another study, which tested the effect of military respirators on participants performing a range of easy and difficult tasks, reported more mixed results. Respirators had no measurable impact on the performance of easy tasks, but the time to complete difficult tasks requiring more hand-eye coordination increased by 17% when study participants wore respirators (8).

In pharmaceutical operations, highly detailed assembly and fault-repair tasks may not be as commonplace as they are in other manufacturing environments. Nevertheless, it stands to reason that any respirator system that allows for a greater range of motion can increase worker comfort and decrease stress. Hooded systems, such as the Sentinel Clear™ system from ILC Dover, that provide a larger field of view and allow workers to turn their heads freely, can reduce any psychomotor deficits and generally help workers stay productive.

4 *COMFORTABLE HOOD DESIGN AND EFFICIENT COOLING REDUCE IRRITATION AND DISCOMFORT.*

Keeping workers comfortable and focused is paramount in today's productivity-driven drug manufacturing. Simulation studies are often used to evaluate the utility and comfort of respiratory systems during the performance of everyday tasks. Though these studies are conducted in non-operational settings without the true demands of real-world pharmaceutical manufacturing, they can still be informative. Multiple studies have shown that PAPR users report greater comfort across a number of measures when compared to non-powered air-purifying respirators, such as N95 masks. For example, one single cohort observational study reported that 100 percent of N95 wearers reported discomfort compared to just 30 percent of PAPR wearers. (9)

There are several explanations for this. The very act of donning a respirator can create a breathing obstacle and increase anxiety. This occurs because respirators, especially non-powered air-purifying respirators, can increase both inhalation and exhalation resistance. At the same time, the use of respirators in hot conditions can cause significant user discomfort by increasing temperatures inside the hood or facepiece. Sweat produced inside a facepiece can also create challenges. It can interfere with breathing, cause exhalation valves to stick, and lead to slippage of the respirator facepiece, promoting leakage. If a worker becomes overheated while wearing a respirator, even more serious issues can arise. As deep body temperature increases, dexterity, cognition, and motor skills can degrade significantly. Disorientation is also possible. (4)

PAPRs, which use a blower to send filtered air over the face of the worker, can help address all of these challenges in a number of ways:

- PAPRs create positive airflow inside the facepiece or hood, so they generally have much lower inhalation resistance. (4)
- The blown air of PAPRs contributes to cooling because it evaporates perspiration and cools the face.
- PAPRs reduce dehydration and worker fatigue caused by overheating, helping to make individuals more productive throughout their shifts.
- Finally, because PAPRs are classified as positive-pressure devices and because contaminants are unlikely to migrate from ambient pressure to a higher pressure, they provide more protection than negative-pressure respirators. (10)

DOUBLE-ENVELOPE ENGINEERING

The Sentinel Clear™ PAPR system features a double envelope — the air-moving unit is an internal fan connected to the filters and the breathing hose. This air-moving unit is encased in a rigid outer shell, so it is protected against mechanical damage.

Even in the unlikely event of a fracture or break of the outer shell, the air-moving unit is not affected. It continues delivering filtered air to the breathing hose and hood with no hazardous leakage, increasing the overall reliability of the complete system.

5 *A LIGHTWEIGHT BATTERY/BLOWER SYSTEM CAN REDUCE FATIGUE.*

Research from multiple studies has shown that the use of a respirator by itself, in terms of breathing supplied air, has no effect on heart rate. But the weight of the respirator equipment, especially if it is carried close to the body, can create cardiac stress. By some estimates, each kilogram of extra weight should be expected to reduce work performance measures. For example, a person walking at a high rate of speed walks for 2.5 minutes less for each additional kilogram he or she carries. (4)

Clearly, the overall weight of a PAPR system is an important consideration, but the weights of common systems can vary greatly. If you review a resource such as the Guide for the Selection of Personal Protective Equipment for Emergency First Responders, which compares a number of tight- and loose-fitting PAPRs side-by-side, the weight variability becomes clear, ranging from approximately 2 kilograms to approximately 4 kilograms. (11)

The Sentinel Clear XE™ integrated battery-blower system weighs just 2.2 pounds (1 kg). That's roughly half the weight of some competing systems, which helps to reduce fatigue over longer shifts.

Another important consideration is how the battery-blower system attaches. An ideal system offers users options to accommodate individual preference. The Sentinel Clear XE™ system features back harness and Quick-Loc™ belt options that support a range of user needs and preferences and can be easily adjusted. The ergonomic harness helps move the mass of the blower and battery up to the middle of the back, where it produces less strain and provides added comfort for the wearer. Workers who are shorter in height or spend a majority of their work time in a seated position would likely prefer the lightweight back harness.

EN certification does not specify minimum flow rates for PAPR systems. However, the Sentinel Clear XE™ delivers an airflow of 220 liters per minute for a full 12 hours when powered by ILC Dover's lithium-polymer battery, which means even more air is available to help the worker feel comfortable. In addition, blower-inflated hoods, such as that of the Sentinel Clear™ Hood, also eliminate internal headbands and forehead contact. This design helps reduce sweat and the incidence of skin chafing, irritation or rash. It also affords extra headroom to accommodate hard hats and safety glasses.

6 *FULL-SHIFT BATTERY LIFE CAN REDUCE DOWNTIME AND MAINTENANCE BURDENS.*

Another factor driving the profitability of pharmaceutical firms is the length of time workers spend producing products and any non-productive downtime. Twelve-hour shifts are not unusual in some drug manufacturing environments. However, a majority of PAPR systems are powered by batteries with run times of eight to 10 hours. This increases the likelihood of a 12-hour shift worker interrupting their tasks to swap out discharged batteries with fully charged batteries. More and more, pharmaceutical companies look to PAPR batteries and related technologies as mission-critical elements that drive purchasing decisions. (2)

New-generation batteries, such as lithium polymer designs, offer the advantage of longer life, while ILC Dover's battery-blower combination is the only standard pack unit to offer a 12-hour run time. And it can be recharged quickly, in just five hours, in a battery charger that comes equipped with an LED that changes from red to solid green when charging is complete. An external battery-life indicator gauge shows the charge level, making it easy for workers to see when battery life is getting low.

7 *INTEGRATED DESIGN FOR BLOWER, FILTERS, BREATHING TUBE AND BATTERY PACK INCREASES FLEXIBILITY*

In addition to less maintenance, 12-hour batteries also mean reduced inventory, compared to 8- and 10-hour batteries. Fewer units in stock and less frequent recharging can also help lower maintenance costs.

Many hooded PAPR systems feature complex, cumbersome wiring and cables to connect their components, not to mention irregularly shaped belts and battery or blower surfaces. These design shortcomings invite snags and work interruptions. There is also potential for wires or cables to disconnect from the battery, causing the blower to cease operation, stopping airflow and compromising the wearer's health and safety. He or she then must leave the work area to resecure the battery connections.

The Sentinel Clear XE™ PAPR is a design-forward system that offers complete flexibility. The battery pack is smoothly integrated into the blower assembly, with filters attached directly to the housing. And the breathing tube offers even greater flexibility to ensure maximum airflow through an operator's range of motion and activities.

8 *POWERED SYSTEMS CAN BE OPTIMIZED TO IMPROVE AUDIBILITY AND EASE OF COMMUNICATION.*

The ability to communicate effectively with team members is of paramount importance in pharmaceutical manufacturing environments. Verbal commands and transmission of critical information through dialog enable workers to collaborate and escalate issues efficiently.

Non-powered respirators, such as N95 masks, offer clear advantages when it comes to speaking and listening tasks. With nothing covering their ears, N95 wearers receive auditory input with few issues, even when speakers' mouths are covered. Powered respirators interfere with hearing in two ways. First, the hood or headtop of a PAPR serves as a sound insulator. Secondly, when the blower is activated, it produces background noise that can be distracting. Several observational studies have noted these issues, with users scoring PAPRs lower for both audibility and ease of communication.

EN 12941 guidelines state that the noise level at each ear, with the blower unit running at maximum flow, should not exceed 75 A-weighted decibels (dBA). Manufacturers of powered respirators are exploring a number of innovations to ensure that their products fall well below the EN-stated requirements. For example, the design of the breathing tube itself and how it integrates with the blower can affect how much noise is produced. Older PAPR designs sometimes had noise levels of 70 dBA — below the EN 12941 threshold but still relatively high. Newer designs have been able to decrease noise levels considerably, with some studied systems achieving noise levels in the range of 60 to 70 dBA at full battery charge and maximum blower speed. (12)

The Sentinel Clear XE™ blower, which features a brand-new tube design and integration, is rated at 63 to 64 dBA, a significant improvement over older designs. With these enhancements in the system's audibility, combined with the other user comfort factors described above, it's clear why PAPRs like the Sentinel Clear XE™ are increasingly favored as the system offering the highest protection combined with the greatest levels of usability.

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