

Pulsed UV Light Systems in Clean Room Isolators

Pharmaceutical and medical device companies are increasingly manufacturing their products in clean rooms equipped with two types of enhanced clean room devices. One device is the simple hood or flow cabinet. The second is a fully enclosed clean work environment known as the isolator or barrier isolator. The common feature of clean room devices is the increased separation of the manufacturing activity from the human clean room technician. A key function of clean room devices is to control microbial contamination near and within the manufacturing area. This is accomplished by air flow through HEPA filters and the construction of walls or barriers. The ultimate success of the clean room device depends upon the ability to transport materials into and out of the clean work environment without the introduction of microbial contamination. Xenon pulsed UV light systems are designed to work in these clean room devices and control microbial contamination.

Completely enclosed barrier isolator manufacturers have designed transfer ports to move material into the isolator while controlling the introduction of microbial contamination. The transfer ports are designed differently than conventional transfer hatches or airlocks. The transfer ports are increasingly equipped with a method to sterilize the surface of materials entering the isolator and to allow a rapid transfer of materials. Systems equipped with slow acting vapor phase hydrogen peroxide or conventional UV light are being displaced with the more rapid decontamination agent, pulsed UV light, that is capable of sterilizing the surface of materials in seconds without significantly increasing the temperature in the chamber. Pulsed UV light systems also sterilize the empty transfer port after each use. No vapor or gaseous decontamination chemical is used or introduced into the clean room.

Completely enclosed barrier isolators and open isolators (hoods) must be decontaminated before and after each use as a clean work environment. Common methods employed by industry include vapor phase hydrogen peroxide, ozone based procedures, liquids such as

peracetic acid or hydrogen peroxide. These systems normally are validated to achieve a 3-6 log kill to meet most application regulatory requirements. Each method requires the surface to be cleaned prior to applying the decontamination chemical. Pulsed UV light is an acceptable alternative that can be applied in seconds without labor and does not involve the introduction of a gaseous chemical or create a toxic waste. Pulsed UV light applications are fully automated and designed as an integral component of the system, eliminating the potential introduction of human-borne microbial contamination.

As clean room technology advances to automation and further isolation of the work environment, equipment and system design should consider the application of pulsed UV light as a safe and effective method to decontaminate surfaces in less than a second without the use of a gaseous or liquid toxic chemical. Pulsed UV light systems do not cause a significant increase in temperature and do not generate waste products.



Illustration of SteriPulse-XL® pulsed UV lamps applied to sanitize the outside of packages containing sterile contents. This non-contact system prevents the introduction of microorganisms to a clean room or likewise sterile area and eliminates the need for chemical vapors.