Containment Technologies

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As new drug compounds are being developed to fight diseases, the potency of these compounds is increasing, which puts the personnel working with them at higher risk. Containment technologies are being employed to protect operators from these potent compounds. Other reasons for containment technologies include cross contamination and product migration.

Containment strategies should be composed of:

1. The exposure potential to the operator (risk assessment).
2. The health risk associated with the degree of exposure for that specific compound (hazard involved and operator exposure level [OEL]).
3. The engineering control system or device required.

The pyramid below helps determine the best containment strategy for the operation. It combines the operator exposure potential, task duration and OEL to arrive at a strategy. For this discussion, three strategies will be examined: containment suites with localized exhaust, downflow booths and isolators.

Containment Suites

Conventional design of manufacturing suites relies on air pressure cascade and air exchange rate to isolate the suite from facility spaces such as hallways. This only affects airborne migration. Therefore, local exhaust ventilation at point of use in the manufacturing suite is employed. Personal protection equipment (PPE) must be used at a minimum to protect the operator from airborne powders. This includes Tyvek suits, gloves and a powered-air purifying respirator (PAPR). Gowning rooms and showers are required for entering and exiting the suite. The cost of gowns and gowning must be considered. (Gown time = 10 minutes x 4 changes/day. De-gown and shower time = 30 minutes x 4 changes/day.)

Other costs and considerations include:

1. Room cleaning costs for a major spill — eight hours plus supplies and lost manufacturing time.
2. Development of cleaning limits and validated protocol.
3. Equipment teardown and cleaning.
4. Facility cleaning time.

Mechanical migration by contaminated operators is handled by using disposable garb that may prevent material transfer to the operators' clothing. Removal of material from contaminated operator contact surfaces, primarily footwear, is required as they exit the decontamination airlock.

Benefits and shortcomings: Containment suites are effective when used for very low potent compounds as shown in the pyramid at left. However, suites may be expensive to operate on an annual basis when considering HEPA filter replacement, testing and disposal. Disposal of gowns and PPE must also be considered. PPE use and decontamination increase operational costs with potential for lost production time. Cross contamination and product migration issues need to be well planned for.

Alternatives: Many companies are using the facility as the secondary source of containment, and using downflow booths or isolators as the primary point-of-use source for containment. Localized containment using isolators or downflow booths provide a cost effective and safer solution at the source. Much less time is devoted to the cleaning of an isolator or downflow booth.

Cross contamination is also reduced or eliminated in isolators and downflow booths. Using isolators and downflow booths may save costs by needing less stringent gowning rooms and shower rooms. Effective containment improves operational capability and flexibility. Localized containment is a much lower cost option and has a shorter delivery time than equipment redesign and testing.

Downflow Booths

A downflow booth is used in the pharmaceutical industry to safeguard operators against harmful dusts generated during many manual powder-handling operations. Clean air from the ceiling plenum is distributed evenly across the entire work area, pushing any breathable dust generated downward and away from the operator's breathing zone.

As the dust moves down to a low level, the high-velocity exhaust grills direct the dust into filters. The onboard filtration system, comprised of a minimum of fine dust filters and HEPA filters, removes the dust before returning clean air into the ceiling plenum. A small amount of air is exhausted after the filters, thereby creating a slight negative environment. Inward air movement into the booth at a low level ensures containment.

Downflow booths consist of walls, a rear bulkhead, exhaust plenums, a filter housing, duct work and supply plenum, and are assembled on site. Materials of construction are of epoxy-coated steel, stainless steel and, at times, a combination of both. Downflow booths are sized based on the operation to be conducted inside the booth, along with the process equipment, scales, product pallets, etc. that are to be used in the booth.

The safe working zone in the booth is less than the actual booth footprint and is exactly located at startup. Typical booth widths range from 1.5 to 5.0 m by 0.5 m increments.

Downflow booths can easily achieve an OEL level of 50 micrograms per cubic meter. However, employing screens (barriers) within the booth can provide additional operator protection to less than 10 micrograms per cubic meter.

Screens can be made from flexible PVC material, with glove ports that can be hung from a rod within a booth or be designed as a four-sided containment zone over a specific area, such as a weigh bench. Rigid screens can me made with or without gloves, and can work in five axis (moving in the booth from side to side, front to back, up and down, rotate and tilt). The screen prevents the operator from having direct contact with more potent compounds.

Benefits and shortcomings: Downflow booths are an excellent source of primary containment, and can accommodate many different processes and pieces of equipment, including scales, drum lifters, pallets, dryers, mills, etc. Booths provide flexibility and operator freedom. Booths are limited by OEL and also may require chill water to reduce the temperature inside the booth. Multiple booths installed in a line may require airlocks or good standard operating procedures to prevent cross contamination.

Isolators

Isolators are used to create a contained environment around the process. The inside of the isolator is at negative pressure to the outside room. Personnel access the inside via glove ports. Products and materials are transferred in and out of the isolator using sophisticated systems (such as split butterfly valves and rapid transfer ports), which safely contain the potent material. Isolators are being used to handle compounds with OEL at less than 1 micrograms per cubic meter.

Materials of construction of isolators can be of flexible material, PVC, or polyurethane film or rigid 316L stainless steel with laminated safety glass viewing windows. Flexible wall isolators are generally used for short-term projects. Flex wall enclosures are generally 20 mils thick and are suspended from a stainless steel support frame. The floor of the isolator can also be made from stainless steel. This is a low-cost solution that can be custom-designed to suit process equipment. Negative pressure can be supplied by a Venturi system using house air. Canister-type filters are used on the inlet and outlet.

Rigid wall isolators use a ventilation/filtration system with safe change push-push HEPA filters. Rigid wall isolators can be cleaned with more aggressive materials than flex wall isolators and can also handle solvents. Spray wands and drainage systems are used for thorough isolator cleaning. Programmable logic control systems are often used for specific internal conditions, including inert environment and humidity control.

Benefits and shortcomings: Rigid wall isolators are able to protect operators when handling potent powders below less than 1 microgram per cubic meter. Care must be used when employing flex wall isolators, as the enclosure is subject to puncture or tears. Flex wall isolators are lower cost, easy to set up, have good visibility and provide good flexibility when working in glove ports. However, they take longer to leak test, have limited resistance to chemicals and require enclosure change.

Rigid wall isolators are highly resistant to chemicals, are more easily leak tested and are more durable. These do require additional lighting, are more expensive and are not as easily moved.

Overall Conclusions

When implementing a containment strategy, before considering the engineering control system or device required, concentrate on the exposure potential to the operator (risk assessment) and the health risk associated with the degree of exposure for that specific compound (hazard involved and OEL).

Facility (containment suite) costs may be attractive, but the risks of not providing the best containment solution may be expensive. Risks include:

1. Operator exposure, which equates to medical costs and possible lost time.
2. The proper use of PPE.
3. Time/production losses due to a major spill.
4. Cross contamination.
5. Product migration.

Primary protection of the operator should be done at the source of exposure by using an isolator or a downflow booth. The facility provides secondary protection. Localized containment using booths or isolators is a much lower cost option and has a shorter delivery time than equipment or facility redesign and testing.

For more information, please visit www.walkerbarrier.com *[1].*

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[1] http://www.walkerbarrier.com/