

WAY 5

Improving Aseptic Compounding while Reducing Costs by Aseptic Enclosures XLTC

Superior to typical cleanrooms and other isolators. This patent pending design provides the most aseptic environment attainable. It is safer, more efficient to use and much less expensive to operate and maintain.

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Company Background

Parenteral production has been our company's focus since its founding in 1992. First in cGMP compliant, FDA registered manufacturing facilities. In that market, since the 1980s, there has been a significant shift in the way facilities are protecting their product and consumers. They have found the traditional clean-room approach often inadequate and resultantly, are upgrading by implementing isolation.

Although the Aseptic Enclosures' product line includes more profitable cleanrooms, our recommendations, first and foremost, are based on technologies that provide the best protection for your pharmacy staff and its patients.

Product Lines

Cleanrooms, Negative pressure rooms, Portable cleanrooms, Isolators, Custom engineering controls, CAIs, CACIs, Hoods & cleanbenches, and related consulting services.

Contamination Control Supplies including: Disinfectants, Sterilants, Decontaminates, Alcohol, Diluents, Sterile Wipes, & Mopping Supplies
 Garbing and Gowning Supplies including: Gowns, Gloves, Booties, Hair Nets, Sticky Mats, Storage, & Waste Containers

Sterility/Microbiological testing supplies and services. Sterile filling style, competency evaluation, media test kits for low, medium and high risk procedural testing. Fingertip testing kits for gowning competency and aseptic technique. Surface contact plates for engineering controls evaluation. Impact air plates for air and HVAC aseptic quality assurance. Consulting services. Our depth of technical knowledge and support capabilities on the above product line is extensive. We can consult on topics ranging from facility's evaluations, through usage training.

Product Overview

■ Improving Patient Care

The events surrounding the recent fungal meningitis infections are tragic. If there is any good to come from its lessons, at least it has brought a heightened awareness of aseptic processing and an urgency to correct deficiencies.

Nearly 100,000 people a year fall victim to Hospital Acquired Infections (HAIs). Roughly 30% of that number is caused by bloodstream infection.

Per day, that number is 274 and 82 respectively. Significantly more people, every day, than in total from NECC's contaminated product.

A "properly" gowned person generates 1,000 CFUs of Viable live organisms every hour. The number one cause of HAIs is touch contamination. The more experienced the compounding technician, the more likely they are to contaminate their work. Our company has witnessed thousands of aseptic cleanroom infractions. This information is at the foundation of our patent pending XLTC series of isolators. Its innovative design helps enforce good procedure and significantly reduces the risks of sample contamination. It is an undeniable aseptic improvement. Again, a "properly" gowned person generates 1,000 CFUs an hour.

■ Cost Containment

Parenteral manufacturers typically will spend upwards of 10 times more to isolate a process than it would cost to put that process in a cleanroom. That is because of the scope and complexities of their processes. Often pharmacists believe their process is too large to contain in an isolator, but as compared to the manufacturing environment that simply is not the case. Ultimately, the hospital process ends upon a, simple to isolate, bench.

Hospital costs for Isolation vs. Clean-rooms are the polar opposite of manufacturers. Isolation equipment is typically 1/10th the cost of cleanrooms. Isolators are faster, easier and much less expensive to install. They are easier and cheaper to clean. They greatly reduce maintenance costs. They yield a much more efficient process. They reduce, and even eliminate gowning costs (avg. \$20.00 per entry). They significantly reduce the risk of CFUs entering the process, thereby reducing "risk associated" costs.

Vital Fact

- A "properly" gowned person generates 1,000 CFUs of viable live organisms every hour!
- The number one cause of HAIs is touch contamination.
- The more experienced the compounding technician, the more likely they are to contaminate their work.
- Poor technique is the #1 source of contamination.
- HAIs are the leading cause of death in US hospitals.

*References upon request.

