

## The Role Of Isolator Technology In Pharmaceutical Manufacturing

*A Q&A with Gary Partington, Sales and Marketing Manager, Walker Barrier Systems*

Gary Partington has over 20 years experience in the pharmaceutical industry, specializing in isolator technology. For the last 11 years, he has been with Walker Barrier Systems (WBS), a developer of containment and isolation systems, where he has served as an applications engineer, technical sales engineer, and, currently, sales and marketing manager. Partington received his B.S. degree in mechanical engineering from New Jersey Institute of Technology in 1981. He is a member of the International Society for Pharmaceutical Engineering (ISPE), the Parenteral Drug Association (PDA), and the American Glovebox Society (AGS).



In this Q&A, Partington discusses the importance of isolation systems in pharmaceutical manufacturing, the impact of government regulations on the use of this technology, and the most important factors to consider when selecting an isolation solution.

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**Please give us some background information about Walker Barrier Systems and the products it supplies to the pharmaceutical market.**

Walker Barrier Systems has over 60 years experience in fabrication of high-quality stainless steel equipment. WBS provides custom isolators for aseptic and containment processes, along with Extract Technology downflow booths for potent powder handling operations in the pharmaceutical industry. We also provide equipment to the fine chemical and nuclear industries. WBS is part of Walker Stainless Equipment, which was founded in 1943 and is located in New Lisbon, WI.

**Why are isolators so important to the safety of the engineers and operators during the pharmaceutical manufacturing process?**

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. 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 that safely contain the potent material. Isolators are being used to handle compounds with occupational exposure limits (OELs) at < 1 micrograms/cubic meter.

**What are the biggest concerns you hear from pharmaceutical manufacturers about isolation and containment? How are you responding to those concerns?**

Ergonomics are always a concern. The operators must be able to effectively clean all surfaces of the isolator interior, perform the process, and reach integrated equipment. WBS uses 3-D modeling in the design phase to eliminate interferences with integrated equipment and offers a mock up of the isolator and any integrated equipment for evaluation by the customer prior to final drawing approval. This allows the operators to simulate the process and make any necessary adjustments to the mock-up. WBS also provides cleaning systems to assist the operator during cleaning.

**How have recent government regulations impacted the evolution and adoption of isolation and containment technologies?**

The FDA has discussed isolator use in the 2004 Aseptic Guidance. While not requiring isolator use in aseptic processes, FDA comments indicate that they see isolators providing improved aseptic conditions. In the appendix it states that isolators "offer tangible advantages over traditional aseptic processing, including fewer opportunities for microbial contamination during processing." It has also been recommended that isolators be used when handling highly potent materials during a filling process.

Customers aware of the FDA's comments are less likely to build a traditional cleanroom when starting a new aseptic process. We have seen more inquiries and projects for fill machine isolators and sterility test isolators as a result.

**What are the three most important things a pharmaceutical manufacturer should consider in selecting an isolation solution?**

There are many things to consider, from price, delivery time, and controls systems to documentation,

location of manufacture, and service. However, I think customers really need to consider what the isolator must do for them, such as:

- ?? What is the process flow into and out of the isolator? What is the process in the isolator?
- ?? If there is to be integrated equipment, is the equipment isolator ready? Does it have a mating flange, and is it leak tight?
- ?? What level of containment or sterility is required inside the isolator?

**What is the biggest obstacle facing isolator manufacturers today? What is your company doing to overcome this obstacle?**

In today's economy, everyone is trying to get the most from their budgets. The market is very competitive. WBS is keeping costs down by continually improving our designs and manufacturing methods. As part of the Walker Group, we are the nation's largest user of stainless steel, which allows us to negotiate better pricing with steel suppliers and keep our costs— and thus our customers' costs— down.

**How do you see the pharmaceutical industry evolving over the next three to five years?**

The use of cleanrooms for aseptic filling and processing will decline, increasing the need for isolators. More and more highly potent drugs will be developed to fight diseases. Containment strategies like isolators and downflow booths will be required to keep operators safe. Some of these products will require specialty environments like low relative humidity or low oxygen levels that are best handled by an isolator.

**What does your organization need to do to prepare for that future?**

We have a very experienced staff of technical sales engineers, designers, and fabricators. We will continue to make improvements to our fabrication methods and designs to meet our customers' expectations.