Clean Rooms Adapt To A Changing Industry

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When you think of the pharmaceutical industry one of the first images that comes to mind is that of the clean room operator. Covered from head-to-toe in a white garment, mask and gloves on, manipulating a piece of sophisticated equipment designed to produce the life-saving drugs we have all come to rely on.

While the role of the pharmaceutical clean room has remained essentially the same over the years; to keep harmful particles and contaminants out of drug products, the way pharmaceutical companies use them and design them has changed. Even the garments themselves have undergone significant changes recently. With operators spending more time in clean room garments, the materials used to make garments have improved to make operators more comfortable and to promote proper donning techniques.

To learn more about some of the recent advancements in clean rooms and clean room garments we spoke to experts in both disciplines to find out what are the latest trends for pharmaceutical clean rooms

Clean Room Construction Trends

As with most other parts of a pharmaceutical facility, clean rooms are moving toward more modular and flexible designs.

Tim Loughran, a clean room consultant, 25-year veteran of the industry and a

principal with Cleanroom Construction Associates points out that in this era of high building costs, companies always have to weigh the pros and cons of building a facility in order to manufacture a product before it gets approved.

“Companies are doing more and more with modular components so they can put off the “go/no-go” decision as long as possible so as to not go forward with unapproved products.” Loughran says.

He has also been seeing more flexible facilities that can be reconfigured for different products, so “companies don’t have to throw out a facility if a product doesn’t get approved.”

Buildings are more wide open Loughran says, and designed for multi-product flexibility. In many cases buildings are left at 75% finished. Companies are not building the last phase of a clean room project until they understand the exact product.

Clean Room Regulations

Contrary to its reputation, Loughran says that dealing with the FDA when constructing clean rooms has become easier as facilities have become less specific. “It’s definitely a less adversarial relationship” he says.

Loughran describes his approach to designing flexible clean room facilities this way, “If I’m building a flexible facility, I want the front end of that facility to be able to handle multiple products or protocols. I design the gowning procedures, and entry hallways to be the most stringent that I need them to be — so that the facility can go toward any product that I might ultimately manufacture. So by default you are exceeding the regulatory requirements in say 9 out of 10 cases — just in case that 10 out of 10 is the product you go forward with, you can meet the requirements of

all of them. By default, the regulatory people are happier because you are going a little beyond what they require."

Clean Room Garment Trends

Heather Torrey, Scientific Segment Marketing Manager, Kimberly-Clark Professional, a company that supplies pharmaceutical companies with every almost every type of clean room garment, sees the industry moving away from large open-air manufacturing processes as they install or upgrade manufacturing lines and are instead moving to isolators and enclosed manufacturing areas. "Operators are still donned in sterile apparel to make sure there is no breach between the operator and manufacturing area, however they have the glass isolator to contain positive air pressure with the isolator gloves, so the operator is putting their gloved hands into another glove in the manufacturing areas."

Torrey also adds that this trend is not only space-effective, but more energy efficient. "People are much more aware of sustainability," says Torrey. "If a pharmaceutical company can create a small environment they reduce waste and energy usage."

Comfort Is King

As the industry moves toward more sterile processing lines, there has been an attendant upswing in the time operators are required to wear clean room garments. As operators are forced to wear garments longer, comfort and ease of use become major factors.

"I would agree with the fact that people are wearing more full—level garments now," says Torrey. "Comfort is important — if you have an operator who is hot and is uncomfortable and is sweating its part of their protocol that they have to leave. They have to leave the clean room area and cool themselves down and re-gown entirely. Being hot and uncomfortable hurts the bottom line for a manufacturer. It takes the average operator who is gowning certified, between 9 and 12 minutes based on ISPE numbers, to gown themselves properly and get ready for an aseptic environment. If someone has to come out 4 times a day instead of 3 — you are losing, in a 20 person facility, hours of productivity every day. Not only does it add up for the manufacturer but it also adds to the frustration for that operator — it's not fun to put that stuff on and take it off. The easier it is and the less often they have to do it the happier everyone is."

"We have designed our A5 Apparel with those concerns in mind, it's not made with Tyvek. With Tyvek there is no way air can get through it. You get hot and sweaty, and sweat will drip down your nose and your gloves. We've created our garments from breathable material that still has excellent filtration - nothing from inside can get through to the clean room environment, but it does allow warm air inside to circulate out. This feature tends to be more comfortable."

Torrey also points out that with the A5 donning is much easier as the garment is folded inside out. The A5 also features a blue garment seam which indicates to the operator where its safe to touch. In addition, the arms and legs are snapped up, which makes it easier to put on as the garment doesn't touch floor. "The garments are kind of accordion packed," says Torrey. "Snaps release as you put your leg through, making it easier on operators."

Regulatory Concerns

Seems like everyone is really concerned where the FDA and European regulatory bodies will go with their next step on "cracking down" on manufacturing," says Torrey. "They want to make sure that their voice is heard and I think people are concerned that what that's going to mean is more regulation and more warning letters." She continues, "All of sudden what was good enough is now being questioned, or what has worked so far is being questioned. People are concerned that their practices, while they may not haven caused any issues in the past, could potentially cause future contamination, so they are really trying to understand what they can do to mitigate future issues."

Torrey says that as far as clean garments are concerned many pharmaceutical companies are starting to see that they can take the same items from the same manufacturer, and know that the packaging and manufacturing specs are global. "It doesn't matter where it's going," says Torrey. "It's the same protocol across the board, and certificates are available to document it."

Since pharma companies operate internationally, they are assured that their clean room garments will have the same quality worldwide.

“It gives them self-assurance, so when the FDA needs documentation they have it.”