The Modern Clean Room

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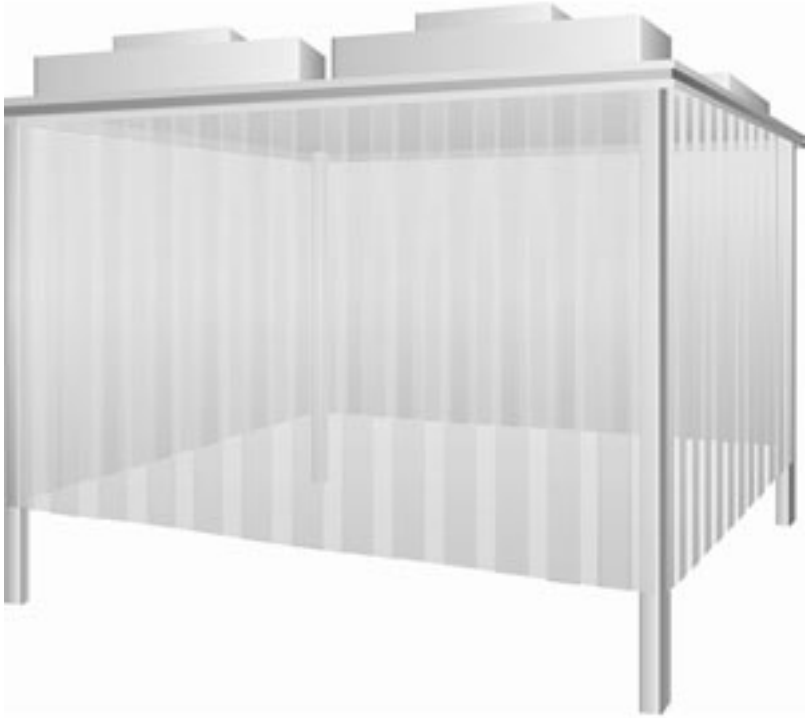

Pharmaceutical clean rooms provide pharmaceutical manufacturers with a clean, safe environment in which to create uncontaminated products. All clean rooms are not identical, however; they vary depending on the size or scale of an operation, the types of materials that are being handled, the operation’s budget and various other factors.

Design is not the only element that is important when it comes to clean rooms; monitoring equipment, filtering equipment, apparel, and proper training for clean room workers are all important aspects. To gain insight into current pharmaceutical clean room trends, Pharmaceutical Processing spoke with providers of various clean room products and services.

The Ideal Clean Room Design

What are pharma companies looking for in terms of clean room design? According to the experts, they are seeking efficiency, energy savings, sustainability, and functionality. Clean room designs that provide solutions to contamination potentials and maximize usable space are also in demand.

Tim Marrs, a sales engineer at the clean room design and build company Clean Rooms West, explains that companies are looking for “a style of construction that provides better solutions to ongoing contamination potentials.” He notes that “Coved surfaces, smooth component transitions, and seamless or heat-weld seams are all architectural features that are trending in pharmaceutical clean room

construction."

Experts agree that many companies are becoming more selective about functionality. According to Bryan Phelan, managing partner at AdvanceTEC, a design and build general contractor company, "most clients are adopting a modular building project execution plan versus using metal stud and drywall." He explains that "modular execution allows you to adapt to that shorter project execution model."

Phelan notes an increase in demand for a "walkable ceiling": a flat ceiling that is not only safer during the construction process, but also simplifies maintenance after construction is completed. Efficiency has become essential for construction time-frames, as well as for the overall design of the clean room.

Becky Wiseman, president of Hutchins & Hutchins, a company that has been serving the clean room industry since 1984, agrees that flexible, modular designs are a current trend. "Flexible facilities that can be reconfigured for different products are becoming the trend due to product lines being disapproved or dropped — a wide-open layout with modular areas is better designed for multi-product flexibility."

Companies are looking for more modular and flexible designs, but they also want high-quality construction. "While all companies are looking for more efficient ways in which to operate their clean rooms, we do not think that anyone will compromise the quality of the materials used, because the end result would be defects in the finished product," Wiseman says.

The Economy &Clean Rooms

Some companies have noticed that fewer large projects are being constructed, a trend that is likely a result of current economic conditions. "One of the things we've noticed since the end of 2009 is a large pull-back in capital spending within the pharmaceutical community in the United States," says Phelan.

"There are certainly [new clean rooms] that are in the planning stages," Phelan continues, "but over the past two years, most of the projects that have gone forward that have remained funded have been either smaller projects or renovations within existing spaces or within existing buildings."

Phelan explains that while clients are waiting longer to make decisions, they still want to have the project completed by their original date. Because of this, Phelan says that it's important for clean room suppliers to "have the skills and resources on hand, ready-to-go; and be ready to go the extra mile to make the projects occur as rapidly as clients would like to see happen."

Wiseman explains that despite the economy, "The number of clean rooms in the United States continues to rise annually." The company has seen an increase in clean room sales, especially in European countries. The demand for clean rooms is still present and may even be growing, but clean room suppliers have had to adapt

to new industry trends; offering new clean room designs, remodels, energy-efficiency and quick construction. “There are a number of companies looking to update clean room facilities by remodeling or renovating,” Marrs explains.

“A few years ago, the use of self-powered HEPA filters in a pharmaceutical application was not an acceptable design practice,” Marrs says. “Today, more companies are installing negative pressure plenums and clean air delivery through self-powered HEPA filters as a more economical way to achieve validated clean room conditions.”

Phelan says that along with the extended decision cycle, the economy has also caused companies “to be more open to ways to save money.” He explains: “every project doesn’t have to be the absolute best of every finish. It doesn’t have to have the best of every architectural feature. It doesn’t have to be the absolute most attractive facility that’s ever been built.” Companies are now looking for functionality and execution and focusing less on form.

Changes in Technology

Jayesh Doshi, CEO of Exceed Filters, says that “Toxic industrial compounds (TICs) are becoming a major issue in industrial environments.” For that reason, Exceed Filters is “developing a new class of media with nanoparticle adsorbent technology and nano-structured fibers of unique composition to filter out these harmful molecules.”

“Future filter media will have integrated nanostructures that have large capacities to adsorb TICs,” for example, says Doshi. “By selecting a specific type of structure, one can selectively filter toxic compounds and obtain very high air quality.”

The “FDA constantly revises its guidance on clean rooms, which drives the filtration technology,” says Doshi. “With new advancements in clean air requirements, the filter industry constantly tries to meet the needs of their customers.”

Clean Room Monitoring

"Protein-based products demand different limits and methods," says Joe Gecsey, life science applications manager at Hach Co., a company that produces clean room monitoring equipment. He explains that different methods must be used when working with "expensive materials in small quantities." He also explains that these materials "handle differently than small-molecule products of the past."

Gecsey says that companies are looking for monitoring equipment that offers "multiple methods of retrieving data," such as equipment with EtherNet, wired, wireless, serial, USB memory stick, and printer options. They are also looking for "automatic testing and verification of instrument functionality, 21 CFR Part 11 compliance for data integrity, and compliance to International Standards such as ISO 14644, ISO 21501, and EU GMP Annex 1."

In the future, Gecsey predicts a "focus on automation, smaller particles, and smaller sample areas such as isolators and RABS." He also sees "interconnection with production equipment in the future," where equipment is halted if the environment is not correct.

Reusable Apparel

Clean room apparel providers are also noticing changes. Jerry Martin, vice president of sales and marketing for Prudential Cleanroom Services, says that many companies are implementing green initiatives. Prudential Cleanroom Services offers reusable apparel that includes everything from coveralls to goggles, helping companies achieve their environmentally friendly goals.

Reusable apparel helps increase sustainability and is also cost-efficient. "It is an advantage for manufacturers in critical environments to evaluate the benefits of reusable products," Martin explained. This trend towards reusables does not compromise quality — the company has an extensive garment process cycle and all apparel is thoroughly tested according to strict quality assurance standards.

Apparel is also impacted by potent and toxic compounds. Martin explains that they generally evaluate the situation on a site-by-site basis, evaluating site requirements

and inspecting garments. Evaluation on a case-by-case basis provides clients with personalized service.

The Future

We asked the experts what they see as the future of clean room technology. The current state of the economy has led to some uncertainties, but overall, clean room providers are seeing opportunities for growth and new developments.

“Energy conservation is critical in today’s clean rooms,” says Marrs. “Clean room designers can no longer use systems that waste energy.” He explains that it will take innovation to create clean rooms that conserve energy without compromising cleanliness — future designs could include monitoring systems that speed up or slow down fans when particulate levels change, using only the energy it needs to maintain particle levels.

Doshi sees other changes in the future: “The need for clean air is increasing. Advancement and improved manufacturing processes producing nanomaterial will create a new market segment for filter industry.” Doshi continues, “Awareness among people continues to increase on the adverse effects of nano-scale air borne particles. As this awareness increases, so will the desire to remove these particles from the air to protect people and improve products.”

Overall, growth and new developments seem to be on the horizon. “In our almost 30 years in the industry, we have experienced an ever-growing need for clean rooms in so many different industries,” Wiseman says. “The future of clean rooms in the next 5 to 10 years will continue to expand, even in areas we would never even imagine.”

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