Thinking Long-Term for Life Science Cleanrooms

How to Balance Today's Demands With Tomorrow's Scale

aes Clean Technology

FOR MOST LIFE SCIENTISTS, the chance to build a cleanroom only comes around a handful of times in their career. It's an exciting period, since it means that manufacturing facility ownership is just around the corner—but there's a lot at stake, too.

After all, not only do researchers wrestle decisions around design and cost for the short-term, but they're also confronting long-term questions of compliance, evolving technologies, and how the cleanroom will progress as therapies scale up and out.

The need to balance short- and long-term factors is pushing life sciences toward a holistic approach to cleanroom planning. That is, for example, not just building spaces that support the first human trials, but making sure those spaces still function in a year, three years, or even a decade down the line when patient supply increases.

These shifting trends in advanced cleanroom planning bring about new opportunities in modular and flexible design, as well as a few challenges. Fortunately, a comprehensive planning program can help researchers navigate the nuances to envision and then develop a facility that supports their growing product development pipeline.

And perhaps more importantly, engaging a consultant to guide through those steps helps the process move along more smoothly. With that kind of support, life scientists can concentrate on what they do best, advancing the science, without having to commit time they don't have to the more intricate details and responsibilities of cleanroom planning.

So if you're on the cusp of a new cleanroom project, here are some factors worth considering—and why investing in a pre-design program is essential.

What is **Cleanroom Pre-Design?**

The drug commercialization lifecycle is complex and multifaceted. As products move through that lifecycle, operational decisions regarding scale-up and scale-out become much more involved, particularly just before Phase 3 clinical trials. Among those decisions is facility design, including how to drive value and performance from the cleanroom without compromising constructability.

These facility-related decisions, made in the early phases of drug development, directly impact commercialization success—from achieving regulatory validation to securing capital funding. That's why many researchers undergo cleanroom pre-design planning through a conceptual design service such as Compass™ from AES Clean Technology.

Taking place a year or more before market launch, cleanroom pre-design aligns facility and process stakeholders to envision the concept, requirements, costs, timing, and long-term growth of the cleanroom. The comprehensive effort acts as a proactive precursor period to map out a strategic plan for the cleanroom. This takes place before the cost commitment is confirmed during the next phase of detailed design.

With AES Compass™, that strategic plan comes in the form of a comprehensive data package in the form of a report that includes a complete analysis of the facility—including architectural systems, manufacturing and transition philosophies, compliance confirmation, drawing sets, timing, projected costs, and more.

The Benefits of Having **a Pre-Design Plan**

The advantages of a front-end conceptual design are two-fold: For one, operational stakeholders will have the quantitative data needed to quickly and cost-effectively move into design, engineering, and construction. They'll also be better positioned to prepare for strategic reviews and other asks from regulatory agencies and prospective investors.

Clients who complete the AES Compass™ program, for example, have the benefit of a substantive key capital project deliverable to use in conversations with sponsors, the FDA, and internal stakeholders. Having that asset can bolster investor confidence in the project, proving you've been thoughtful and strategic about GMP and overall facility planning. It can also support the pathway to approval, as agencies and auditors typically expect to assess the design concept during initial review.

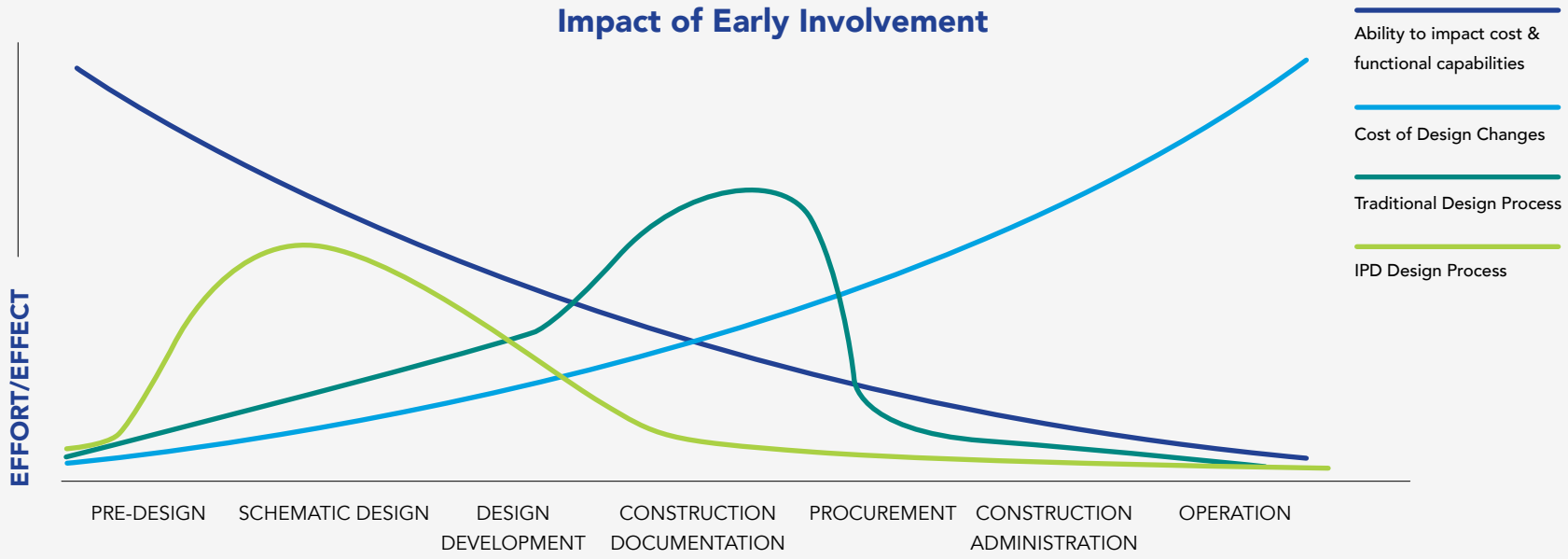
Since the start of the Compass™ program, the service has achieved an average client satisfaction score of 9.8 on a 10-point scale.

aes Clean Technology

Additionally, it's within this pre-design process when drug developers can identify potential pitfalls that could delay or derail manufacturing in the short or long term, and help resolve them before construction begins. Such challenges might include immediate compliance hurdles or obstacles involving the physical limitations of scale-up.

Skipping this step can be risky. Manufacturers who overlook pre-design can incur costly and time-intensive barriers to scale-up when problems inevitably happen, such as having to revise unsanctioned design attributes or being unable to flexibly grow the facility as manufacturing evolves.

In general, the earlier problems are found, the better. Pre-design planning helps uncover and address surprises at the outset so that schematic design, design development, construction documentation, procurement, and subsequent phases require less effort with lower cost.



Factors to Consider in **Long-Term Planning**

As you navigate the pre-design process, several factors are worth exploring to help ensure the cleanroom scales up and out appropriately. These include concerns related to future expansions, traffic and flow, and long-term compliance.

- Iterations in **Expansion**
- The Flow of **People, Products, and Processes**
- **Compliance,** Now and in the Future
- Planning for the **Knowns and Unknowns Ahead**

aes Clean Technology

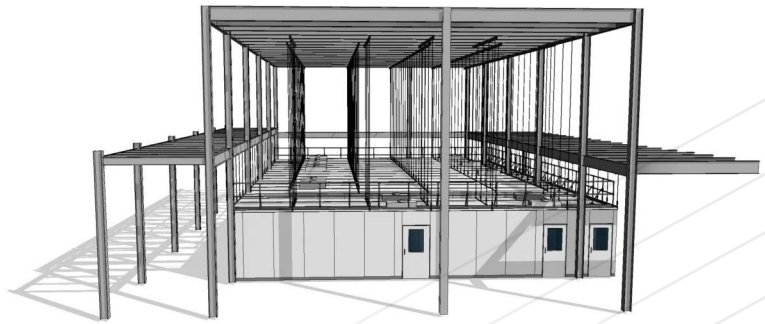
Iterations in **Expansion**

Even if you anticipate what your product volumes might look like for the immediate future, those estimations can always change down the line.

That is, advancements in automation technology, regulatory approvals, and changing market conditions can all affect scale long-term. But if you're locked into a legacy facility that you've since outgrown, it can limit workflows—costing time and funding, and potentially the outsized capital cost of needing to build a new cleanroom from scratch.

These circumstances point to the need for future cleanroom expansion planning. Programs should have the flexibility to add on, change out equipment, update processes, accommodate more staff, or feasibly fit in other changes as workflows evolve. With pre-design planning that considers the long-term needs of the space, they can.

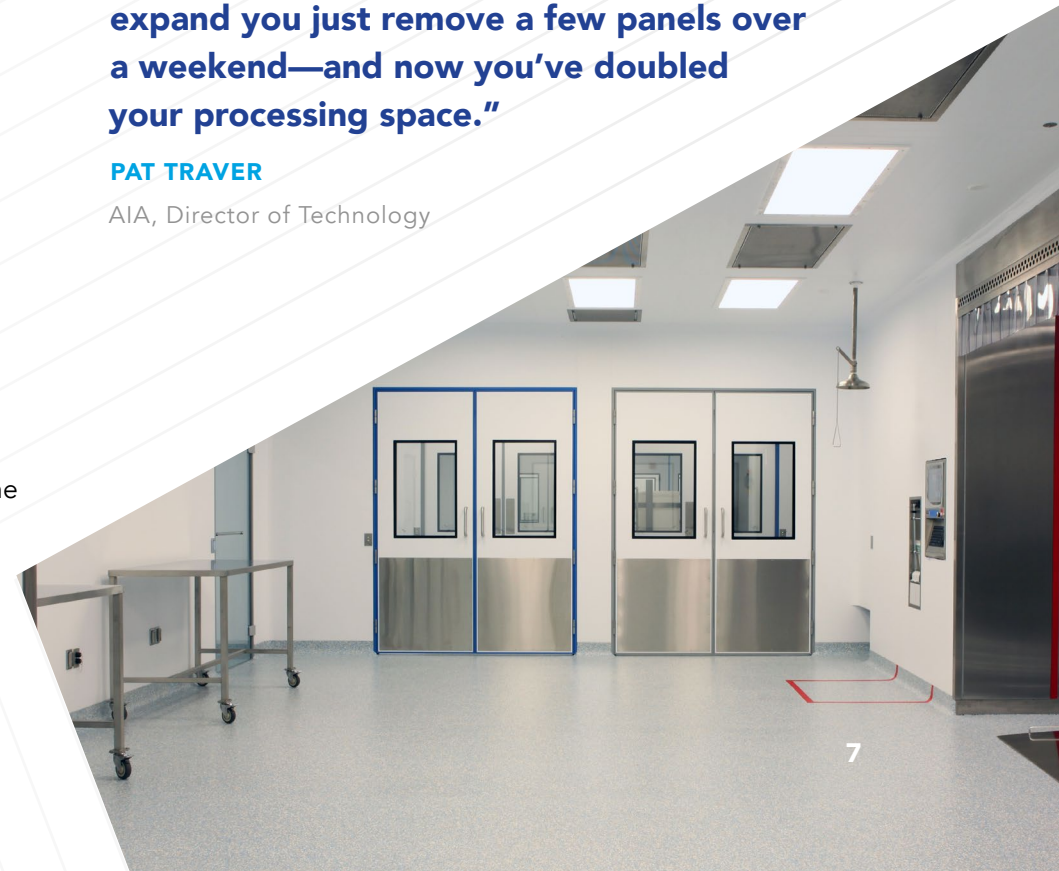
For example, such planning accounts for adjacent areas like warehouse space that could someday be made into additional cleanroom square footage, if ever needed. Those kinds of flexibilities over the short- and long-term have driven interest in modular cleanrooms instead of "stick-built" structures that often can't keep pace with scale or particle generating facility alterations. In addition, these modular options have the benefit of helping spaces comply with cleanliness requirements so that they can remain operational during the next phase of construction.



"With this type of advanced expansion planning, we can build out an adjacent facility expansion while you remain operational. To expand you just remove a few panels over a weekend—and now you've doubled your processing space."

PAT TRAVER

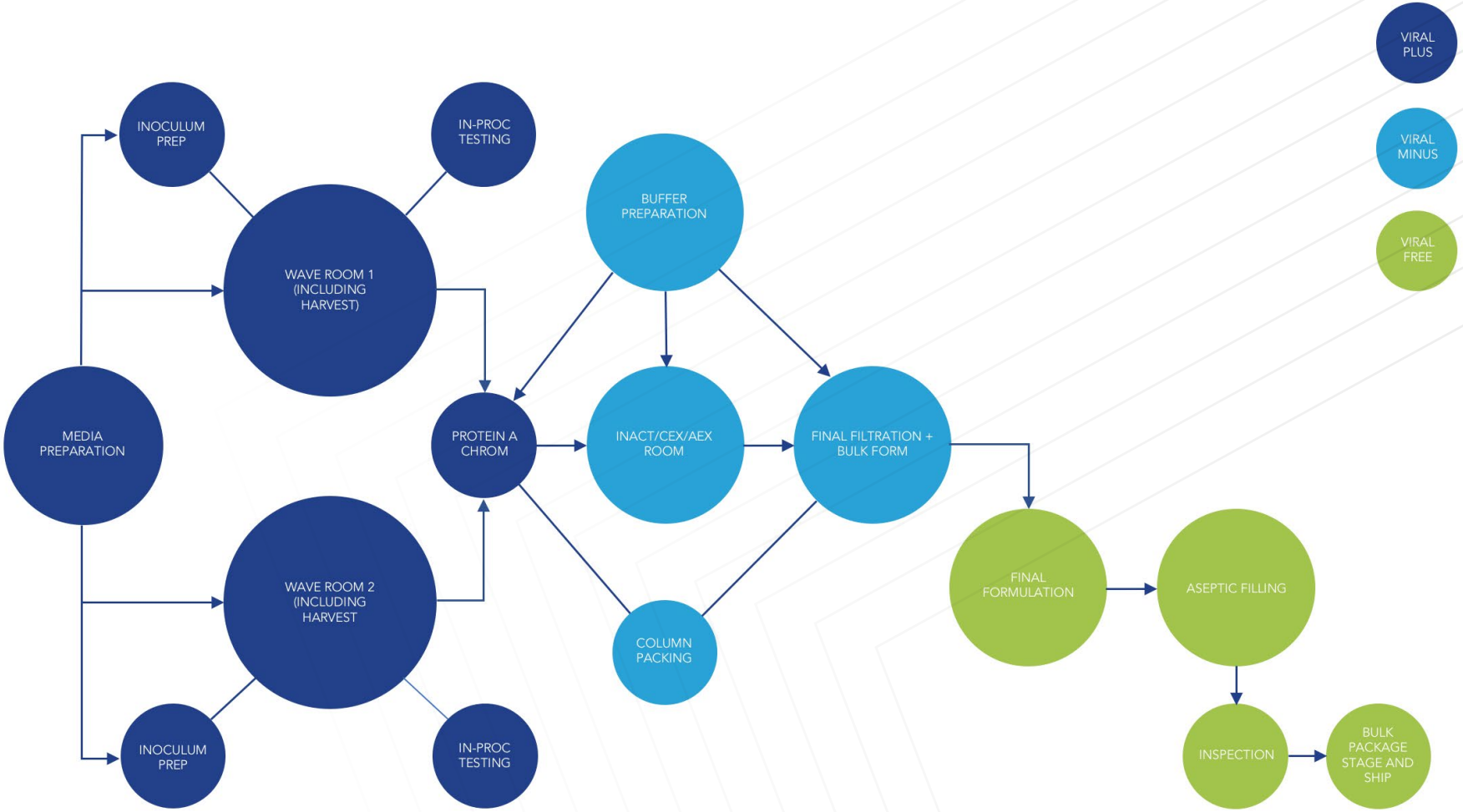
AIA, Director of Technology



aes Clean Technology

The Flow of **People, Products, and Processes**

OVERALL PRIMARY PROCESS FUNCTIONAL ADJACENCY DIAGRAM



The compliant flow of people, products, and processes moving through a facility creates a complex operational dynamic that can affect manufacturing, and that dynamic becomes even more complex as the product scales up. But as thorough as they may be, schematics don't fully convey how the cleanroom will manage these complexities in flow within an operational environment.

That's what makes having a comprehensive pre-design partner so beneficial. They can bring experience in strategic and cost value to life across various operational scenarios so that researchers can assess their downstream impacts.

Additionally, planning will tackle essential questions at the outset: How do you get people and materials in and out of cleanrooms as efficiently and compliantly as possible? How will those workflows change once production goes up and the cleanroom is presumably a busier place? Pre-design planning also helps with situations that commonly get missed until further into the engineering stages, such as accounting for room sanitization functions, utility usage, material storage, and gowning. It's important to preempt these missteps, as improperly timed changes during detail design can kill any hopes of self-ownership due to cost implications.

Even thoroughfares can be oddly deceiving on standard layouts, often appearing bigger on paper than they are in real life. This can create the temptation to make corridors and hallways smaller to pack in more processing room. A pre-design partner can help manufacturers understand how these seemingly minor changes can impact operations—such as bumping elbows, scraping walls, dinging doors, forklift traffic jams, or other challenges of a finite space.

Most importantly, remember this: Every second is precious. A pre-design partner can help you make the most of every one of them by orienting unit operations, equipment, and adjacent spaces. When the flow is efficient and future-proofed, it can fully support scale—no matter how that scale evolves moving forward.

"If I need to get from point A to B, how much time does it take to do that? 30 seconds? Multiply that by several times a day, or a month, or a year. How much time is that wasting? How can we reduce that time? This is why efficiency in design is so important. When we do our job well, it helps reduce the cost of that product and saves a lot of money."

PAT TRAVER

AIA, Director of Technology

Compliance, Now and in the Future

A cleanroom that complies with building codes, GMP guidelines, and other regulatory and jurisdictional requirements now may not always remain compliant as production volumes surge—and unfortunately, many things can get missed without comprehensive pre-design planning to account for evolving compliance goalposts.

As one example, consider elements such as transition spaces, airlocks, pressure cascades, and containment. These factors are integral to the cleanroom design and will need to compliantly support long-term output goals. However, they often get overlooked when seemingly more important things—like where to put the bioreactor—take priority. Pre-design planning helps ensure facilities meet all applicable standards, codes, specs, and regulatory/industrial requirements, down to every tiny detail, to mitigate these risks.

And yet, domestic compliance may not be the only factor to consider. International requirements may matter too, even if your program won't distribute outside the United States right away. Pre-design planning can help prepare for future international compliance requirements if global distribution is a possibility down the line. From the EMA to the ANVISA and beyond, a pre-design partner will have the experience to guide manufacturers through the many facility-related components on the pathway to market launch.

Planning for the **Knowns and Unknowns Ahead**

Comprehensive cleanroom planning that accounts for the short- and long-term is critical to the viability of manufacturing because it supports evolving scale at all junctures of the product's lifecycle.

For all its importance and influence on commercial success, cleanroom planning can sometimes come as an afterthought—something that manufacturers consider just weeks or even days before construction starts. This is risky: Deprioritizing this essential step undercuts important opportunities to identify potential barriers that can lead to more costly and time-intensive changes later on.

Drug developers can reduce these interruptions by working with an experienced pre-design partner who helps reconcile the knowns of the present with the unknowns of the future. When done well, long-term cleanroom planning can future-proof facilities for whatever happens—be that a surging demand or setbacks from unforeseen market conditions.

Take COVID-19, for example. Clients of AES Clean Technology experienced little to no impact in 2020 in terms of their cleanroom suitability for pandemic demand because they were built with the future in mind. They could and continue to withstand whatever comes next. Can you?

After all, the chance to develop a cleanroom only happens a few times. If you have the opportunity in front of you, make the most of it. Work with a pre-design partner to build your facility to meet the needs of today, and tomorrow too.

Set your project up for sustainable success with a dedicated pre-design partner.

LEARN MORE

AES GUARANTEES CLEANROOM PERFORMANCE

TEMPERATURE | HUMIDITY | PRESSURIZATION | CLEANLINESS | CONTAINMENT

aes Clean Technology

AES Clean Technology is the best in class modular cleanroom provider. AES backs that claim with guaranteed compliance of the cleanrooms they design build. AES minimizes the risk of project schedule, cost, and compliance by controlling every aspect of the project. AES is the only USA based cleanroom company that self-performs all facets of the design build process including: engineering, manufacturing, and the installation of cGMP modular cleanroom facilities. Working with AES, you can rest assured that your project is built on time and on budget, guaranteed. With over 30 years experience, AES expertise in cleanroom solutions is second to none.

LEARN MORE