


AES Clean Technology Value Proposition 2001

- **PRODUCT** cleanroom
 - **INDUSTRY** cell and gene
 - **VALUE PROPOSITION** Faciliflex combines the best of modular and podular construction
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Many Advantages for Pre-designed Modular Cleanrooms

- AES Clean Technology's Faciliflex Integrated Cleanroom Delivery System is a guaranteed Cleanroom System that gives pharmaceutical organizations flexibility & customization for upcoming cleanroom design build projects.

This analysis covers

- Advantages for a single project
- Ease of expansion
- Advantages in duplication
- Comparison to alternatives from stick built to pre- built modules

Faciliflex is Ideal for Cell and Gene Therapy Companies

- Faciliflex Express is a pre-designed cleanroom solution that delivers a commissioned cleanroom in as little as 6 months. Pre-designed standard cleanroom layouts are the next generation for snap together installation of modular panel systems. Faciliflex Express has 3 models 5k, 15k, and 30k representing cleanrooms of approximately 5,000, 15,000, and 30,000 square foot. Each model is a fully integrated solution and includes design, material, HVAC, and installation.
- Faciliflex Express is ideal for cell & gene therapy companies that need to rapidly bring their therapies to the patients. The traditional process of specifying a cleanroom has thousands of decision points. These decisions are both choices about the macro environment, down to the minutia. The process is time consuming, and introduces risk at each interface.
- The decision process results in cost variation, and creates unknown outcomes. Faciliflex Express eliminates the guesswork with a proven off the shelf solution that provides:
 - Faster speed to patient
 - Reduced cost
 - Fixed cost
 - Proven design
 - Phased flexibility

The following video shows how modules can be placed in various configurations with maximum flexibility

- <https://www.youtube.com/watch?v=tnNsCCif0A>

AES Faciliflex for Record Breaking Delivery Time

Although it started as a mechanical systems designer, AES pioneered modular cleanroom design nearly three decades ago as the company began integrating wall and ceiling systems into its manufacturing portfolio. As their modular offerings became more advanced, the Faciliflex line became a way of meeting the needs of an expanding range of clients - from supplying modular components to soup-to-nuts mechanical and architectural design, manufacturing, and installation services.

According to AES, the Faciliflex project approach helps clients by removing cleanroom design and installation as a risk to overall project timelines. It was a philosophy quickly put to the test in 2020 with three separate Operation Warp Speed clients, eight COVID-19 design build projects, and over a dozen additional COVID-19 installations with wall and ceiling systems. Four of their fast-tracked cleanroom builds, ranging from 2,000 to 13,000 square feet, were completed in record-breaking times.

"Typically, the industry commonly uses a design-bid-build approach to a cleanroom construction project," said Trista Hager, a project development engineer at AES. "Since time was a limiting factor, however, we worked with our clients to approach the project on a design-build basis, leveraging target value design and integrated project delivery."

Pharmaceutical Prospects published by Mcilvaine Company

5000 ft² and 30,000 ft² examples

- Clinical research & small manufacturing
 - Bidirectional personnel & material flow
 - Approximately 5,000 sf all encompassed manufacturing
 - 3 process suites ~ 250 sf each
 - Outdoor DX unit, same unit for all suites, constant pressure & motorized dampers
 - Aligns with accelerated development programs (i.e. Break-through, Orphan Drug)
 - Complements application of single use technologies!
 - Flexible, adaptable, and expandable designs and spaces for all your equipment needs
- Multi-product development. Each suite has a different product, larger scale for each product
 - 3 process suites (2,000 sf ea.) Cell Therapy Focus. 100% OA unit indoor chilled water & active pressure
 - Approximately 30,000 sf all encompassed manufacturing
 - Unidirectional personal & material flow
 - Aligns with accelerated development programs (i.e. Break-through, Orphan Drug)
 - Compliments application of single use technologies!
 - Flexible, adaptable, and expandable designs and spaces for all your equipment needs

Lots of cell and gene applications

- Imagine if designing a cleanroom facility was as simple snapping together all the building blocks you need to create your perfect design—that is the driving concept behind Faciliflex Express. Endlessly customizable, yet guaranteed to work together in creating a custom cleanroom that meets your needs.

- <https://www.cellandgene.com/doc/faciliflex-cleanroom-module-for-drug-manufacturing-0001>

APPLICATIONS

- Antibody drug conjugates / Potent Compounds
- Viral Vectors
- Gene therapy
- Peptides
- Autologous

- Oligonucleotides
- Allogeneic
- Manufacturing filler and related substances
- Monoclonal Antibodies
- Cell Banking
- Inspection / Packaging Operations

Faciliflex Combines the Best of Modular and Podular

- Faciliflex combines the advantages of podular and modular construction
- The cost effectiveness of modular/pre-fab cleanrooms largely varies based on the magnitude of space, prequalification activities and documentation and type of facility. Modular/pre-fab cleanrooms typically provide modular components with more standardized packages, which cost more than stick built but reduce field installation labor cost and hidden costs, like temporary parking etc. Modular/pre-fab cleanrooms also tend to house more single-use-based bioprocessing. Modular/pre-fab construction is accomplished by the engineers in a factory environment. Such controlled conditions on the manufacturing floor generally deliver higher quality and more reproducible results which often far exceed those obtained by traditional stick-built cleanroom that are finished at the construction site. Since the units are build off-site, delivery times are kept as manufacturing activities can be ramped up by shift work.
- These factory-based construction methods deliver precise and fully compliant systems while also offering customization and adaptability. The advantages of modular system are increasing the demand for and shifting the trend towards modular systems, with this shift or trend already evident in most major markets.

Pharmaceutical Projects- Mcilvaine Company