

Modular Cleanrooms

Design | Manufacture | Install



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Performance and Speed

A Single Resource for Total Cleanroom Confidence

AES offers a single resource for virtually every cleanroom application. Our staff of cleanroom professionals create solutions that fit the way you function – designing more performance, speed, cleanliness and compliance into every dollar of your cleanroom investment. Our in-house expertise spans every aspect of cleanroom planning, design, construction and commissioning support - accurately and efficiently navigating complex regulatory and technical issues. Our innovative pre-engineered modular pharma system is at the core of every AES solution. Manufactured exclusively in the USA by AES, the AES Pharma System assures the highest levels of performance.

Concurrent engineering and procurement tasks, combined with the compressed field activities of modular construction, effectively reduce the overall project schedule and assure compliance at every phase of the project life cycle.

PARALLEL ACTIVITIES SEQUENCING = ACCELERATED PROJECT DELIVERY

Engineering

Pre-Purchase Materials & Equipment/Fabrication

Construction On Site

Commissioning



AES Corporate Overview

AES Clean Technology, Inc. **designs, manufactures, and builds** modular cleanrooms and custom cleanroom equipment for a variety of manufacturing facilities to include pharmaceutical, biotechnology, life science and technology industries, and in compliance with regulatory standards such as ISO, FDA, cGMP, and EU guidelines.

Our mission is to provide quality cleanroom facilities and custom cleanroom components and systems designed to exceed industry standards and to achieve complete customer satisfaction and lasting success.

Our promise to our customer is that you will always come first.
Your project requirements, schedule and budget drive our team.
We want to meet and exceed your expectations for our performance.

Our goal is to build a relationship with our customer through successful projects – not just “make a sale.” That is why the quality and safety of your cleanroom project are always our uppermost priorities.



Design/Build Capabilities

AES provides full-scope design/build cleanrooms for manufacturing facilities serving Pharmaceutical, Biotechnology, Medical Devices, Life Sciences and High Technology Industries. AES offers turnkey solutions and accepts single source responsibility for the overall cost, schedule, and performance of the cleanroom facility. The AES team takes responsibility for all facets of a project from early design concept and budgeting to final certification and project turnover.

Engineering and cleanroom design

Starting with initial consultation, AES' team of professional engineers and cleanroom specialists evaluate user requirements, site conditions, and any factors that may impact the design approach to develop an initial "Basis of Bid" document. AES can evaluate existing spaces, code compliance, regulatory criteria to be addressed, and the impact, if any, to on-going manufacturing operations. Specified requirements for temperature, humidity, pressurization and cleanliness levels will also be determined.

Manufacturing

The AES Modular Pharma Walkable Ceiling and Wall System including flush doors and windows is manufactured in our 80,000 square foot manufacturing facility in Suwanee, Georgia. AES implements and maintains a comprehensive program for the full scope of manufacture from receiving of raw material through crating and shipping of finished product. AES panels are manufactured "clean" and stay clean at the installation site. The face of each AES wall or ceiling panel is protected by a polyethylene film prior to crating. This poly film protection remains on the wall or ceiling panel until the panel is ready for PVC cold welding which creates the fully monolithic finish.

Project and construction management

A professional construction team is assigned to each project. The team is properly managed to coordinate activities and meet submitted project schedules, budget and design requirements. AES Project and Construction Managers employ high performance project management principles and software to ensure well executed cleanroom facilities, built to specification - on schedule and on budget. AES provides its own highly skilled labor technicians who have been trained for proper installation of the AES Modular Pharma System.

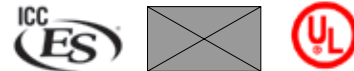
Documentation

Each project concludes with a detailed Turnover Package, complete with As-Built drawings, executed commissioning protocols, test reports, operating instructions and data sheets.

The AES Advantage

- High level of experience with pharmaceutical, biotechnology, medical devices, life sciences and high technology projects
- Single source for engineering, fabrication, and construction
- 80,000 sf manufacturing facility
- Professional design and construction
- Clean build protocol
- Quality Control procedures and standards
- Award-winning safety program

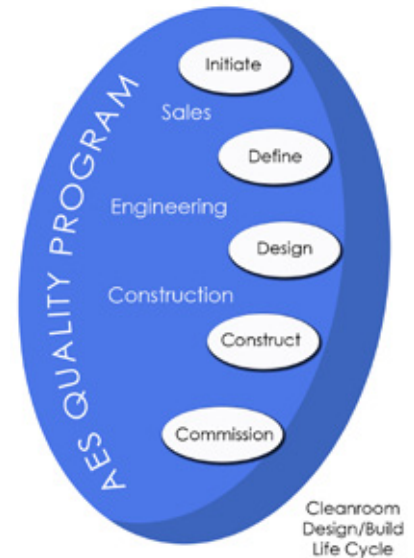
AES modular system advantages



- Superior aseptic finishes
- Predictable performance
- Clean construction
- Reduced project safety risk
- Accelerated project delivery
- Tax advantages
- Near zero maintenance
- Flexibility for late arriving process equipment and future adaptations
- Predictable transition to commissioning and qualification
- Walkable ceilings – can eliminate some catwalks or mezzanines
- FM Global Approved
- ICC Approved
- Class 1 Building / Grade A Product for Flame Spread + Smoke Develop Standards
- Standard UL listed raceways
- Made in the USA

Single-Source Responsibility

Design → Manufacture → Build → Commission



The **AES Modular Pharma Wall and Walkable Ceiling System** is executed as a complete installed system. Installation is performed by highly skilled technicians, specifically trained for proper installation of the **AES Pharma System**.

AES Safety

Safety is the highest priority for AES. It is incorporated into all tasks performed in our Corporate Office, Our Factory and on the project site.

The AES corporate and jobsite safety policy corresponds to the Occupational Safety and Health Administration's (OSHA) Occupational Safety and Health Act of 1980, Section 5 (a) (1) and OSHA regulations as found in 29 CFR 1910 and 1026 covering General Industry and the Construction Industry.

Safety organization and accountability

AES corporate and jobsite safety programs are governed by the Director of Quality and Continuous Improvement.

AES initiates self-assessments to establish quarterly goals for improved safety. Yearly audits by a third-party safety and risk assessor serve to verify compliance with the safety policies at AES' corporate and manufacturing facilities, as well as on the jobsite.

Safety performance

AES maintains an EMR (Experience Modification Rating) less than 1.

Jobsite safety program

OSHA trained and certified AES Site Management Personnel execute jobsite safety programs, to include daily meetings to review tasks and safety requirements, weekly safety talks and all safety documentation.

All AES personnel and subcontractors are required to comply with the AES Corporate Safety Policy as well as all project and/or site specific Health and Safety Plans.

Fewer personnel on-site lowers safety risk. Installation of the AES Pharma System is executed by a team of skilled technicians.

AES Quality

Commitment to quality

The AES quality system is based on the principle of designing, building, and manufacturing for lasting success.

A quality program for cleanroom execution governs all aspects of our company and is overseen by the Director of Quality and Continuous Process Improvement.

Construction Quality Plan (CQP)

A Construction Quality Plan is developed specifically for each AES project to define quality performance objectives and to monitor compliance with meeting stated objectives.

Generated by AES during the engineering phase and executed in the field from day one of construction, the CQP describes how quality activities are documented and defines the commissioning activities for all systems within the AES scope of work.

AES Clean Build Protocol for modular cleanroom construction maintains optimal cleanroom conditions throughout the construction phase.

The CQP is provided at the conclusion of the project to support the Client's validation efforts.



3 Steps to Cleanroom Project Success:



Early planning with AES sets the stage for a successful project. Cleanroom facilities must be compliant not only to regulatory requirements, but also to strict environmental criteria that protect the products manufactured within the facility. AES Compass is a process of developing the initial concept for a cleanroom's design by combining our facility expertise with our clients' processing expertise. This initial engagement delivers tremendous value through a robust conceptual design package that fully defines the project's expectations. The net result is a package of deliverables that are both technical and commercial in nature – focusing not only on the compliant design of the facility, but also on its cost, schedule, and execution strategy.

By leveraging our experience from millions of square feet of successfully completed facilities, AES seamlessly develops a cleanroom system that wraps around a client's process. We utilize a standardized approach that leverages optimized strategies for material and personnel movement, integration of the latest in process technology, and confirming the host building infrastructure that is required to support the cleanroom facility.

The cost of this compliance planning effort is less than one percent of the total project cost, and the output is exceptional. The AES Compass program provides a business case executive summary, manufacturing and transition philosophies, basis of design information, a (FDA Type C) drawing package, a detailed project estimate, and a Level 1 schedule.

3 Steps to Cleanroom Project Success:



2

AES Clean Technology has a complete architectural and engineering team necessary to develop cleanroom projects for the following disciplines:

- Architecture
- Mechanical Engineering
- Electrical Engineering
- Structural Engineering

AESiST is a continuation of the AES Compass program, developing the design comprehensively from BIM coordination through manufacturing and construction.

AESiST is the perfect cleanroom design support for project architects and engineers.



3 Steps to Cleanroom Project Success:



INTEGRATED CLEANROOM DELIVERY

3a

AES' Faciliflex program provides guaranteed performance of the cleanroom facility – not only the beautifully compliant fit & finish of our modular cleanroom construction, but also the strict environmental performance guarantee – all combined into a fully functional asset. Faciliflex is our exclusive integrated cleanroom delivery method. This program focuses on providing guaranteed performance and high-quality finishes, all delivered at a fixed cost and schedule, thereby reducing risk for our pharmaceutical and biotech clients. Faciliflex can create a cleanroom facility inside a new building, or it can retrofit box-within-a-box construction inside an existing building. Our modular process deploys a repeatable cleanroom solution in a rapid and predictable manner, regardless of the host building context.

Throughout the design, construction, and commissioning phases of projects, there are often many handoffs between members of the project team. This traditional approach for facility execution often created risk for the client because each handoff has potential for miscommunication or gaps in responsibility. AES' Faciliflex strategy is designed to specifically minimize those risks because AES is solely responsible for providing a cleanroom that performs as expected.

Faciliflex guarantees not only fit & finish, but also the performance of the cleanroom:

- Temperature
- Pressurization
- Containment
- Humidity
- Cleanliness

3 Steps to Cleanroom Project Success:



CLEANROOM SYSTEM + INSTALL

3b

Even without our complete Faciliflex program of guaranteed environmental performance within the AES cleanroom, you can still leverage AES' best in class cleanroom wall and ceiling systems to deliver pre-engineered modular construction to your project. Our pharmaceutical and biotech cleanroom clients still implement the same beautifully compliant cleanroom envelope, but the AES scope of services is scaled back to that of a cleanroom "box" integrator. Although our services are reduced with this strategy and the environmental performance resides with another member of the project team, we still leverage our 35 years of experience with functional cleanroom environments when we integrate our cleanroom architecture and critical components within it. This solution is regularly leveraged by the world's leading architect & engineering teams as well as construction management firms in order to improve their offering to the life science community. AES Box combines our modular solutions with our experienced installation team to construct a tight and compliant cleanroom envelope.



Partial Client Listing – Industry Leaders

AAI Pharma Services	Genesis Packaging Technologies	Regeneron Pharmaceuticals, Inc.
AbbVie	Genzyme	Roche Diagnostics USA
ALK-Abello	GlaxoSmithKline	Saint-Gobain Performance Plastics
Almac	Greene Tweed & Co.	Sanofi Pasteur
American Surgical Co.	Grifols	Schering-Plough
Amgen	Haemonetics	Schott North America
Apex Industries	Immunomedics, Inc	Shire
AstraZeneca	Integra Life Sciences Corporation	Spark Therapeutics
Atrion Medical Products Inc.	Johnson Matthey	St. Jude Children's Research Hospital
Avid Bioservices, Inc.	Lifecell Corporation	StemCytex
Baxter International	Lonza Inc.	Stryker
Bayer	MedImmune	Taro Pharmaceutical Industries, Ltd.
Bristol-Myers Squibb	Merck & Co.	Teleflex Inc.
Brooks Instruments	Morgan State University	TEVA USA
Camfil Farr Inc.	Musculoskeletal Transplant Foundation	Transcoil, LLC
Catalent Pharma Solutions	Northwell Health	Transenterix, Inc.
Colorcon	Novartis	Uhlmann Packaging Systems
Cook MyoSite Inc.	Nutramax Laboratories	University of Nebraska
Cook Pharmica	Janssen Biotech, Inc.	University of Pennsylvania
Cryopharma, S.A. de C.V.	Paragon Bioservices, Inc.	University of Pennsylvania Health System
DesignRx	Patheon, Inc.	Valois of America, Inc.
Dendreon Corporation	Pfizer	Vistakon Pharmaceuticals, LLC
Eli Lilly and Company	Praxair	Vitrolife
Emergent BioSolutions	Princeton BioMeditech Corporation	West Pharmaceutical Services, Inc.
Ethicon Inc.	Progenics Pharmaceuticals, Inc.	XBiotech USA
Food and Drug Administration	Promega	
Fluortek	Progenitor Cell Therapy	
General Econopak Inc.	Qiagen	

AES Project Examples



Cell and Gene Therapy Facilities



Cell and Gene Therapy Facilities



Cell and Gene Therapy Facilities



Cell and Gene Therapy Facilities



Biotechnology Facilities



Biotechnology Facilities



Aseptic Filling Facilities



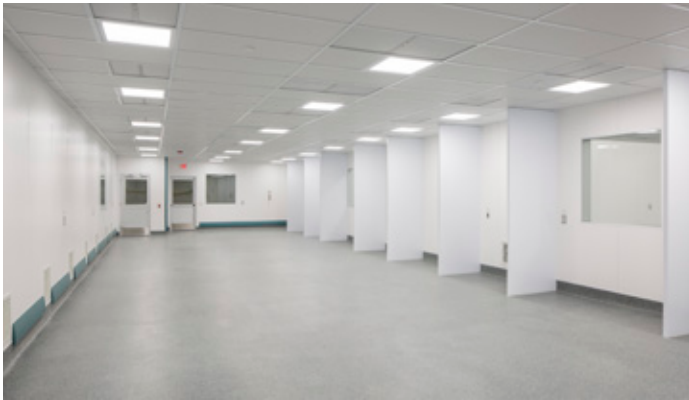
Pharmaceutical Manufacturing



Medical Device Facilities



Medical Device Facilities



Pharmaceutical API Facilities



Packaging Facilities



AES Turnkey Cleanroom Mechanical Systems

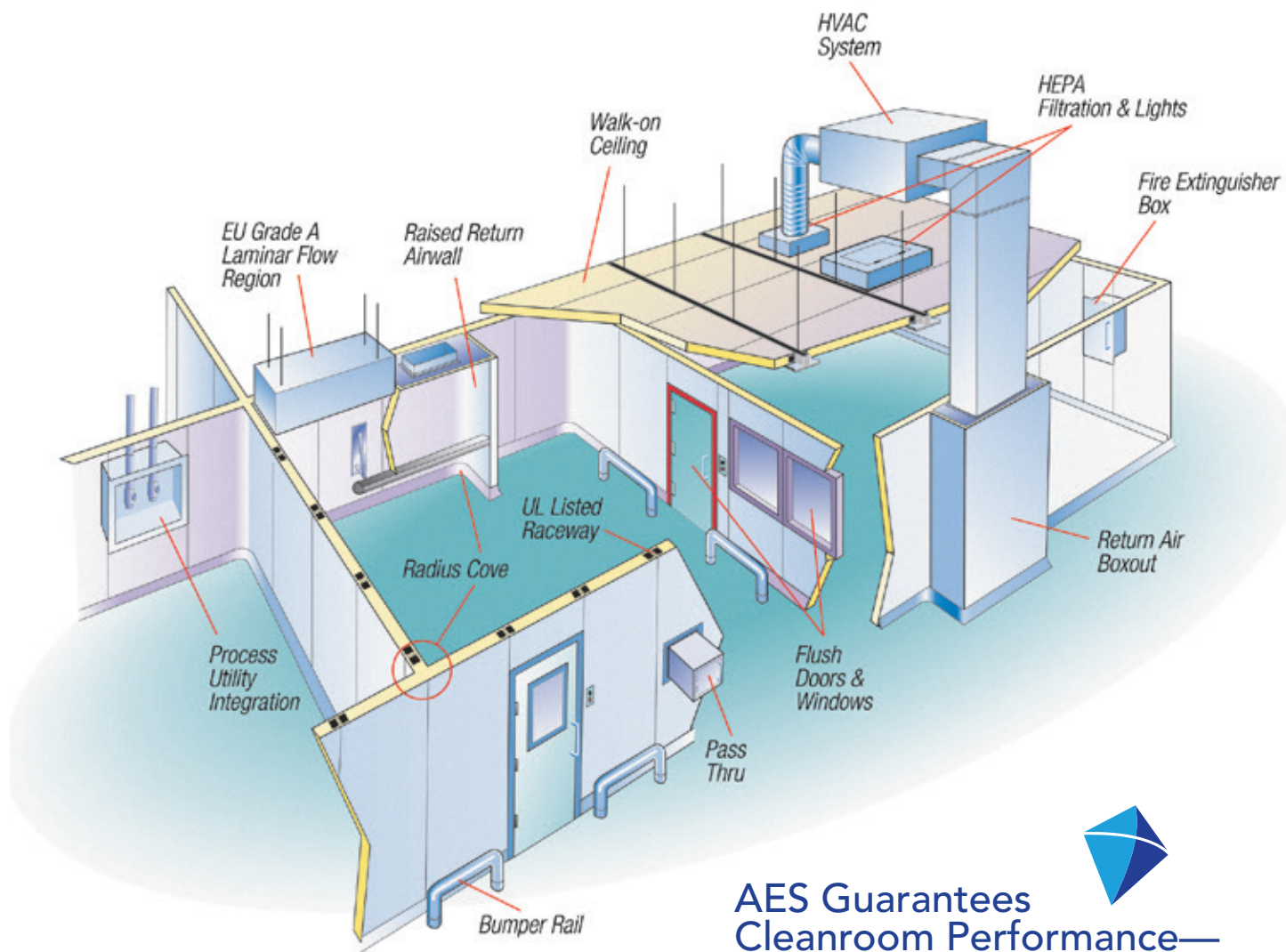


Process Utilities and Integration



AES Walkable Ceiling System





**AES Guarantees
Cleanroom Performance—**

Temperature | Humidity | Pressurization | Cleanliness

Compliance is beautiful.

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