



SIMPLEX CLEANROOMS WHITEPAPER

5 PHASES, START TO FINISH

What to Expect
When Subzero Engineering
Designs and Builds a Customized
Simplex Cleanroom for Your Company



This white paper provides an overview of the 5-phase, start-to-finish process that Subzero Engineering uses to design and build a Simplex modular cleanroom.

The five phases are:

- 1 Consulting/Proposal**
Subzero's engineers consult with you about your company's needs, goals, and work processes for the cleanroom, and provide you with a proposal.
- 2 Design & Layout**
Subzero's engineers create design drawings of the cleanroom, which you can then overlay with your layout of equipment.
- 3 Client Review, Modification, & Approval**
You review the cleanroom plans, make suggestions for changes, and approve the design.
- 4 Manufacturing**
Our manufacturing facility creates the cleanroom components.
- 5 Installation**
Subzero's site services team installs the cleanroom at your work location, OR you handle the installation yourself.

This white paper looks at how Subzero's engineers collaborate with you to customize the cleanroom according to your company's needs.

It also gives an overview of what you, the client, are responsible for, both before (e.g. permits, flooring, HVAC) and after (e.g. testing, cleanroom protocols, employee training) the cleanroom is built.

Introduction

A cleanroom is an enclosed room that provides a controlled and contaminant-free environment.

Many industries use cleanrooms, including manufacturing, semiconductors, pharmaceuticals, life sciences, and defense industries.

In general, a cleanroom is used for:

- 1 *Manufacturing or producing any type of product that must be made and shipped contaminant-free.*
- 2 *Any process that must be performed free of airborne contaminants.*
- 3 *Any type of research that must be performed in a clean, sterilized location.*

In a cleanroom, special air handling units called Fan Filter Units (FFUs) provide continuous air changes. The fans in the ceiling direct incoming air through High Efficiency Particulate Air (HEPA) filters, which remove airborne pollutants such as dust, microbes, and aerosol particles as the air enters the room. The pressurized air is then pushed down and exits the room through vents near the floor, taking away additional contaminants from employees, equipment, and materials. **Figure 1** shows how this works.

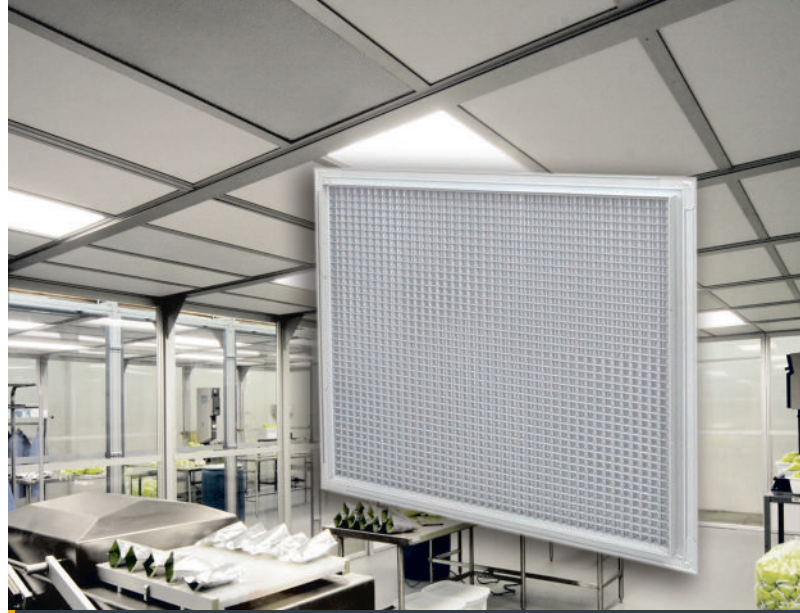


FIGURE 1: How air flow is directed through the cleanroom by fan filter units in the ceiling

In general, the ISO class rating of a cleanroom is determined by the number of air changes per hour (ACPH), which in turn is determined by the speed of the fans and the number of filters in the ceiling-based FFUs. The more air changes per hour, the more contaminants are removed, and the higher the cleanroom's ISO class rating.

In this white paper, we explore how Subzero Engineering designs and builds a Simplex modular cleanroom for your company. Subzero's engineers specialize in designing and building cleanrooms that are made-to-order for your business, your employees, and your needs.

In building a custom modular cleanroom, Subzero uses a 5-phase, start-to-finish process.

The five phases are:

- 1 *Consulting/Proposal*
- 2 *Design & Layout*
- 3 *Client Review, Modification, & Approval*
- 4 *Manufacturing*
- 5 *Installation*

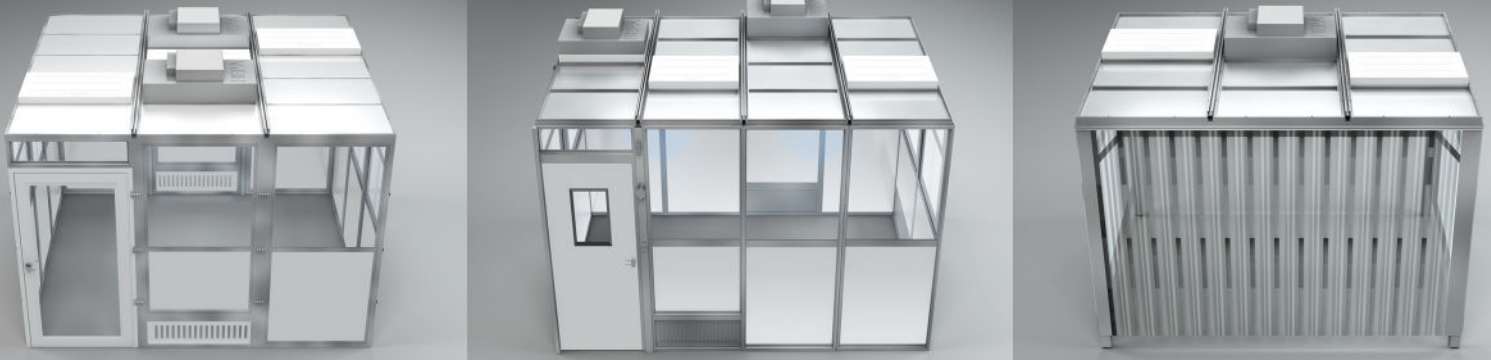


FIGURE 2: Simplex Airlock, SIS 797 and SIS 212

Subzero considers your company to be an equal partner in designing and building a cleanroom. Throughout the 5-phase, start-to-finish process, we continuously consult with you, our client, to get your input and feedback. This helps us to create a cleanroom that is custom-made to meet your company's needs, goals, and expectations.

Subzero's Simplex Products – A Quick Review

Before we examine Subzero Engineering's 5-phase, start-to-finish process, we first need to review the Simplex product line. Subzero designs and builds modular cleanrooms, constructed from ready-made components, which offer more flexibility than a permanent (or stick-built) cleanroom. Subzero's modular cleanroom products include:

Simplex Airlock

Constructed of 1/8" rigid or softwall panels held together with external latches, the Simplex Airlock cleanroom is suitable for a quick up-or-down installation. It can easily be moved, expanded, or reconfigured, making it ideal for companies that do multiple relocations or have temporary contracts that require a cleanroom facility.

Simplex SIS 797

Made of 1/8" to 3/8" rigid panels, the Simplex SIS 797 features smooth, easy-to-clean interior

surfaces. The Simplex SIS 797 is used for the cleanest cleanrooms (up to ISO 4 applications), where the highest level of a contaminant-free environment is required.

Unlike the Simplex Airlock, the Simplex SIS 797 is typically a one-time build-in-place cleanroom. If necessary, it can be moved, reconfigured, or enlarged. But since the wall panels are held together with self-tapping screws instead of latches, it requires extra effort to disassemble and reassemble it.

Simplex SIS 212

Featuring heavy-duty framing with a softwall panel perimeter and a strip door entrance, the Simplex SIS 212 cleanroom can be placed on casters (wheels) for portability. It is generally used in one of two ways:

As a solo cleanroom.

For example, you can set up an isolated clean environment for welding in a manufacturing plant.

As a cleanroom within a cleanroom.

For example, you can establish an ISO 5 enclosure within an ISO 7 cleanroom to protect certain tools from contamination.

Simplex Airblock

A simple isolation system, using solid softwall panels and/or anti-static vinyl strips. Like the Simplex SIS

212, the Simplex Airblock can be used either as a standalone application, or to provide a cleanroom within a cleanroom. But the Simplex Airblock is a fixed-in-place softwall structure, a partition attached to the wall. It is less portable than the Simplex SIS 212, but is sometimes more cost-effective.

Every cleanroom project is different. The type of cleanroom you need is based on a variety of factors. But for now, you should know that Subzero Engineering has the products to build your company a custom modular cleanroom that suits your needs.

NOTE: For purposes of this white paper, we'll assume that you already know which ISO class rating (e.g. ISO Class 7) you require for the cleanroom you wish to build. For an in-depth review of the ISO ratings system, see the Subzero Engineering white paper, "What To Know When Considering A Cleanroom."

The 5-Phase, Start-To-Finish Process

In designing and building a modular cleanroom, Subzero's engineers go through five phases of construction. Again, in each of these phases, we continuously collaborate with you, our client, to create a custom cleanroom that meets your company's needs.



Phase 1: Consulting/Proposal

In Phase 1, our engineers meet with your company, We ask you a series of questions that help us to define your specific needs and goals. In general, the main questions are:

- ? *What are your goals for using the cleanroom?*
- ? *What ISO level do you hope to achieve?*
- ? *How contaminant-free do you need the cleanroom to be?*
- ? *How many employees will work in the cleanroom?*
- ? *What workflow and processes will be carried out in the cleanroom?*
- ? *What equipment and/or materials will be present in the cleanroom?*
- ? *What is your budget for the cleanroom?*

Obviously, our questions get a bit more nuanced. Below are some of the major topics that we explore with you. Please think carefully about these questions. Your answers will help our engineers to design and build a cleanroom that is customized for your company.

Space Considerations

Questions concerning space fall into two categories:

- The actual physical location where we will build the cleanroom.
- The workspace inside the cleanroom where your employees will do the work.

How much allowable, usable space do you have in your work location where the cleanroom will be installed? This helps us to determine how large the cleanroom needs to be, and where it can be constructed in relation to its surrounding environment.

How many employees will be working in the cleanroom at any given time? Will it be five people? Ten? Twelve? What is the room's potential maximum occupancy? The cleanroom needs to be spacious

enough to allow each of your employees to “have their own space,” operate their equipment safely, and move around freely without bumping into each other. The more people are in the room at once, the larger the cleanroom itself will need to be.

Workflow and Processes

What workflow and processes will your employees perform in the room? What, if any, operational guidelines do your employees need to follow? What will the end result be (e.g. a product, a scientific discovery)? If speed is a factor, at what speed do you hope they will perform these processes and/or produce the end result?

Equipment and Materials

What is the general layout of the equipment inside the room? Will the equipment be permanently installed, or will you need to periodically move it in and out of the cleanroom? How much space does each equipment piece require (above and behind), not just for employees to operate it, but also for maintenance and cleaning purposes?

What kind of materials will be used? Does this material need to be pre-cleaned in any way before it enters the cleanroom?

Safety Issues

Are there safety issues regarding cleanroom equipment that need to be addressed? Some possible issues include:

- ✓ Heat or exhaust fumes generated by the equipment
- ✓ Moving parts
- ✓ Piping and electrical drops above the equipment

There may also be safety issues regarding the outside work area. For example, if you build a cleanroom alongside an existing wall, you will need at least 3

feet of open space in front of an active circuit panel, for safety and to allow employee access to it.

Budget

What is your overall budget for a new cleanroom? What features are absolutely essential? What features are optional? How does your budget align with your overall goals (e.g. the ISO rating you hope to achieve)?

Our Proposal

Using your answers to these questions, Subzero’s engineers will create a proposal that outlines the design, manufacturing, and installation of a customized cleanroom. This proposal may include:

- ✓ The type of cleanroom needed (e.g. Simplex Airlock, Simplex SIS 797)
- ✓ The proposed dimensions of the cleanroom (e.g. length of exterior walls, height of ceiling, height of ceiling plenums)
- ✓ The important cleanroom features (e.g. number of fans and HEPA filters)
- ✓ Any important accessories (e.g. wall switches, electrical or plumbing outlets, pressure gauges, access panels, glove ports, a pass-through)
- ✓ The cost of manufacturing, shipping, and installing the cleanroom components
- ✓ An estimated timeframe for manufacturing, shipping, and installation of the cleanroom that addresses your speed-to-deployment needs
- ✓ Future expansion considerations
- ✓ Material requirements

When you accept our proposal, you send a Purchase Order to Subzero Engineering to begin Phase 2 – the Design & Layout process. We’ll get to that in a minute. But first:



What YOU Are Responsible For – Part 1

There are certain matters that your company is responsible for, both before and after the cleanroom is built at your work location. Here are the things that you need to think about before the cleanroom is installed.

Permits

You are responsible for investigating and acquiring any local, city, and state permits needed to build the cleanroom. For example if you live in an area or state (i.e. California) that is prone to earthquakes, you may be required to obtain seismic permits for building a cleanroom. Contact your local Authority Having Jurisdiction (AHJ) for permit information.

Flooring

You can build a cleanroom on any floor surface – epoxy paint, vinyl sheet, ceramic tile, or polished and sealed concrete slab – provided it is crevasse free. But your company is responsible for doing any floor work that needs to be done prior to cleanroom construction, or for hiring a General Contractor to do it for you.

One option to consider is “coved flooring.” This is a special type of flooring, with rounded profiles installed along the sides of the cleanroom where the floor meets the wall. Coved flooring makes the room easier to clean, and may be required for some cleanroom applications, such as food inspection.

Electrical, Plumbing, and HVAC Systems

You are responsible for installing and/or renovating any electrical or plumbing systems that will supply electricity or water to the cleanroom, or hiring a contractor to install them.

You are also responsible for providing heating, venting, and air conditioning (HVAC) to the cleanroom. This is a very important consideration. In an environment where multiple employees will be working at any given time, the presence of people raises the room temperature considerably. You want to provide enough air conditioning to allow your employees to work comfortably in the clean space.

Contact your Subzero Engineering dealer to discuss your requirements and options regarding flooring, electrical, plumbing, and HVAC systems for cleanrooms. If you don't already have a GC in mind, your Subzero dealer can provide recommendations.



Phase 2: Design & Layout

In Phase 2, Subzero's design engineers use AutoCAD (Solidworks) to produce approval drawings of a custom cleanroom, based on the information you provided in Phase 1.

In designing the cleanroom, Subzero's engineers take numerous considerations into account. These include:

Walls

Subzero's engineers pay special attention to both the inside and outside layout and dimensions of walls in the cleanroom. The design of the modular cleanroom may include hardwalls, softwalls, or a combination of both. The types of walls we use (rigid walls vs. softwall) will influence the cleanroom's level of cleanliness and ISO Class rating.

Airlocks

An airlock is a transitional space that separates the cleanroom from the surrounding work area, preventing contaminants from entering the room with your employees. Depending on your requirements and your desired ISO rating, Subzero's engineers may include one or more airlocks in your design plans.

Fan Filter Units

FFUs combine air-directing electric fans with HEPA filters that clean particulates from the air. As mentioned, the number of FFUs and the rotating speed of the fans determines the number of air changes per hour, which helps to establish the cleanroom's ISO rating. In designing your cleanroom, Subzero's engineers will take into account how many ceiling-based FFUs you will need.

Vents

Your cleanroom requires a certain number of vents in the lower walls, in relation to the number of FFUs in the ceiling. Subzero's engineers will include the correct number of vents in your design. The placement of the vents helps to ensure proper air movement.

Single-Pass vs. Recirculated Air

Subzero's engineers will recommend whether your cleanroom should be a single-pass room (e.g. air moves in and out of the room in a single pass) or a

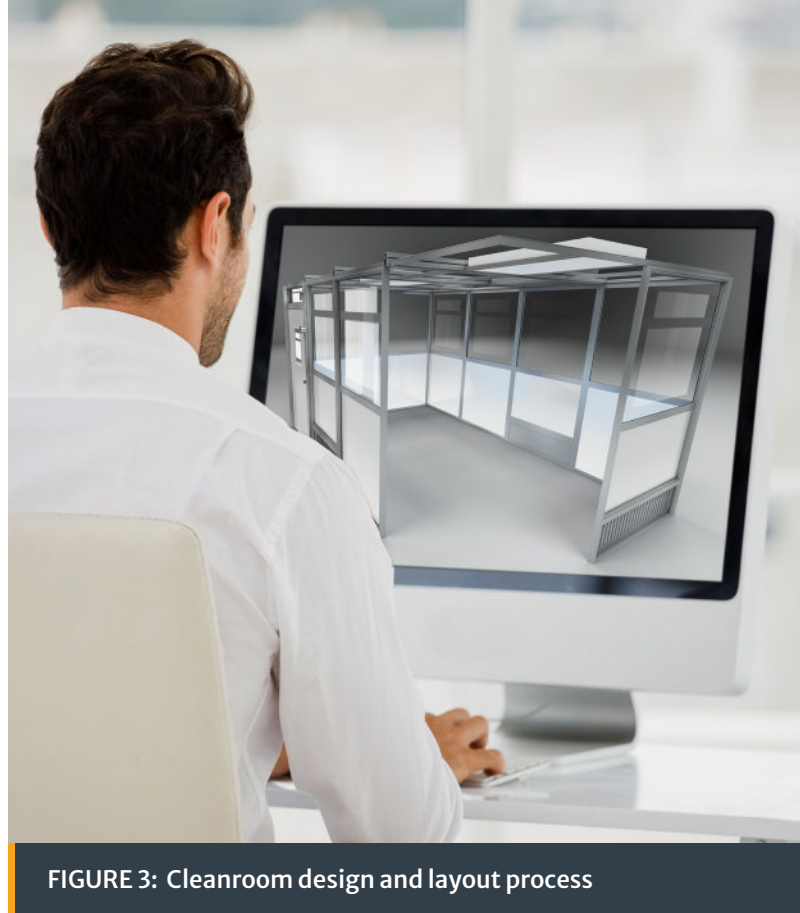


FIGURE 3: Cleanroom design and layout process

recirculated air room (e.g. air continuously exits the room through vents, and re-enters through FFUs). This determination is based on several factors, including your desired ISO rating and your setup for HVAC to provide heating and cooling to cleanroom employees.

For more about these concepts, including a complete discussion of the uses of single-pass vs. recirculating air flow, see the Subzero Engineering white paper, "What To Know When Considering A Cleanroom."

Layout Considerations

Your company is responsible for the layout of equipment inside the cleanroom. Although Subzero doesn't include this layout in its approval drawings, we can provide you with step files that allow you to overlay your equipment layout on the cleanroom design, to make sure the equipment fits properly inside the room.

In designing the cleanroom, we consult with you on special equipment layout requirements. For example, will the equipment be periodically moved in and out of the clean space? If so, we may design the cleanroom with larger doors, to make these moves easier for your employees.

We also consult with you on the best ways to organize your equipment inside the cleanroom. For example, if a work table is placed in front of a wall vent, it may block the air from carrying contaminants out of the room, creating a “dead space” where particles are trapped. You need to carefully arrange work tables, chairs, and equipment, to maintain proper airflow. (Subzero uses a Computational Fluid Dynamics (CFD) tool to verify airflow through the clean space.)



Phase 3: Client Review, Modification, and Approval

In Phase 3, you will be asked to review the design plans, and to double-check the cleanroom’s various features (e.g. fans, filters, vents). Subzero’s engineers will consult with you on the aesthetics and functionality of each feature, and how they fit within your company’s goals, workspace requirements, and budget.

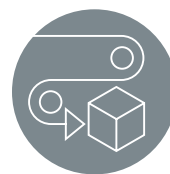
During this phase, you can request changes – for example, a vent might be moved from one wall to another to preserve airflow while allowing for better equipment placement. If necessary, Subzero’s engineers will produce a set of revised approval drawings, based on your feedback. Once you approve the design plans for the cleanroom you want, Subzero notifies the factory to begin manufacturing the components.

Keeping the costs down

Let’s say you review the cleanroom plan, and it meets your goals, but its overall cost is still too high. Subzero’s engineers can suggest additional design changes that may help to keep the cleanroom within your company’s budget. These might include:

- ✔ Replacing certain hardwalls with softwalls inside the cleanroom.
- ✔ Removing certain features, such as an extra airlock room.
- ✔ Utilizing existing walls and ceilings in your work environment. For example, in a large manufacturing plant, we can build the cleanroom on the side of a large room, so that an existing wall serves as the “back wall” of the cleanroom.

You can also choose to downgrade your ISO Class goals, to bring the costs down. For example, if you decide that you can get by with an ISO 7 cleanroom, instead of an ISO 6, Subzero’s engineers can revise the design plans accordingly, removing FFUs and vents. (In the future, you can always upgrade your modular cleanroom to achieve a higher ISO Class rating.)



Phase 4: Manufacturing

In Phase 4, Subzero creates the elements of the cleanroom at their manufacturing facility, using various aluminum profiles to create the modular components. Aluminum profiles are shaped metal objects that allow us to ensure that each component (wall and ceiling panels, floor and cover plates, etc.) has a standardized shape and size. Several of our aluminum profiles are pictured on the next page.

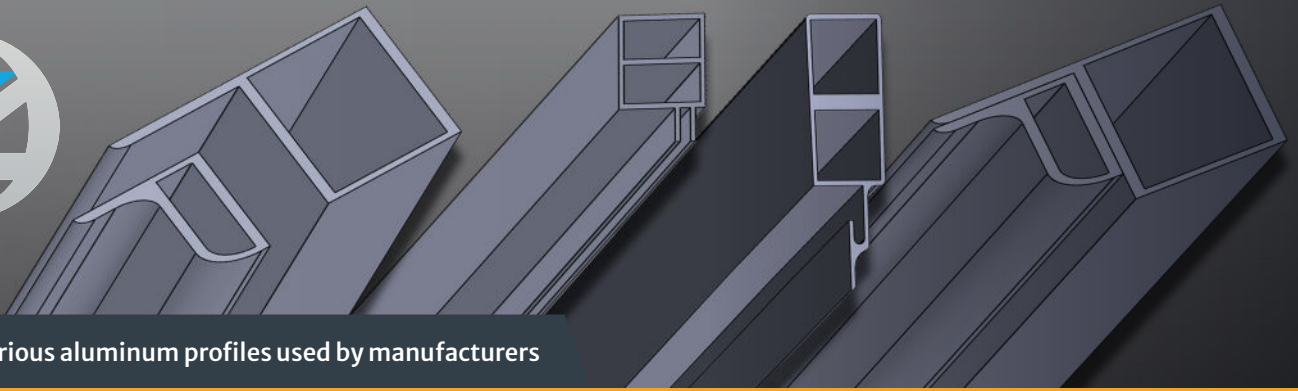


FIGURE 4: Various aluminum profiles used by manufacturers

Subzero manufactures its cleanroom components at a 155,000 sq. ft., state-of-the-art facility, using a highly-streamlined assembly process. Our facility includes a cleanroom research and development center, a demo room featuring full-scale physical examples of all Simplex products, and massive storage areas for spare components, which helps us to eliminate supply chain issues. The facility is located at a logistical hub, enabling quick shipment of components to anywhere in North America.

The manufacturing phase starts once you return a purchase order to Subzero. Typical manufacturing time for all components is 4–6 weeks, with an additional 1–2 weeks to ship the components to your work location. Actual manufacturing time varies, based on project size.



Phase 5: Installation

The last step, Phase 5, is the installation of the modular cleanroom at your work location. You have several options here:

- ✓ Have Subzero’s site services team install the cleanroom for you.
- ✓ Hire a general contractor to install the cleanroom for you.
- ✓ Install the cleanroom yourself.

Your best option is to have Subzero’s site services team install the modular cleanroom at your work location. A factory-supplied project manager will lead the installation, managing up to 40 installers on larger construction projects. Our trained engineers have the skills and experience to build your cleanroom with speed and efficiency, ensuring that it meets the expectations of your executives and your employees.

When Subzero installs the cleanroom for you, a single purchase order covers both materials and installation. Also, if you allow Subzero’s site services team to install the cleanroom for you, we triple our warranty from 1 year to 3 years.

If for whatever reason (i.e. security clearances) you decide that you must install the cleanroom yourself, we make it easy for you. When the cleanroom components arrive at your work location, all panels and parts are clearly labeled, and all the necessary elements – including easy-to-follow instructions – are included in the installation kit. You or your GC can install the cleanroom with a minimum of tools.

But again, we strongly urge you to let Subzero's install the cleanroom for you!

What YOU Are Responsible For – Part 2

There are things that your company is responsible for after the cleanroom is installed. Remember: A cleanroom is only a cleanroom if you keep it clean. It is your responsibility as a company to maintain the cleanliness and integrity of your cleanroom as a strict, contaminant-free environment. This means you are responsible for the following:

Testing

Once the cleanroom is in place, your company should hire a third-party tester to come in and examine it. Usually, this will be a local cleanroom certification specialist. Their testing procedures may include:

Air flow testing

Using calibrated instruments, the tester checks for proper flow of air through the clean space.

Airborne non-viable particle testing

The tester uses a calibrated particle counter to test the level of cleanliness, according to ISO class standards.

Integrity leak testing

The tester tests all HEPA filters for leaks or deficiencies.

Room differential pressure testing

If you request it, the tester may measure air pressures in different rooms, and/or do comparison testing of air pressures between the cleanroom and the outside environment.

Airborne and surface microbial testing

The tester tests for the presence of microbes. Usually, this is done for healthcare/pharmaceutical companies.

If your cleanroom doesn't meet the right standards – for example, if particle testing puts the room at ISO 7, when your goal is ISO 6 – the tester may make recommendations on how to improve cleanliness to achieve the correct ISO Class rating. They may recommend that you review your company's procedures for personnel and equipment flow, gowning, facility cleaning, etc., and make improvements.

You should schedule regular, ongoing third-party tests of the cleanroom (e.g. annually) to ensure continued ISO compliance. If you are unsure who to contact for cleanroom testing, your Subzero dealer can recommend a local-third party tester. Or you can do a web search (keyword: "cleanroom certification [+ your city or state].")

Cleanroom Procedures and Protocols

Your company should establish strict procedures and standards for the cleanroom. This starts with designating a "Cleanroom Executive in Charge." This person will be responsible for:

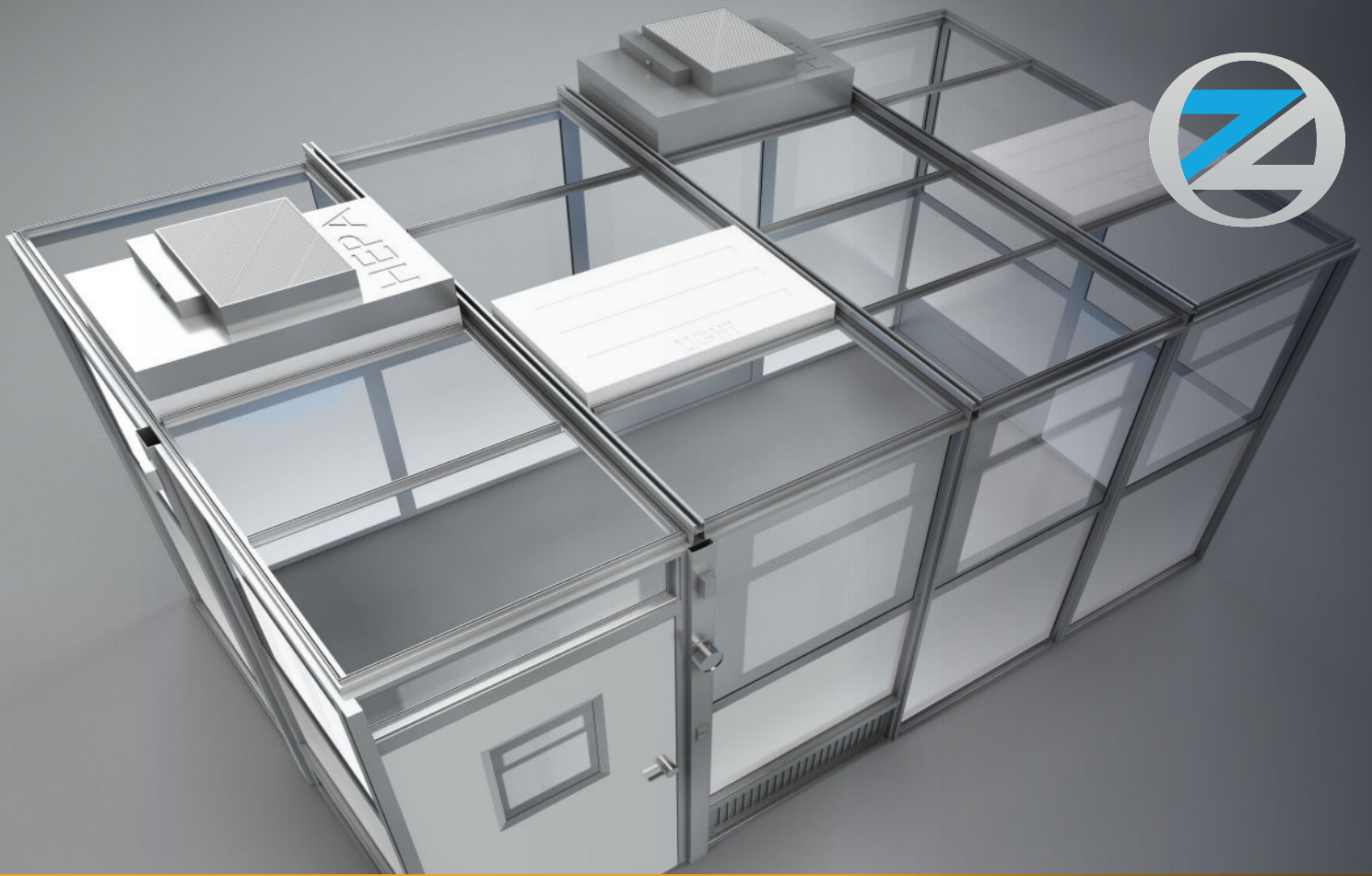
- ✓ Establishing procedures and protocols that employees must follow – before, during, and after working in the cleanroom.
- ✓ Overseeing employee training for those procedures.
- ✓ Enforcing the procedures, including shutting down the cleanroom if it is contaminated.

Training

Your employees must be trained in procedures and protocols for the cleanroom. Your company is responsible for setting up this training.

Accessories

Your company is responsible for buying accessories for the cleanroom, and for having adequate supplies on hand. These accessories may include:



- ✓ Employee wearables, including special uniforms, lab coats, hair bouffants, beard nets, booties, and disposable plastic gloves.
- ✓ Cleanroom accessories such as replacement HEPA filters and sticky mats.

Cleaning & Maintenance

Your company is responsible for establishing regular cleaning and maintenance schedules for the cleanroom. You should determine how often (e.g. daily, weekly) the clean space will be cleaned, and what will be used to clean it. You should also schedule any necessary maintenance procedures (e.g. replacing sticky mats every two weeks, and replacing HEPA pre-filters every 4–6 months, and main HEPA filters every 4–6 years).

Conclusion

Subzero Engineering is committed to the highest quality of product, installation, and service to our customers. Throughout the 5-phase, start-to-finish process – through Consulting, Design & Layout, Client Approval, Manufacturing, and Installation – we continuously consult with you to ensure that your cleanroom is set up to your specifications, that it is tailor-made to your company's needs and requirements. You can rest assured, we've got your back!



Partner with Subzero Engineering for a tailor-made cleanroom solution that meets your exact specifications.