

HOW TO STICK-BUILD YOUR cGMP CLEANROOM

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Anyone living in the Pharma engineering world knows that for a top-notch, progressive cGMP facility, a modular cleanroom system is the way to go when fitting out your graded cleanroom manufacturing spaces and controlled environments. First costs may be higher than a typical stick-built facility, but the pros far outweigh the cons. For example, when compared to a metal stud / gypsum wallboard stick-built system, a side-by-side comparison clearly shows the advantages of modular.

Modular Vs. Stick-built					
Line Item	Modular Cleanroom (MCR)		Stick-built system (Metal Studs/ GWB)		Comments
	Pro	Con	Pro	Con	
FDA Perception	X			X	<i>MCRs look cleaner.</i>
Cleanability	X			X	<i>MCRs easier to clean due to monolithicity.</i>
Durability	X		X		<i>Both systems can be robust and fitted with wall protection.</i>
Flexibility	X			X	
Maintenance	X			X	<i>Stick-built requires painting every five years.</i>
Schedule	X			X	<i>MCRs get installed quicker.</i>
First Costs		X	X		
Integrated low wall return	X			X	<i>The MCR "Airwall" low wall return system allows flexibility of plenum size and does not require expensive, visible grille.</i>
Availability of skilled labor		X	X		<i>MCR installers need to be trained to install these specialized systems.</i>
Ability to surface mount appurtenances such as control panels, HMIs, etc		X	X		<i>A stick-built cleanroom allows for simple blocking in wall cavity to support weights up to 300 lbs.</i>
Access to Utilities and Services	X			X	<i>Walkable ceilings in MCRs provide unobstructed access to utilities from above cleanroom.</i>
Manpower Loading (construction)	X			X	<i>MCR construction requires less tradesman in the field.</i>

In terms of FDA perception, top of the line modular cleanrooms (MCRs) don't just appear cleaner, they usually are cleaner. All surfaces are flush, seams are practically undetectable, and corners are perfectly coved, so cleaning is easier and more effective. MCR systems with uPVC finishes are resistant to robust cleaning protocols such as VHP, Spor-Klenz, and Vesta-Syde. Panels have less of a profile at only 2" so floor space is conserved, compared to metal stud walls which are typically 7-1/4" thick. For stick-built walls with epoxy

painted finish, the paint will eventually fade and become compromised from these powerful cleaning agents and frequency of cleaning. New coats will be required every five years at a minimum and, of course, this requires manufacturing shutdown. The best of the MCRs include AES Clean Technology, Plascore, Dagard, CleanSpace, and several others. With MCR systems, you will pay for the positive attributes previously mentioned, but are practically guaranteed a successful cleanroom. With stick-built you are at the mercy of the subcontractors.



For many startups, generic pharma manufacturers, and contract manufacturers, a “State of the Art” facility is just not in their budget. For these companies, first costs usually take precedence over almost everything else. As such, stick-built is pretty much the way to go. Stick-built systems could include furred masonry, but metal studs with an applied panel system is much more common. Gypsum wallboard, aluminum/uPVC liner panels, or paperless gypsum wallboard are the norm. Wood studs, or any wood products, should never be specified as they promote microbial growth. Metal stud wall systems with wallboard can be clad with PVC, FRP, or a resinous wall system. Altro Whiterock, Takiron, and Glasbord are common manufacturers for these types of systems. These cladding systems can be installed full height or as a 48” high wainscot and are usually adhered to the wallboard. Keep in mind, however, that for FM insured facilities, only cladding systems meeting FM 4882 can extend full height. Takiron is one such product. Liner panels such as AES Adaptwall is a half-inch thick uPVC liner panel that can be attached directly to the metal studs.

When using gypsum wallboard, a paperless panel such as Densarmor Plus will get you much better spore counts than regular gypsum wallboard, although it is slightly more expensive. If gypsum wallboard assemblies (including paperless) are not finished full height with a cladding system, a prime and two-coat, high-gloss epoxy paint is the more durable and chemical resistant paint finish. Surprisingly, epoxy has excellent resistance to many of the harsh chemicals seen in pharma manufacturing. These include Acetic acids, acetone, and many types of alcohols.

For cGMP Grades D to A (or ISO 9 to 5), a stick-built wall and ceiling system as described previously is a perfectly viable solution, however labor trades familiar with pharma cleanroom construction are critical for both architectural and HVAC construction. In some areas, this labor force is difficult to find. For architectural construction, door frames need to be flush and plumb. Often, a door or window frame will be flush with the wall at the top and bottom of the frame, and out as much as a quarter inch in the center. Resinous floor

bases will want to be flush with the wall surface. Three-quarter inch corner coves will need to be installed on all internal corners, as well as three-way corners where the ceiling and two walls meet. Trimtex and ClarkDietrich are two major manufacturers of corner beads. Contractors need to be familiar with these challenging details.

When stick-building a cGMP cleanroom facility, ledges and crevices should be nonexistent. Bases should have blocking in the wall surface they are ascending (for impact resistance), door frames should be welded, not knock-down, to eliminate seams and doors, and frames should be either stainless steel, FRP or PVC. If the budget is tight, epoxy-painted hollow metal will suffice, however they will need to be painted at least every five years. In wet conditions, hollow metal doors and frames should be galvanized. Windows will require glazing that is flush with the frame (and the frame with the wall surface) on both sides. Again, no ledges! Resinous flooring can often be a problem with stick-built because installers are challenged with getting the integral base level, as it extends the perimeter of the room and, at the same time, flush with the wall surface. The resulting joint treatment is important. The resinous base material can either be tapered or separated via a zinc or stainless-steel J-bead.

In my thirty-something years as an architect, I've seen many failed attempts at achieving some of these details. Here are some of the worst.



Photo 1



Photo 2

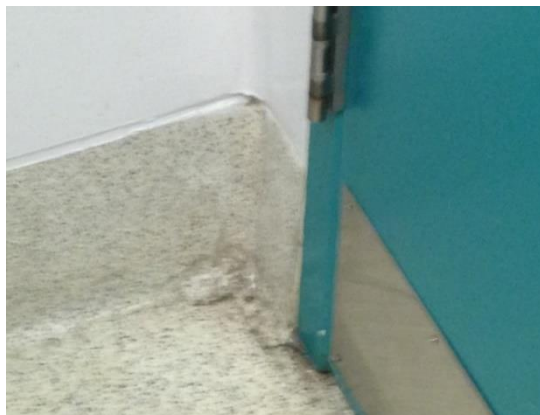


Photo 3



Photo 4

In Photo 1, stopping the frame 6" from the floor is perfectly acceptable, however I would much prefer relying on a steel frame to protect my wall edge than an epoxy base. Continuous exposure to material handling traffic will result in the condition shown in Photo 2. Photo 3 is just bad workmanship by both the flooring installer and the carpenter. One can see (and that *one* may very well be an FDA inspector) the flooring material "gooped" in the corner and the sloppy caulking between the base and wall surface. Photo 4 shows what happens to hardware in a cleanroom when it is not stainless-steel material.

In summary, when planning for a successful, cGMP-compliant stick-built cleanroom, the following are my recommendations. These are the "shalls" of cGMP compliance and FDA perception.

1. Walls in a cGMP cleanroom shall:
 - a. Be smooth, cleanable and seamless.
 - b. Not have crevices, ledges, open joints, or chipping / scratched paint.
 - c. Be perfectly plumb and level.
 - d. Have minimal surface-mounted appurtenances.
 - e. Have maximum recessed appurtenances.
 - f. Have resinous or seamless vinyl bases that are flush with the wall surface and coved.
 - g. Use 6" studs to allow a cavity for utilities and services, and for recessing equipment and control panels.
 - h. Have 3/4" coves at inside corners and three-way corners.
 - i. Use paperless gypsum board finished with epoxy paint or clad with FRP or uPVC.
2. Ceilings in a cGMP cleanroom shall:
 - a. Be paperless gypsum wallboard.
 - b. Be gasketed with hold-down clips if vinyl-faced suspended tiles are used.
 - c. Have stainless steel access panels where utilities valves, switches, etc. need to be accessed and there is no walkable ceiling.
 - d. Be finished with epoxy paint if gypsum wallboard.
3. Doors, Windows, and Frames in a cGMP cleanroom shall:
 - a. Be uPVC, FRP, or Stainless Steel
 - b. Have fully flush tops and bottoms.
 - c. Have door and window frames that are flush with finished wall surface.
 - d. Have hardware that is stainless steel and recessed or mortised where possible.
 - e. Have glazing that is flush with door or window on both sides.
 - f. Have sealant joints between the frame and wall surface that are flush with both materials.
Sloppy sealant joints are one of the most punched items on a punch list.
 - g. Have hospital stops where air segregation is not an issue.
 - h. Have hands-free door operating devices in cGMP Grades C and cleaner.
 - i. Have frames that are single rabbet.
 - j. Have frames that are welded and not knock-down.

