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Design Now or Pay Later: When Cleanroom Airflow Gets Locked In

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Every now and then, I get a message that starts, “Hey Adam, quick question about cleanroom design.” If you’ve worked in sterile compounding design long enough, you know that “quick question” rarely means quick. It usually means we’re about to unpack airflow physics, microbiology, architecture, and the occasional existential crisis about why cleanrooms are designed the way they are.

Recently, I was asked about the placement of a low wall return in their anteroom during a full cleanroom renovation. The engineers wanted the return placed near the sink on the clean side of the line of demarcation (LOD). The pharmacy team wondered if it would make more sense on the “dirty” side of the room where personnel are garbing.

Both sides had good reasoning. And this is one of those situations where multiple answers can technically be correct, depending on how the room’s airflow strategy is designed and verified under USP <797> and, if hazardous drugs are involved, USP <800>.

But the discussion does highlight an important aspect: the anteroom is one of the most underestimated contamination control spaces in the entire cleanroom suite.

The Most Important “Middle Room” in the Suite

In a typical three-room sterile compounding suite, the anteroom sits between the uncontrolled pharmacy space and the buffer rooms. It’s the space where personnel perform garbing, materials transition into the controlled space, and also where pressure relationships begin to establish airflow direction.

In theory, the anteroom acts as a buffer between dirty and clean operations. In reality, it’s also the place where:

- people move the most
- particles are generated
- workflow errors occur
- microbial contamination is introduced

The Line of Demarcation: More Than Just Tape

Under USP <797>, the line of demarcation (LOD) separates the “dirty” side of the anteroom from the cleaner side leading toward the buffer room.

The LOD isn't just a visual cue it supports contamination control by separating:

- personnel entry activities
- garbing procedures
- movement of materials

Ideally, airflow patterns should work in conjunction with the LOD so that particulates generated during garbing don't migrate toward the buffer room entrance. This brings us back to the original debate: Where should the low wall return go?

The Case for the Dirty Side

One argument is to place the return near the garbing bench or on the dirty side of the LOD. The reasoning is simple: personnel movement during garbing is typically the largest particulate-generating activity in the anteroom. Capturing contaminants near the source can help prevent those particles from drifting toward the clean side of the room. From a contamination control standpoint, this strategy makes a lot of sense.

The Case for the Sink

The engineers in this case proposed placing the return near the sink on the clean side of the LOD. Again, this isn't wrong. Sinks introduce moisture, plumbing surfaces, and microbial reservoirs. Splashing and water activity can generate microorganisms that linger in localized airflow patterns.

A return located near the sink can help evacuate those contaminants and prevent stagnant air zones around the plumbing fixture. So now we have two valid contamination control strategies. Which one is better?

The Best Answer: Both

If space and budget allow, the best design solution is often the simplest. Install two low wall returns. One near the sink and one in the initial garbing area at the LOD.

This approach improves overall air evacuation and supports better top-down airflow movement through the room. However, construction budgets have a way of reminding us that "ideal design" and "approved project cost" are not always the same conversation.

When Hazardous Drug Rooms Enter the Picture

Things get even more interesting when the cleanroom suite includes hazardous drug compounding rooms under USP <800>. In these suites, the HD buffer room must be maintained under negative pressure relative to adjacent areas to contain hazardous drug contamination. That pressure relationship means air is constantly being drawn from the anteroom into the HD buffer room, which introduces a potential problem.

If the anteroom contains elevated particulate or microbial contamination due to garbing activity, personnel crowding, or poor airflow evacuation, that contamination can become collateral damage pulled directly into the hazardous drug buffer room.

When environmental monitoring excursions occur in a hazardous drug buffer room, experienced investigators often look to the anteroom. Because these negative-pressure environments can pull in contaminants from adjacent spaces, the root cause is frequently traced to anteroom activity. While these excursions are often remediated by adjusting personnel workflows, a proactive design strategy ensures the anteroom functions as a robust protective barrier rather than a point of failure.

Don't Forget the Pressure Cascade

Anteroom airflow performance isn't determined by return placement alone. Other factors include:

- air changes per hour (ACPH)
- supply diffuser placement
- room pressure relationships
- door undercuts allowing airflow exit

In positive-pressure suites, airflow should cascade from: **Buffer room → Anteroom → General pharmacy space**, often exiting under the door leading out of the cleanroom suite. That undercut isn't an accident; it's a crucial part of the airflow design that allows the room to breathe properly, protect the space, and flush out contaminants that are being brought in (in real time).

The Smoke Study Problem Nobody Talks About

At some point, someone usually says, "We can confirm everything with smoke studies." And that's true. Airflow visualization testing during commissioning is the best way to verify that:

- airflow moves from clean to less clean areas
- turbulence is minimized
- contamination is evacuated effectively

But here's the part that doesn't always get discussed. Smoke studies typically happen after construction is complete, which means the cleanroom is already built, sealed, balanced, and operational.

So, if the smoke reveals poor airflow patterns, slow clearing times, or extreme turbulence, the options for fixing the problem may be limited. Changing return placement, diffuser configuration, or airflow pathways at that stage usually means additional construction and additional cost.

And suddenly everyone in the room is quietly wondering, "Who exactly wins this argument now?" Being correct about design flaws is useful, but it's far more useful before the drywall goes up.

The Real Lesson in Cleanroom Design

Cleanroom design debates aren't really about who is right. Engineers, architects, and pharmacy teams often approach the problem from different perspectives. Engineers focus on airflow mechanics, pharmacists focus on operations and contamination control, and architects focus on spatial design.

The most successful cleanrooms come from collaboration between all three disciplines. And sometimes that collaboration results in the simplest compromise of all: two low wall returns—one near the sink and one near the initial garbing area. Having redundancy in contamination control is never a bad thing, even if the construction budget sighs dramatically.

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