



Mitigating Mold Contamination Risk in Biopharmaceutical Facilities: By Maik Jornitz

A Critical Comparison of Gypsum Wall Systems and uPVC Cleanroom Panels

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Abstract

Biopharmaceutical manufacturing demands an environment in which microbial control, durability, and cleanability are maintained without compromise. While much attention is directed toward HEPA systems, airflow design, and aseptic processes, the architectural materials used in cleanrooms have an equally significant impact on environmental integrity. Mold, in particular, poses a severe risk: it spreads rapidly, thrives in moist and organic environments, and can trigger devastating consequences ranging from product loss to facility shutdowns.

The choice between gypsum wall construction and uPVC cleanroom panels has become increasingly important as regulatory agencies intensify scrutiny of facility surfaces and the robustness of contamination-control infrastructure. Gypsum systems, though common in general construction, carry intrinsic vulnerabilities due to their porosity, moisture retention and absorption rates, and susceptibility to surface degradation. By contrast, uPVC systems are engineered explicitly to resist microbial growth, withstand rigorous cleaning cycles, and maintain long-term structural integrity.

This white paper explains why gypsum-based wall systems elevate mold risk in biopharma facilities and why uPVC cleanroom panels have become the preferred material for ensuring environmental control and regulatory compliance.

Understanding Mold Risk in Controlled Environments

Mold spores are present in virtually all indoor and outdoor environments. In a controlled manufacturing space, the presence of a single spore may lead to contamination of exposed product, rapid colonization of hidden cavities, and persistent environmental positives that are extremely difficult to eliminate.

Biopharmaceutical facilities typically maintain high humidity control, but even minor water intrusions—from cleaning activities, pipe leaks, HVAC condensation, or vapor migration—can create conditions that support mold growth. Once established, mold may remain undetected for long periods behind coatings, within wall cavities, or inside porous building materials. When spores eventually spread into the classified environment, even low-level contamination can halt production and initiate extensive investigations.

The Challenges of Gypsum Wall Construction

Although gypsum wallboard is commonly used in commercial construction, its properties make it incompatible with areas requiring strict microbial control. Gypsum is inherently porous and hygroscopic, meaning it readily absorbs moisture from the surrounding environment. This moisture penetration can occur through micro-cracks, pinholes in coatings, delamination of FRP cladding, or even through vapor diffusion. Once absorbed, moisture becomes trapped within the wallboard, creating conditions highly favorable for mold growth.

Another issue is that gypsum degrades under repeated exposure to the disinfectants routinely used in biopharmaceutical facilities. Harsh sanitizing agents can lead to bubbling, cracking, and peeling of surface coatings, progressively creating more pathways for moisture intrusion. Even minor impacts from equipment or carts can fracture the board or create fissures that are difficult to seal properly. Over time, these weaknesses accumulate, making gypsum systems increasingly fragile and more prone to microbial infiltration.

When mold colonizes gypsum, remediation becomes exceptionally challenging. Typically, the affected section must be entirely removed and replaced. Because mold contamination often spreads behind the visible surface, identifying the full extent of the damage requires destructive inspection, prolonging downtime and increasing the likelihood of regulatory findings.

Increasing Regulatory Scrutiny

Regulators such as the Food and Drug Administration and the European Medicines Agency expect facilities to use materials that are cleanable, durable, and resistant to microbial growth. In recent years, inspections have increasingly focused on the suitability of construction materials for repeated disinfection, the presence of cracks or surface degradation, and the risk of microbial harborage within facility structures.

When mold is detected whether in viable air samples, surface monitoring, or behind facility walls inspectors frequently question the adequacy of the facility material choices. Gypsum walls have repeatedly been cited in observations for their inability to withstand routine sanitization and for harboring moisture that can lead to contamination. Such findings may escalate into warning letters, import restrictions, or mandated facility renovations. The renovation process itself often requires partial shutdowns, extended requalification periods, and demonstrations that new materials eliminate prior contamination risks.

Consequences of Mold Contamination

The operational and financial consequences of a mold incident can be severe. Any affected batches typically must be destroyed, and in cases where contaminated product has been released, recalls may follow. These events can cost millions and have long-lasting effects on customer trust and supply continuity.

Facility shutdowns are another major consequence. Remediation often involves removing contaminated gypsum drywall, replacing it with cleanroom-compatible materials, cleaning and sanitizing surrounding areas, and conducting thorough environmental requalification. The downtime required for reconstruction, coupled with lost production capacity, frequently exceeds the direct cost of repairs.

Beyond immediate operational issues, mold events erode regulatory confidence, damage reputation with partners and clients, and can negatively influence market valuation. In some documented cases, unresolved mold issues have led to full facility closures.

uPVC Cleanroom Panels: A Superior Alternative

uPVC cleanroom panels offer a material solution that inherently avoids the vulnerabilities associated with gypsum. Unlike gypsum, uPVC contains no organic material and does not absorb moisture. Its non-porous structure prevents water penetration and eliminates the internal cavities where mold typically grows. This characteristic alone significantly reduces contamination risk.

The seamless installation of uPVC panels further enhances microbial control. Panels can be heat-welded at the joints to create a continuous, monolithic surface that does not crack, peel, or delaminate. This type of construction eliminates the crevices where contaminants might lodge and simplifies cleaning, allowing for more aggressive sanitization without degrading the wall surface.

uPVC also provides excellent chemical resistance, maintaining integrity under frequent exposure to disinfectants such as hydrogen peroxide, quaternary ammonium compounds, and chlorine solutions. Its durability reduces the need for repairs or replacements and minimizes the risk of inspection findings related to surface damage. Over the lifespan of a facility, uPVC systems typically require far less maintenance and lead to fewer operational disruptions.

From a cost perspective, though uPVC panels may involve a higher initial investment than gypsum drywall, the long-term economics overwhelmingly favor uPVC. The reduced risk of contamination, avoidance of repeated repairs, and prevention of costly shutdowns result in a significantly lower total cost of ownership.

Conclusion

Mold contamination poses a serious threat to biopharmaceutical manufacturing, with far-reaching operational, financial, and regulatory implications. Gypsum wall systems, due to their porosity, moisture retention, absorption rates and susceptibility to chemical and mechanical degradation, introduce unacceptable risk into cleanroom environments where microbial control is critical. uPVC cleanroom panels provide a structurally superior and contamination-resistant alternative that aligns with regulatory expectations and supports long-term operational reliability.

For organizations committed to maintaining GMP compliance, protecting product integrity, and preventing costly contamination events, transitioning from gypsum systems to uPVC cleanroom panels represents a strategic, high-impact investment in facility resilience and patient safety.