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Category 3 Compounding—Sterile, Stringent, and Slightly Scary

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There are similarities between USP <797> Category 3 compounding and 503B manufacturing, but they are far from identical. In terms of facility design, gowning expectations, cleaning and disinfection protocols, and overall stringency, Category 3—compared to traditional Category 2 compounding—touches the rim of CGMP-like expectations. This month, we highlight key similarities and differences in how these types of sterile compounding facilities operate.

What we know about USP categories and operations

Most pharmacy health systems typically operate within Category 2 compounding, while some blend Category 1 and 2 practices, depending on departmental functions. But what about the more stringent, challenging, and often elusive Category 3 tier? Why do so few pharmacies pursue it, and are any pharmacies stepping up to meet these rigorous standards?

One thing is certain: pharmacies cannot switch back and forth between Category 3 and Category 2 compounding to suit temporary needs. Once a facility elects to assign beyond-use dates (BUDs) longer than the limits established in USP <797> Table 13, all aspects of operations—competency evaluations, air quality monitoring, handling of supplies and materials, and other controls—must consistently adhere to Category 3 standards.

What to know about 503B requirements

503B outsourcing facilities are FDA-registered pharmacies that must comply with Current Good Manufacturing Practices (CGMP), including validated processes, environmental controls, batch records, sterility and stability testing, and robust quality management programs. They are subject to FDA inspections and must maintain documentation of all operations, deviations, and corrective actions. Unlike 503A pharmacies, 503Bs can manufacture compounded drugs without patient-specific prescriptions and must follow FDA labeling requirements and adverse event reporting.

503Bs may use only approved bulk drug substances, and most states require additional pharmacy licensing to distribute interstate. These facilities are designed for large-scale production, giving hospital networks and other healthcare providers the ability to secure reliable drug supply, mitigate shortages, and leverage standardized processes, but the compliance, operational, and cost burdens are substantially higher than traditional 503A or Category 3 compounding.

What to know about Category 3

Some might say the "C" in Category 3 stands for "Costly." The financial considerations are significant across every aspect of the program. From operations to supplies and materials, higher costs are inevitable. This includes the investment in staff training, ongoing competency evaluations, and maintaining full-time personnel to manage the environmental monitoring program, which is essential for confirming that the facility's design and operations remain in a state of control.

Design and construction are often where most people start. Imagining what the cleanroom suite will look like and defining the necessary parameters is arguably the fun part, despite it quickly becoming clear that costs are already higher than anticipated. What is often overlooked, however, is where planning truly enters the CGMP realm: validating equipment and processes, developing a robust quality management program, conducting sterility and endotoxin testing, and performing stability validation studies.

Even with careful planning, these activities remain costly, and traditional pharmacy leadership may not always be fully aware of or have the specific knowledge needed to create and implement comprehensive programs to fuel a Category 3 compounding setting.

Are pharmacies considering Category 3 compounding?

Yes, but not enough to tip the scales. Large health networks or those with a significant patient population may consider Category 3 compounding as a solution to reduce reliance on vendor outsourcing by bringing certain needs in-house. Several hospital systems have already pursued this approach, and others are likely to consider following suit.

Hospital systems have been rethinking their approach to sterile compounding, with many evaluating whether it makes sense to centralize operations into a single-hub location. On the surface, centralization promises cost savings, improved quality oversight, and reduced reliance on outsourcing partners such as CAPS or other 503B facilities. However, as with any structural change, the benefits come with significant challenges.

For many hospital networks, the solution may not be purely centralized or purely decentralized. A hybrid model often offers the best of both worlds: a central hub producing high-volume, stable Category 3 preparations, while satellite pharmacies continue handling immediate-use or short BUD items on site. This model potentially reduces risk in specific areas while ensuring responsiveness for urgent needs and capitalizing on many of the cost and quality benefits of centralization.

However, remaining partners with 503B facilities is important. Even with a strong central hub, hospitals may still need to rely on outsourcers for certain preparations that are too resource-intensive or complex to produce in-house. With that said, strategic collaboration should be an element to operations, rather than total independence from outsourcers.

Risks and reward

A Category 3 central hub must still comply with patient-specific prescription requirements. Each hospital's prescriptions must be securely transmitted, verified, and matched before compounding, requiring robust technology and seamless workflow integration. For networks operating across multiple states, pharmacy licensure and compliance with each state's board requirements must also be maintained. It's important to note that this practice is highly restricted and only permissible under specific circumstances. High-volume central facilities are also more likely to draw FDA attention if their operations resemble those of a 503B outsourcing facility rather than a traditional 503A pharmacy.

There are inherent operational vulnerabilities in a central-hub Category 3 model. If the hub experiences a sterility failure, contamination event, natural disaster, or regulatory shutdown, the entire health system's compounding capability could be disrupted. Unlike a decentralized model where individual sites can absorb local failures, a single-site model magnifies the consequences of downtime.

However, outsourcing to 503B facilities can be costly, particularly when purchasing daily or short-dated preparations. By investing in a central pharmacy hub that operates at Category 3 standards, hospital networks can extend beyond-use dates for sterile preparations, allowing for larger batch sizes and reduced waste. Over time, this can lead to considerable cost savings compared to outsourcing. Additionally, producing Category 3 compounds centrally gives hospital systems greater control over their supply chain and allows them to create stock cushions to better manage drug shortages.

Summary

Centralizing sterile compounding into a single hospital network hub presents both opportunity and risk. The promise of cost savings, better quality oversight, and supply chain resilience is real—especially with the possibilities afforded by Category 3 compounding under USP <797>. However, the logistical, regulatory, financial, and cultural challenges of such a move should not be underestimated. For large health systems, the most successful strategy will likely be a thoughtful mix of centralization, decentralized local compounding, and selective outsourcing. In an era of increasing drug shortages and rising quality expectations, flexibility and balance will be key to sustaining both patient safety and operational efficiency.

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