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The Consultant Boom — Expertise or Just a Business Card?

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Have you noticed that everyone seems to be an "industry consultant" these days? It raises a few fair questions: What is the role of a consultant? How does someone become one? And what actually makes a consultant valuable to a specific client base?

In this month's Compounding Chronicles, we examine blurred lines between certifiers and consultants and how these roles can commingle, where conflicts can quietly form, and how blended roles can unintentionally undervalue service to clients.

The Consultant's Role

Industry consultants are high-level problem solvers. They bring a fresh perspective to challenges that internal teams may be too close to or simply too overloaded to solve. More plainly put, a consultant bridges the gap between where an organization is today and where it needs to be.

Depending on the scenario, a client may require a team of consultants, each responsible for a specific area of expertise. A consultant is not "a person with opinions." A consultant should be a true subject matter expert (SME) with demonstrable competency, a track record, and a deep understanding of the risks tied to their recommendations.

And this is where the line gets thin: There is a meaningful difference between independent consulting and vendor-based advice. Both can be helpful, but they are not the same thing, and they do not carry the same incentives.

Can certifiers be consultants?

The reality is that certifiers have always been "consultants" to some measure. Controlled environment certifiers became increasingly valuable to sterile compounding pharmacies after the major revision of USP <797> in 2008. That revision accelerated the adoption of more advanced cleanroom designs, more engineering controls—and new to many pharmacy teams—viable environmental monitoring.

For certification companies that had been operating long before the early 2000s, cleanrooms were not a new concept. While USP <797> introduced major operational changes to hospital pharmacies, cleanrooms already existed across other industries with established design principles, airflow concepts, and performance expectations.

In many cases, the shock of new USP requirements, such as air changes per hour, ISO classification, pressure differentials, HEPA filtration, and cleanroom layouts, was partially navigated with the help of certification professionals who had been living in this world for years.

At the time, even facility departments, architects, and construction planners sometimes struggled to interpret and apply USP-aligned cleanroom expectations. Certifiers often became the translator between pharmacy operations and the engineering world.

The Challenge: When Certifier and Consultant Become the Same Thing

The problem begins when the certifier is also positioned as the consultant and the vendor for the "solution." When a consultant is also the seller of services or the organization responsible for the final compliance evaluation, the line between guidance and sales becomes dangerously thin.

A classic example emerged in the early USP <797> era with viable sampling. Many pharmacies began associating viable environmental monitoring with the certification process itself. This created an opportunity for certifiers to recommend sampling plans that were not operationally meaningful, were not scientifically justified, or were simply excessive.

Some organizations leaned heavily on sample quantity approaches that were never designed for sterile compounding quality programs (e.g., applying ISO 14644-1 grid-based logic without a risk-based rationale). In those cases, more samples meant more revenue but not necessarily better patient safety.

When the same entity provides both the recommendation and the billable service, recommendations can become unintentionally tied to the vendor's bottom line rather than the client's best interest.

Over time, the outcome is predictable: Clients lose trust because they can't tell whether they're buying a solution or being sold a product.

A consultant's primary value is their ability to critique a system honestly. But if you designed the system, you are naturally less likely to identify flaws in it later, especially when you return as the certifying body. Even with the best intentions, human nature and business pressures can compromise independence

We've seen this play out in real life with facilities that invested heavily in equipment or ISO 5 devices that looked compliant on paper but performed poorly in practice. Sometimes the problems were technical. Sometimes they were design-based. Sometimes they were simply unrealistic for workflow.

The Bigger Issue: Scope-Creep and "Helpfulness" that Becomes Risk

There is another dynamic that is becoming increasingly common: A pharmacy identifies an operational gap and turns to the certifier for help. The certifier wants to be helpful; The client wants a solution. The relationship is good. The request is urgent.

And then the certifier agrees to take on work outside its established scope or beyond its professional competency, either to keep the client satisfied or to expand services.

This is where good intentions become dangerous. Scope-creep can compromise pharmacy operations, weaken quality systems, and expose both the facility and the certifier to avoidable compliance and liability concerns.

What Responsible Consulting Should Look Like

Pharmacies do rely on certifiers for technical guidance, especially related to environmental controls, engineering standards, and testability. In many cases, certifiers also "go to bat" for their pharmacy

customers by helping interpret evolving expectations and explaining why certain designs or contractor decisions will not perform as intended.

That relationship is important. But it must stay responsible. Certifiers should absolutely advise on certification requirements, test methods, and what is needed for cleanroom performance to be measurable and compliant. However, they should avoid overstepping into areas where they are not truly qualified or where independence could be compromised.

Here are practical ways to improve this dynamic more responsibly:

- Separate sales from consultation whenever possible
- Create an internal divide between consulting support and compliance evaluation
- Deliver recommendations based on scenario assessment, not a service menu
- Consult on certification and testability—and stay within your expertise
- Hire specialists when expanding into new services (don't "fake it until you make it")
- Read constantly—regulations, standards, technical guidance, and enforcement trends
- Invest in training that is adjacent to certification but rooted in competency

Because in this industry, being helpful is not the same as being qualified.

Summary

IV compounding and cleanroom compliance are too complex for blurred roles and casual consulting. Certifiers play a critical part in sterile compounding success, but credibility depends on independence, defined scope, and professional competency. When consulting becomes sales, when evaluation becomes self-validation, or when expertise is overstated to meet client demand, everyone loses: the pharmacy, the vendor, and ultimately the patient.

The best organizations in this space are not the ones that claim they can do everything. They're the ones that know exactly what they do well, stay disciplined in their scope, and build trust by being honest especially when the right answer is, "This isn't our lane."

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