Specializing in Flexible Batch Manufacturing for Clinical Programs

Singota® Solutions is a CDMO located in Bloomington, Indiana, USA that specializes in Parenteral, Early Phase Drug Development and Aseptic Filling projects.

Temptations are high for small and/or early-stage pharmaceutical companies to partner with well-known CDMOs. Their reputation as service providers along with their ability to provide additional services (e.g., drug substance manufacturing), can make them attractive as potential partners for early-stage companies.

However, these larger CDMOs primarily are interested in large, high-volume batches that generate enough revenue to meet their business goals. While they can serve smaller companies in need of small batch fills, such work is not their priority. Recent industry trends, like orphan diseases, have proven the need for small batch manufacturing. At Singota, these are the companies we work with every day.

Still, smaller and earlier-stage companies remain, for the most part, overlooked by larger CDMO partners because contract values for small batch sizes are often not as lucrative as higher-volumes drugs. Large CDMOs often balance the needs of emerging programs against larger commercial manufacturing commitments.

When issues arise with a larger CDMO and schedules start shifting, smaller and earlier stage organizations often bear the

consequences. Such issues can cause delays in the lab, manufacturing, communications with PMs, and CDMO responsiveness. As these delays accumulate, they can impact project timelines and lead to outcomes that do not fully meet client needs or expectations. Significant scheduling delays at CDMOs, coupled with poor communication, can create high levels of frustration and anxiety for the client. A CDMO’s main goal is to maintain responsibility, value timelines of each client, and forward progress on its project matters.

Singota is committed to backing our early-stage and smaller clients through their important developmental work. When a sponsor or client needs a flexible partner to support manufacturing across a clinical program, Singota's flexible batch sizes and scheduling model allow for clients to have a voice in when

manufacturing objectives are realized. At Singota - client's are never sidelined.

Singota once helped a virtual company that was in a tough position. The manufacturing team had an aggressive schedule surrounded by uncertainty that their current partner was not meeting. They contacted Singota in the spring, requesting a fill over in the summer.

As spring came to an end, the issues they had encountered made them cut off the project. They promised Singota they would reach out if things changed. Two months later, the client reached back to let us know the project was back on. Now in an even greater time crunch, they needed help with formulation as they lacked a sufficient amount of API to work with. This client had no manufacturing methods identified or developed. Additionally, their formulation was not well-understood and the available API had been manufactured for earlier-stage research activities and required additional development work to support clinical manufacturing.

For a CDMO, helping a client navigate a situation like this requires a coordinated effort across the organization to meet both technical objectives and development timelines. This client required a GMP-ready process to develop material for human studies. This is a common challenge for early-stage companies, which are often advancing their science while simultaneously building the infrastructure and processes needed to support development. While these organizations are typically led by talented scientists, their priorities can shift quickly as programs evolve, creating the need for a flexible and responsive development partner.

This type of challenge is precisely where Singota excels. We brought the manufacturing and QC expertise they needed to complement their strengths. We helped add dedicated scientists, manufacturing associates, and project managers to their project – not just to accomplish milestones but actively helping the client figure out next steps. For example, recommending a different assay, manufacturing approach, or formulation that fits better in the client’s timeline. Ultimately, we were able to provide the material to the client within their tight timeline.

Singota Prioritizes: the small vertical company who is trying to figure things out as they go. Of course, it is easier to work with client’s that have all the details worked out; they hand us the finished package, we execute it, and we are done. But we also see great value in helping clients with the easy-to-provide services.

That commitment is reflected in the experience of another small virtual company that turned to Singota after experiencing repeated challenges with its previous CDMO partner, including missed deadlines and poor project coordination. This is a common challenge for smaller companies that rely on separate CDMOs for drug substance (DS) and drug product (DP) development. Delays in DS development and manufacturing can push back DP production.

In many cases, the issue stems from lack of flexibility. Large CDMOs are typically designed to support established commercial manufacturing campaigns whose schedules are predictable years ahead of time, versus an in-development drug with inexact timelines. Smaller and earlier stage

organizations can be crippled by the financial penalties associated with canceling and rescheduling a GMP manufacturing slot with a large CDMO. Accordingly, Singota's incoming client would have to reserve five or six time slots with their previous CDMO over the course of a few months with hope that they would be able to get their batch filled as quickly as possible, avoiding delays and possible penalties.

Singota is built to help navigate the trials and tribulations encountered by early-stage, small companies. Our scheduling process is designed to accommodate evolving timelines common in early-stage development projects. Expecting to fill some time in Q4? We will target that as a window of opportunity and, as we get closer to that time, we will refine down to the exact date. If the client realizes, "Q4 is not going to work. We need to bump this to Q2 next year," our flexible scheduling allows that to happen.

Many small and/or early-stage companies are unaware that they can partner with a CDMO specifically designed to meet their unique development and manufacturing needs. As a result, they often do not actively seek out this type of specialized support. Singota's operating model is built to serve this segment of the market. Our business model is built around supporting emerging organizations, whereas larger CDMOs are typically structured to prioritize high-volume projects that deliver greater financial returns.

This distinction allows us to provide solutions that larger providers often cannot justify operationally, including GMP filling runs with batch sizes of only a few hundred vials, rather than requiring manual filling, and the flexible scheduling needed to accommodate the uncertainties and evolving timelines inherent to drug development. For Singota, these capabilities are core to our business; for many larger CDMOs, they are not economically practical to prioritize.

Singota Solutions is a U.S.-based CDMO headquartered in Bloomington, Indiana, specializing in formulation development and aseptic fill/finish manufacturing for injectable drug products. From early-stage development through cGMP manufacturing, Singota combines scientific expertise, advanced robotic filling technology, and flexible batch size capabilities to support the unique needs of emerging and established biopharmaceutical companies. Learn more about Singota's integrated development and manufacturing services at **www.singota.com**.

To discuss your current or future injectable drug development program, contact solutions@singota.com to schedule a conversation with a member of the Singota Business Development team.