SPECIALIZING IN SMALL AND EARLY-STAGE PARTNERS, NOT JUST SMALL BATCHES

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

For small and/or earlier-stage pharmaceutical companies trying to advance a small volume drug product through preclinical and clinical trials, the temptation to partner with large, well-known CDMOs for aseptic manufacturing can be alluring. Their reputation as service providers for large pharmaceutical companies, along with their ability to provide additional services (e.g., drug substance manufacturing), can make them attractive as a potential partner 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.

The recent industry focus on orphan diseases and shift away from drugs that serve millions of people (e.g., cholesterol or heart drugs) has amplified the need for small batch manufacturing. At the same time, pharmaceutical developers have realized that serving a small population offers the opportunity to charge a premium for therapies they develop. Accordingly, new modalities such as cell and gene therapies are growing rapidly.

Still, smaller and earlier-stage companies remain, for the most part, ill-served by larger CDMO partners. Again, this is not due to a lack of expertise or professionalism in those organizations. These larger CDMOs will go to great lengths to take care of big-batch, big-name clients, but the experience of companies that bring small batch sizes and early-stage projects to large CDMOs can be very different. Because contract values for small batch sizes are often not as lucrative as those for higher-volume drugs, partnerships with companies producing small batches are not prioritized.

When issues arise at the large CDMO and schedules change, those smaller and earlier-stage organizations bear the brunt of it. Such issues span delays in the lab, manufacturing, communications with PMs, and CDMO responsiveness as a whole. Significant scheduling delays at the CDMO, coupled with poor communication, can create high levels of frustration and anxiety for the client. Making the product, meeting the client's base need, is not enough: a CDMO should be making sure that client feels its needs are cared about, its timelines are valued, and forward progress on its project matters.

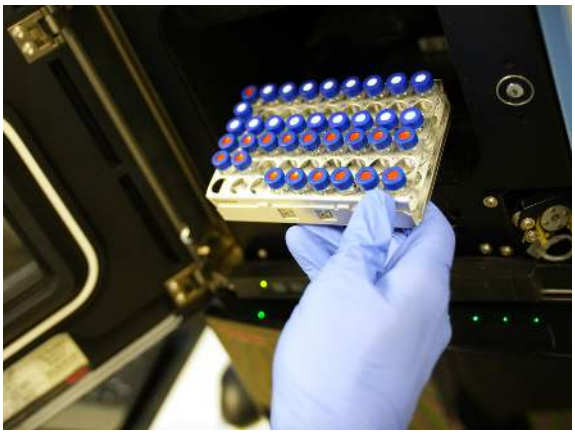
Singota is committed to backing our early-stage and smaller clients through their important developmental work. If a company needs one small batch now and another in 18 months, we work hard to earn the right to produce that next batch in 18 months, rather than fit it in if the project is advantageous on our end.

We recently provided fills for a completely virtual company that was in a bind. The manufacturing team had an extremely aggressive schedule surrounded by an enormous amount of uncertainty. They initially sought filling for small batches throughout the next year, as their needs were not being met by their current (at the time) partner. They contacted Singota in the spring, requesting a fill over the summer.

Spring begins giving way to summer, ink is about dry on the final proposal, and the client encounters an issue: they cut the project off and promised to reach back out if things changed. About two months later, the client reached back out to let us know the project was back on. Now in an even greater time crunch, they needed help with formulation and lacked a sufficient amount of API or drug product to work with. This client did not have manufacturing methods identified or developed. Their formulation was not well-understood and the only active pharmaceutical ingredient they had was not produced to GMP standard and was of questionable quality.

For a CDMO to help a client in such a scenario — achieving both the technical milestones and timelines required — takes an organizational effort. This client required a GMP-ready process to develop material for human studies. Such is often the case with early stage companies: where the client is, so to speak, building the plane while it's in the air. Most of these organizations are driven by good scientists, but things are dynamic and move very fast for them.

And this is where Singota shines brightest. We provided the manufacturing and QC expertise they lacked, dedicating seasoned scientists, manufacturing associates, and project managers to their project — not just accomplishing 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 ambitious timeline, and they're excited about the next campaign with us based on that experience.



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

Another small virtual company engaged Singota for help after its CDMO partner missed several deadlines or had the wrong project element ready at the wrong time. The final straw for the client's CMC director was the mess into which the manufacturing schedule devolved. It is common for small companies to utilize CDMOs on both ends: one CDMO develops drug substance (DS) material that heads to the drug product (DP) manufacturer. But DS development and manufacture often encounters delays, pushing back DP production.

However, many of the bigger CDMOs are used to dealing primarily with established, repeatable, commercial GMP batches. Their manufacturing schedule is 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/rescheduling a GMP manufacturing slot with a large CDMO. Accordingly, Singota's incoming client — even though they wanted to fill just one batch — 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. We do not require clients to sign up for a specific time slot. Expecting to fill some time in Q4? We'll target that as a window of opportunity and, as we get closer to that time, we'll 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 — no harm, no foul, just move on.

Our client was incredulous at this news at first, scanning the contract for loopholes, but finding none. That's just what an understanding and a dedication to serving the needs of smaller companies, in the earlier stages of development, looks like.

Final Thoughts

Many small and/or early-stage companies are not aware of the need, or the possibility, of finding a CDMO that specializes in meeting their specific requirements, so they do not think to seek out such a partner. Singota is uniquely equipped to handle this subset of clientele. Our business model centers around this type of work, whereas, for the big CDMO, it just doesn't make financial sense to jump through the hoops that would be required for them to prioritize such organizations' needs, whether it is batch sizes of a few hundred vials filled on a line, in a GMP environment (versus being hand-filled), or agile scheduling that accommodates the unknowns of development.

Singota Solutions is a US based CDMO in Bloomington, Indiana. Singota specializes in formulation development and aseptic fill finish for injectable projects. Once a formulation is established, Singota utilizes state of the art robotic filling technology and focuses on smaller batch size requirements. For more information, visit **Singota.com** & visit us on **LinkedIn** to explore how Singota has established itself as a one-stop solution for all your developmental needs.

Contact **solutions@singota.com** to schedule a meeting with our business development team to further discuss your current or future projects.