

SINGOTA: FASTER FROM FORMULATION TO FILL/FINISH

By Andrew Beshenwor, B.S. Biochemistry, Singota Solutions

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

Securing a drug development and aseptic fill/finish partner to support clinical applications can feel like a gamble. Cookie-cutter business approaches often lead to similar responses, even from boutique or otherwise seemingly different CDMOs:

"Maybe we can slot you in six months from now."

"Those materials will not be available for some time."

"Small batches are not our priority."

Singota has built its business — processes, equipment, communications, and more — with a focus on meeting clients' tight timeline requirements. We regularly help early-stage clinical clients (preclinical through Phase 3) progress from finalization of a project plan to filling a manufacturing batch within 8-12 weeks. Critically, Singota is flexible enough in both its internal operations and its client relationships to accommodate even the most complex projects.

For example, we often are approached by clients anticipating a clinical trial in two or three months, for which they need released material. One recent client, developing a COVID-19-related drug, approached us with a peptide and requested we develop a formulation and fill it. Within four months, Singota was able to fully develop the formulation, execute a tech transfer from our lab into our manufacturing suite, fill a batch, and complete final QC release. We encountered unexpected issues with Active Pharmaceutical Ingredient (API) formulation and buffer excipients, requiring our formulation scientists to not only devise solutions within a tight timeframe, but to do so with only a few milligrams of API.

Meticulous planning on the front end makes difficult work on the back end feasible. During the initial project assessment, numerous conversations take place between Singota's technical operations and business development representatives, including whether the necessary excipients are available in house (or the lead times to procure those materials are known) and how to work individual client needs into our available manufacturing slots to meet the project timeline. This up-front feasibility discussion and planning enables a project plan to move quickly as soon as it is executed.

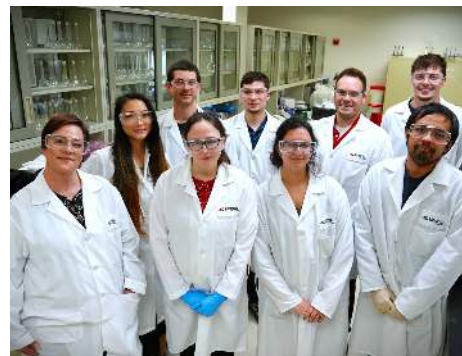
Constant internal communication about day-to-day operations (e.g., tracking a product's evolution to ensure successful manufacture) and upcoming projects is critical to maintaining flexibility on behalf of our clients. By striving to maintain a collaborative culture, versus the siloed departments of larger CDMOs, Singota strives to cut out much of the bureaucracy of internal communications, allowing for well informed stakeholders throughout the process and faster decision-making.

From an operations standpoint, the efficiency with which we complete batch records and execute tech transfers empowers us to work on multiple projects at any given time. Each client will determine their own dosing parameters, but due to the state-of-the-art filling machine, few variables on the recipes need to be changed. Inspection and finishing, even as custom jobs, tend to proceed similarly across clients. In serving the small-batch needs of numerous clients, we must be careful in our prioritization of the schedule, which requires clear, prompt communication with our project managers and our customers to fulfill ambitious timelines.

For example, we know, when a new project comes in for development, the lab and project manager will provide the timeline and execution communications to manufacturing. Day-to-day communication with the lab will be increased if a project is more challenging or demands tighter timelines than standard turnaround. This back-and-forth also helps us to quickly create appropriate records and ensures we can be flexible if something needs to change. Such agility is not possible in larger organizations.

In addition to focusing internally on streamlining processes that impede fast development and bolstering efficiency (e.g., decoupling sample plans from the batch record), continuous improvement is embedded in everything Singota does, from manufacturing and internal processes to warehousing of materials and issuance of material to orders in ERP. We are not afraid to — and sometimes, we must — change the way we operate to meet clients' timeline demands.

Such improvements may entail streamlining procurement of materials. Consider that raw materials often are purchased in huge volumes by large commercial manufacturers, rendering some scarce or with long lead times for smaller organizations, and that some vendors simply cannot meet our clients' timeline needs.



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Conclusions

Singota's drug development and aseptic fill/finish capability is the result of a calculated approach. Our manufacturing equipment, internal/external communications, and SOPs all have been designed with speed in mind. By foregoing commercial-scale manufacturing, we eliminate a lot of time-consuming operations, granting our customers greater timeline flexibility — and empowering us to focus on their developmental needs.

We continually reassess our practices to ensure we maintain manufacturing slot-scheduling agility, the ability to make process adjustments, and the means to pursue any other improvements that might accelerate delivery of our customers' products into the clinic.

To learn more, visit us at [Singota.com](https://www.singota.com) and on [LinkedIn](#).

Some common excipients from larger vendors regularly suffer supply constraints and extended lead times; being able to pivot and onboard new vendors in a short timeframe may be the difference in meeting a client's clinical timeline. Anticipating client needs and front-end planning, ensures we are prepared for projects sooner, and can complete them faster, than competing CDMOs.

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](https://www.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.