Urgent Fulfillment of Laboratory Study Request

Singota Solutions was contacted by the Director of Pharmaceutical Development of a small, research-focused biotechnology company – a versatile company for its size, with three compounds deep in clinical trials for diverse indications. Singota had previously provided solubility testing for five new, experimental compounds for this client; that project went smoothly and helped establish a working relationship.

Problem

Shortly thereafter, the client urgently needed help when another laboratory suddenly withdrew from a stability testing program needed for a high-value preclinical toxicology study. The client needed seven-day stability data with its formulation to give the study site confidence in the project before they actually began administering doses to animals. **There was a significant risk that without the data, the preclinical site would cancel the study, which was scheduled to start two weeks from the date when the client contacted Singota.**

Solution

Singota's project management team worked with the client to develop and document specific requirements, a project scope, a timetable, and a budget in a single day, only to find out from the client that the active pharmaceutical ingredient would not be available for delivery to Singota until just six days before the trial was set to begin. Thus, it was no longer possible to provide seven days of data.

"As soon as the material came to our laboratory, we immediately began to formulate," Ken Chomistek, Product and Analytical Development Manager, says. "We filled the large molecule formulations into vials, which we subjected to different thermal stability conditions. We performed our T_0 testing and were able to do the T_1 testing that Saturday. The following Monday morning, our scientists came in early to complete the T_3 testing. The data from the time points were summarized, peer-reviewed, and quality assurance reviewed. We delivered this data such that the client and the study site were able to move forward with the animal study with confidence."

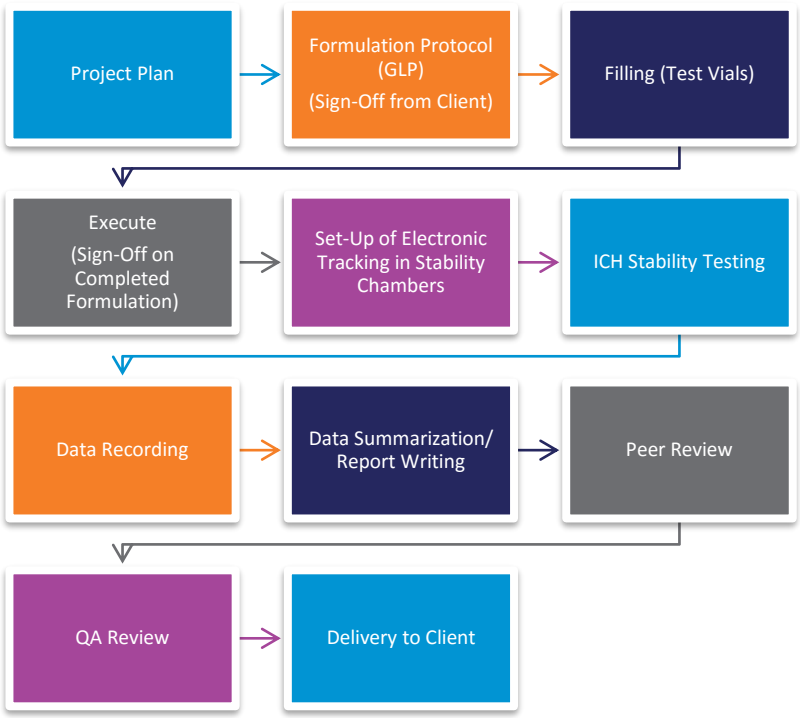
Singota continued the study to secure the rest of the seven days' data as it became available. As a result, the study site proceeded with the animal testing based on three days of data, satisfied that the product was suitable for the toxicology study – saving the client the money it already had invested in the preclinical phase.

"We had the expertise and the flexibility to meet our client's requirements quickly," Chomistek says. "Multiple people worked extended hours on the project. It also helped that the client's project manager

was based in California, because it gave us three additional hours [each day] of access to the client's resources."

The commitment from the client included quick turnaround on requests for review of documents, such that testing could move from one step to the next with the required approvals. Singota was working to fulfill the client's requirement; however, the client was looking to Singota for expert guidance on the design of the process of pulling everything together from the project requirements to the final stability report.

The urgency of the project required Singota to have the organizational resources, committed team, and the flexibility to expedite the client's work without delaying or compromising other ongoing development and analytical testing projects.



Process flow diagram of tasks required to complete client's stability program

Keys to Success:

- Expert scientific and project management staff;
- GLP procedures and cGMP analytical testing processes already in place;
- Availability of additional internal scientific resources who were not engaged in the project, to provide peer review and impartial QA expertise;
- Effective coordination between the Laboratory and Supply Chain service teams;
- The experience as a contract service provider to balance resources and priorities such that extraordinary situations can be handled without exceeding our service capacity.

Impact

- The client was able to complete a scheduled GLP animal study, which represented a significant financial investment, while maintaining the confidence of the preclinical researchers at the study site.
- The client maintained the schedule, and the momentum, of the preclinical development of the compound, which was in risk.
- The stability study was Singota's second project for this client, and the client has engaged Singota for four additional projects within a span of three months, including projects requiring other Singota facilities and services.