

Truly “Focused on Faster” for Aseptic Filling

Over the last few years, more small batch projects are emerging as pharmaceutical companies are developing therapies targeting rare diseases. Along with those products comes an increase in outsourcing projects requiring short lead times for aseptic filling.

Situation

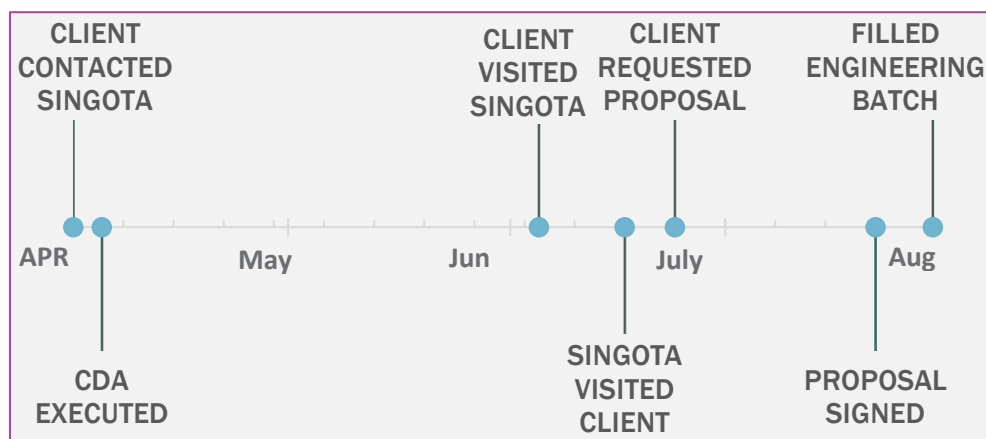
In April 2019, Singota Solutions was contacted by the Director of Formulation and Drug Product Manufacture of a small, research-focused biotechnology company looking to develop a relationship with a CMO partner. Their small molecule, Phase I / II project was several months out, so a general discussion occurred about Singota’s capabilities. In July 2019, three months after contacting and learning more about Singota, the client received incredibly positive results in the clinic for their current program and was instructed by leadership to push ahead quickly with an aseptic fill for another trial. They urgently needed to get their finished drug product clinical supplies to their distributor by December to make it in the clinic by January 2020.



Solution

Singota provided the client with a manufacturing questionnaire which included the product details. The client quickly provided responses to Singota, which allowed Singota’s business development and technical team to turn around a proposal within one week. The proposal included project specific requirements, a project scope, a

timetable, and a budget. Additionally, legal review of a Master Services Agreement, completion of a Quality Agreement, and the specific project details had to occur quickly and concurrently. The client had one week to review and return the proposal, in order to meet the aggressive timeline, so Singota could begin the work.



Timeline of Interaction Between Client and Singota

Singota’s proposal met all the client’s technical expectations. The client signed off on the proposal and a Singota Project Manager was assigned. Batch records were written and approved in one week and the client was on-site to watch their engineering batch being filled the first week of August. “Singota designed its processes to meet client needs, but specifically to fit tight timelines when projects like these come up. Everyone in this industry wants faster to market, but when your client needs it, we strive to be a CDMO that can meet those expectations with flexible and quality service,” said Laura Englander, Senior Business Development and Marketing Manager at Singota.