



Senior Director of Regulatory Affairs CMC

Case Study #4085

Search Metrics:

28 Days until hired candidate was presented
2 Total candidates presented
90 Days until search completed

Client:

Mid-sized pharmaceutical company on the verge of their first product approval. Filed first NDA and had frequent CMC questions with no CMC subject matter expert in place. Responses to the agency had to be addressed and a long-term solution was required.

Objectives:

- I. Lifecycle management and addressing agency inquiries on a commercial product
- II. Preparing CMC sections for 2 INDs in the next 12 months
- III. Establish the CMC regulatory department by creating SOPs and hiring additional staff

Prestige Solution:

On site meeting to conduct full needs analysis
Implement the Prestige Performance Search methodology
Develop unique Performance Profile describing objectives of role
Selectively introduce profile directly to target audience