PRODUCT PROGRAM MANAGEMENT

Program Management of Formulation Optimization

THE NEED

A growing biotherapeutic company, advancing a proprietary cytotoxic drug (against various cancers) with a better toxicity profile than the drug of standard treatment, required a much-needed revision of their drug formulation. The drug formulation, was effective and safe, however, the manufacturing process was not compatible for scale-up. Their drug product manufacturing partner was not able to resolve their formulation-driven manufacturing issues, leaving the client company with the option of meeting the immediate clinical demand through the manufacture of multiple small-scale batches, a scenario not viable for future commercial supply.

THE APPROACH

- Primecore developed the business case for the updated formulation that included multiple options including optimizing the existing to a completely new formulation.
- Planning stage included the decision to outsource the development activities to a service provider specializing in formulations containing cytotoxic drugs.
- Proposed a project management structure enabling the development activities to be governed, managed, and monitored without stretching internal resources or impeding clinical progress.

THE SOLUTION

Primecore presented a comprehensive development roadmap enabling the client company to confidently hand over the management of all formulation development activities.

- Primecore led the identification, evaluation, selection, and engagement of the development partner; prepared the request for proposal (RFP) and reviewed all the proposals generated. A total of eight potential candidates were evaluated and three shorted list for consideration.
- Primecore navigated contract negotiations and facilitated the technology transfer process, ensuring all critical raw materials and supporting analytical methods were in place for the selected partner to commence development activities quickly without hold-ups.
- Primecore managed the development program, inclusive of all project meetings between the client company and development partner, offering both management and SME expertise.

THE RESULTS

- *A development partner with relevant experience and working knowledge of hard to solubilize cytotoxic drugs was identified. The partner also possessed a proprietary drug solubilizing platform, affording the client company the option to generate new foreground IP should they opt to utilize the platform for their drug formulation.*
- *A revised stable formulation was developed within 12 weeks of initiating the program. The revised formulation showed promise of improved storage conditions; a switch from -80°C to 2-8°C and a stable, scalable manufacturing process.*
- *The proposed revised formulation required minimal 'non-clinical bridging studies' in order to integrate it into the existing clinical program with minor revision of the approved IND.*

PRIMECORE