Parsolex
PARTNER SOLUTIONS EXCELLENCE

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TECH TRANSFER FOR SMALL-SCALE COMMERCIAL PRODUCTION

Background

A global, large-scale pharmaceutical manufacturer had produced for many years a legacy drug product that cured a highly contagious and difficult-to-treat disease. Over the years, the demand for the drug product waned and manufacturing the drug product in one of its facilities was no longer cost-effective. The company was searching for a small-scale, fully current good manufacturing practices ("CGMP") pharmaceutical contract development and manufacturing organization ("CDMO") that could manufacture the small-volume drug product more economically. Parsolex was chosen to be that contract pharmaceutical manufacturer.

Challenge

The global pharmaceutical company had to be able to transfer the process technology and analytical technology in a timely manner. The new partner had to establish the supply chain and coordinate all the parties involved, including a new international active pharmaceutical ingredient ("API") supplier, regulatory consultants, analytical testing provider and re-packager.

The API was known to be both moisture and temperature sensitive. Additionally, the physical properties of the API included poor flow ability and required special capsule manufacturing capabilities. Parsolex worked in partnership with this major pharmaceutical manufacturer throughout the technology transfer of both the CGMP manufacturing and the analytical methods. Additionally, Parsolex worked with regulators to gain FDA approval to manufacture and market the drug in not only the United States but also worldwide.

To complete the technology transfer, Parsolex established a supply chain by negotiating and coordinating multiple relationships, including an international bulk API supplier, regulatory consultants, specialty analytical testing providers, re-packager and cold-chain management.

Owing to the small volume of drug product produced annually, expiration of the API kept in inventory was of great concern in terms of minimizing waste. Moreover, owing to the limited use of the drug, expiration dating of the final product was also of concern.

Solutions

Parsolex now operates the only FDA-approved site in the world to manufacture this lifesaving drug. Furthermore, Parsolex is now responsible for all aspects of commercialization for this drug, including final product release testing, distribution and marketing. Parsolex is proud to maintain the commercial supply of this vital drug that is a cure to a highly contagious, difficult-to-treat condition that the World Health Organization ("WHO") suggests will impact nearly half a million people each year, with cases found in nearly every country surveyed by the organization.

To address concerns of API and final product expiration, Parsolex was able to design a process that increased batch sizes by 50% and develop a packaging

approach to extend shelf life of the final product by 50% through accelerated stability studies, intermediate stability studies, and long-term stability studies.

Let us know how we can help with your Tech Transfer and Commercial Production challenges today.