CASE STUDY

How Syngene's tech transfer approach helped a biotech company fast-track NDA approval for a novel compound to treat infections

Syngene

Putting Science to Work

Overview

A leading biotech company was looking for a partner who could manufacture registration batches of their drug for NDA approval. The drug was a novel compound with an innovative mechanism of action for treating infections.

Syngene ensured 100% first-time-right technology transfer by designing the right set of experiments and manufacturing limited number of batches of the drug. We also successfully completed the manufacturing of three registration batches, including securing NDA approval in less than two years from the date of technology transfer.

The requirement

The client is a US-based biotechnology company pioneering innovative medicines to help millions of patients overcome and prevent difficult-to-treat infections that are becoming increasingly drug-resistant.

Their lead candidate was a novel agent with an innovative mechanism of action that could become an essential therapy for treating severe infections. The biotech company had partnered with a small-scale CRO based out of Canada for early phase- 1 and phase-2 clinical supplies. They were looking for a long-term partner who could manufacture registration batches of their drug for new drug application (NDA) and take up commercial manufacturing at a later stage.

Scope of engagement

The company decided to partner with Syngene as their NDA registration batch manufacturer and commercial supplier. Syngene was required to manufacture Phase- 3 registration batches, including subsequent commercial drug product batches. The decision to partner with Syngene was based on Syngene's successful regulatory track record of 28 years, where Syngene had cleared a host of global regulatory audits. We also had the right talent pool and the relevant technical "know-how" for the regulatory filing of registration batches and beyond.

The scope of engagement was as follows:

- Technical transfer
- Manufacturing registration batches
- ICH stability services
- Filing for NDA
- Supporting responses to NDA queries
- Scaling-up to commercial scale, process validation
- Commercial-scale manufacturing of the drug product

The above tasks involved scaling up processes to enable commercial-scale operations, manufacturing process validation batches, undertaking packaging, and ensuring commercial batch stability.

Technology Transfer for manufacturing and analytical

Syngene initiated the technology transfer process for manufacturing and analytical methods as a first step. While an in-depth review is part of any technology transfer process, it was particularly critical in this case as we did not have the time or raw materials to conduct additional trials. The mandate was to complete the technology transfer process with just one batch – a major challenge.

Using an in-depth risk assessment and control strategy, we successfully transferred the manufacturing process for the drug from the client's site to Syngene using just one batch. We did this by mapping the critical process parameters and devising an appropriate control strategy to ensure 100% 'first-time-right' technology transfer.

After completing the manufacturing of three registration batches and filing for NDA, we proactively initiated planning for process validation of commercial batches.

The biotech company had several other product requirements for commercial formulation. This comprised a unique embossing on both sides of the tablet, a distinctive packaging configuration, and additional testing requirements. We built all the requirements into the product during the process optimization trials and process scale-up stages. We also ensured compliance with stringent quality and regulatory requirements to secure NDA approval.

NDA approval and beyond

The biotech company went on to receive NDA approval for its novel molecule. The entire process, from registration batch manufacturing to product approval, took less than two years.

We are now partnering with the company for clinical supplies of the same drug but of different strengths and for new indications. We are also partnering with them to supply matching placeboes for clinical studies to support their global clinical studies for new indications.

Conclusion

Our success in getting NDA approval for the biotech company's novel molecule only goes to prove that Syngene is a trusted partner for Phase-3 registration batch manufacturing and beyond for companies working with new chemical entities (NCEs). With appropriate quality systems in place, we offer flexibility in the delivery of clinical supplies (early-phase versus late-phase). We also have the capability to become a one-stop partner to biopharma companies for entire clinical supply cycle requirements – early preclinical to GMP manufacturing of commercial supplies.

Our collaboration with the biotech company has extended into manufacturing additional strengths of the drug. We have also initiated discussions for proof-of-concept studies for second-generation manufacturing formulation, including an injectable formulation for treating severe infections.

To learn more about our Formulation Development services, contact our team

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About Syngene

Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022) is an integrated research, development and manufacturing services company serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods and specialty chemical sectors. Syngene's more than 5200 scientists offer both skills and the capacity to deliver great science, robust data management and IP security and quality manufacturing at speed to improve time-to-market and lower the cost of innovation. With a combination of dedicated research facilities for Amgen, Baxter and Bristol-Myers Squibb as well as 2 Mn sq. ft of specialist discovery, development and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK and Merck KGaA.

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