Recipharm

Accelerating an innovative high potency oncology therapy to market

High potency therapies continue to redefine what is possible for patients with limited treatment options. This includes innovative new hormone receptor downregulators, which are helping to extend the lives of patients with terminal cancers.

For the producers of these therapeutics, the path from development to commercial readiness is complex and, due to the acute needs of patients, time-critical. Success often depends on having an experienced partner, a contract development and manufacturing organisation (CDMO) that can anticipate challenges and deliver consistent operational excellence at speed.

When a global pharmaceutical company sought to produce a hormone receptor downregulator for oncology applications, Recipharm rose to the challenge. Leveraging deep expertise and experience with highly potent active pharmaceutical ingredients (HPAPIs) at its site in Leganés, Spain, the Recipharm team produced the therapeutic within a tight timeline, helping to bring its benefits to patients around the world.

COMPLEX CONSIDERATIONS FROM THE OUTSET

From its beginning, the project presented a series of technical and operational hurdles.

- **High potency requirements**
  The formulation of the therapy requires handling of HPAPIs, which can pose a health risk if inhaled. To ensure operators' safety, production of this formulation relies on HPAPI facilities with specialised containment infrastructure, such as negative pressure rooms, and filtering equipment, such as advanced air-handling systems. From initial sampling to the final stages of packaging, all operators at such sites must be properly dressed in personal protective equipment and trained on equipment handling and safety protocols.
- **A condensed timeline**
  The client required the project's rapid progression through technical batches, clinical supply and validation. This urgency was driven by both an acute patient need and the competitive pressures of the pharmaceutical market.
- **Supply chain challenges**
  The project relied on specific components and materials from suppliers approved by the client, some of which were based overseas. This element of global logistics added complexity and risk to already tight schedules. Securing critical materials and aligning them with production timelines would therefore require careful coordination and proactive planning.

BUILDING A PARTNERSHIP

Given its experience producing high potency therapies, the Recipharm team were prepared for these considerations and duly entered into the partner's structured onboarding process. This included a due diligence phase, in which cross-functional experts from the client side assessed Recipharm's systems, processes and capabilities across its specialised HPAPI facility. This open and transparent approach helped to build confidence early, establishing a strong foundation for collaboration.

Dedicated subject matter experts were assigned across quality, engineering and manufacturing science, creating clear points of contact and enabling fast decision making. A robust governance structure was implemented, including regular meetings and defined escalation pathways to ensure alignment at both operational and leadership levels.

Crucially, Recipharm adapted to the client's established ways of working. Understanding that global pharmaceutical organisations often operate through layered approval and communication processes, the team aligned with the client's existing structures. This flexibility ensured progress continued without disruption.

PROACTIVE PROBLEM SOLVING

Anticipating technical and operational challenges from the outset, Recipharm established a responsive project approach that enabled the team to identify risks early, act quickly and keep the programme moving.

One key issue involved supplier alignment. The client preferred a specific supplier for critical components, which differed from Recipharm's established site suppliers. Where possible, Recipharm helped to identify alternative suppliers closer to the manufacturing site to minimise transportation time and possible delays. A European packaging provider, for instance, was chosen to supply pre-designed bottles to enclose the eventual therapeutic.

Recipharm also worked proactively to address yield challenges. The partner's initial expectations accounted for substantial material loss, an estimation that reflected the uncertainty of working with a new molecule. Through engineering improvements and process adjustments, however, Recipharm consistently exceeded these expectations, achieving markedly higher yields and reducing waste of high-value materials.

In parallel, the Recipharm team applied advanced statistical analysis and design of experiments to optimise the manufacturing processes. By combining in-house expertise with client knowledge, data-driven adjustments were implemented to improve performance and consistency. This collaborative approach enabled continuous refinement of the process, leading to significant gains in efficiency.

ENGINEERING THE UNEVENTFUL WITH RECIPHARM

The therapeutic was produced on time, safely and to the high standards the client had expected.

"From the outset, the client had confidence in the rigour of our high potency containment strategy and our approach to operator protection," highlighted Ana Clemente Gaspar Lopez, Head of Project Management Office at Recipharm, Leganés.

"Our systems are designed to safeguard product quality while protecting employees working with HPAPIs. The client particularly valued the way we monitor containment performance and generate evidence that operations are being carried out in a controlled, safe environment."

"The client also valued our established experience supporting products for the Japanese market, which was a key target for the therapy's rollout," noted Raquel Linacero, Senior Project Manager at Recipharm.

"This is a highly specific market with distinct expectations, and relatively few companies outside Asia have the practical expertise required. Recipharm has produced for Japan for many years, supported by specialists who understand the requirements of this market."

The project reinforced the value of a partnership built on clear communication, respect and flexibility. From regular engagement with the client's teams in the U.S. to the timely delivery of a complex high potency programme, the team demonstrated the technical discipline and collaborative mindset needed to support demanding global launches.

About Recipharm

Recipharm is a leading contract development and manufacturing organisation (CDMO) headquartered in Stockholm, Sweden. We operate development and manufacturing facilities in France, Germany, India, Italy, Portugal, Spain, Sweden and the US and are continuing to grow and expand our offering for our customers. We are supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 30 years, we have partnered with our clients throughout the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and time again. We conduct our business as we always have and continue to deliver value for money with each customer's needs firmly at the heart of all that we do.

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