PORTON

CASE STUDIES

Agile and Fast:

Enabling Rapid Market Launch of Innovative Drugs from Preclinical to Commercialization in 18 Months

Background:

Clinical Phase	Preclinical to Commercial
No. of Steps	20+ Steps
Sites	Chongqing Changshou Manufacturing Site, Jiangxi Yichun Manufacturing Site, Hubei Xiaogan Manufacturing Site.

Highlights:

- 5 Synthetic Routes / 20+ Gen. Processes.
- 400+ mt products produced, output surged in 6 months.
- 150+ TCs & reports with development and commercial teams.
- Excellent project transfer and management capabilities ensure cross-team and cross-site collaboration and successful delivery.

In response to the surge in demand within the healthcare market, a client needed to expedite the launch of an innovative drug product while facing challenges such as process instability, mass production demand, and tight delivery schedules. As a CDMO company serving the global innovative drug industry, Porton has extensive experience in providing R&D and manufacturing services. Porton offers comprehensive, reliable, swift, compliant, and all-inclusive services, spanning from R&D to delivery, ensuring clients' commercial success.

Efficient Process Development and Scale-Up Production

Through rapid and efficient process development, analytical method development, technology transfer, supply chain development, and capacity planning and optimization, Porton completed the development of 5 synthetic routes for the project. We successfully achieved scale-up production and delivery from gram-level to several hundred tons, involving more than 20 process iterations.

Excellent Capacity Planning and Operations to Quickly Meet Large-Scale Delivery Demands

To meet the client's supply chain demands, it was necessary to achieve large-scale production delivery in a short period. While gradually optimizing the process, Porton improved product yield and cleverly adjusted its delivery solutions through capacity planning. As a result, production was scaled up within 6 months, with a total output exceeding 400 tons.

Superior Project Transfer and Management Capabilities to Facilitate Cross-Team and Cross-Site Collaboration

To ensure rapid delivery, Porton coordinated R&D and production resources across multiple sites, spanning 2 R&D centers, 3 manufacturing sites, and 4 cities. Through exceptional technology transfer and project management capabilities, along with effective supply chain coordination and strong teamwork, Porton ultimately facilitated the flawless delivery of the project.

In just 18 months and at an industry-leading speed, Porton progressed from small-scale R&D to pilot-scale delivery and then to commercial production. This journey encompassed rapid process development, the establishment of a stable supply chain, and commercial capacity planning. Over 150 technical documents and reports were produced to support clients in swiftly advancing early clinical projects towards market launch. Porton's end-to-end advanced technology service platform, excellent project management, and outstanding production operations capabilities were fully implemented and validated in this project.

As a CDMO company serving the global innovative pharmaceutical industry, Porton has leveraged its strong R&D and manufacturing capabilities to successfully provide CMC services for multiple drug pipelines of global clients, safeguarding their commercial success and enabling the public's early access to good medicines.

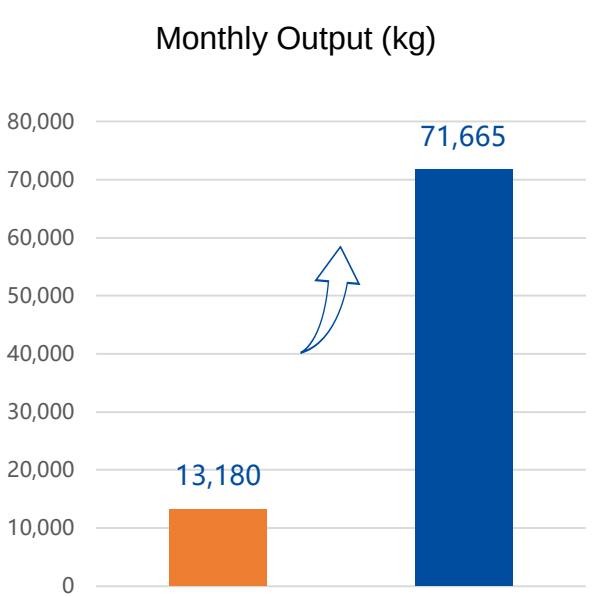
Achievement

20%
of the total separation steps were reduced through route optimization.

+30%
The overall yield is improved.

+25%
increase in capacity was achieved through PMI reduction and equipment optimization.

500-1000 kg/batch
The batch size achieved.



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