De-risking supply

Building a Resilient Active Pharmaceutical Ingredient Strategy Beyond China

Case Study

ESTEVE CDMO

DE-RISKING SUPPLY: BUILDING A RESILIENT ACTIVE PHARMACEUTICAL INGREDIENT STRATEGY BEYOND CHINA

Program Background

A global oncology-focused biopharmaceutical company, originally founded in China, sought an additional API manufacturer outside its home market to strengthen supply security and ensure continuity for a commercial oncology therapy. The product has been launched across multiple countries, with the U.S. and EU representing the largest market contributions.

ESTEVE CDMO needed to demonstrate late-stage expertise, recent FDA/EMA approval, and capacity to deliver up to 15MT per year in commercial stage. Key requirements included high-pressure hydrogenation, jet milling under containment, and strong process consolidation, all within an 18-month transfer-to-PPQ completion timeline. ESTEVE CDMO was chosen for its integrated European network, offering the scale, technical capability, and regulatory track record to meet these demands.

Challenges and Key Factors

The program's complexity was defined by three critical factors:

- **Scale:** The product required multi-ton annual supply
- **Specialized Process Needs:** The synthesis involved high-pressure hydrogenation combined with jet milling — both advanced technologies that are heavily relied upon across the industry and therefore in constant demand.
- **Time:** The customer imposed a strict 18-month deadline

The combination of volume, highly specialized technology, and speed shaped the design of ESTEVE CDMO's response.

ESTEVE CDMO

Solution Overview & Execution

ESTEVE CDMO proposed a networked, dual-site manufacturing strategy in Europe, supported by robust synthesis & analytical tech transfer, alongside an experienced EHS team ensuring a safe and compliant transfer to the new sites.

Familiarization & Tech Transfer

- Applied scale-down simulations and 25L lab batches to ensure reproducibility before scale-up.
- Conducted safety studies, including explosivity testing on retained API.
- Completed nitrosamines and PMI risk assessments to strengthen regulatory compliance.

Analytical Package

- Transferred and validated the required analytical methods.
- Coordinated analytical readiness with manufacturing milestones to maintain timeline integrity.

Manufacturing Network Strategy

- Celrà: Equipped with two hydrogenators (3m3 and 4.5m3), both >10bar.
- Lliçà de Vall (LdV): Vessels up to 12m3, enabling 250kg batch sizes and reducing campaign frequency.

Execution Plan

- **Phase 1** – **Familiarization & Validation**: An 18-month program focused on process familiarization and validation across multiple sites.
- **Phase 2** – **Commercial Manufacturing**: After validation, a one-year ramp-up is planned to enable annual deliveries of up to 15MT.

The multi-site approach incorporated partial deliveries and continuous campaigns to ensure continuity and scalability.

Outcome: The program advanced on schedule, demonstrating ESTEVE CDMO's ability to combine technical rigor, parallel execution, and supply resilience in a single integrated solution.

Summary

This case highlights ESTEVE CDMO's strengths as a late-stage and commercial partner:

- A global oncology biopharma company sought to **de-risk its API supply by securing a secondary manufacturer outside** China for a high-volume oncology therapy.
- **ESTEVE CDMO was selected for its Global network**, advanced capabilities in high-pressure hydrogenation and jet milling, and proven regulatory track record. By implementing a dual-site manufacturing strategy with synchronized tech transfer, safety validation, and analytical readiness, ESTEVE CDMO met an aggressive 18-month PPQ timeline.
- **The program progressed on schedule, ensuring up to 15MT annual supply capacity** and significantly strengthening the **client's global supply resilience.**

ESTEVE CDMO global partner for complex challenges, delivered on time.

ESTEVE CDMO

ESTEVE CDMO, *The Science of Collaboration*

ESTEVE CDMO is a global pure-play partner in small-molecule APIs and advanced pharmaceutical intermediates, collaborating closely with our customers to turn complex science into scalable solutions.

Powered by 1,500+ experts worldwide and recognized as the 2025 CDMO Leadership Award Global Champion in Small-Molecule API, we support programs from early development through large-scale commercial manufacturing.

Our end-to-end capabilities include process R&D, analytical and stability services, CMC, and commercial intermediates, with proven expertise in Spray Drying and HPAPI (up to OEB5) across six sites in the U.S., Spain, Mexico, and China.

THANK YOU

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