



ESTEVE CDMO



**Lightspeed Global API
Delivery Through
Multisite Collaboration**

Case Study

LIGHTSPEED GLOBAL API DELIVERY THROUGH MULTISITE COLLABORATION

Program Background

A global pharmaceutical company selected Esteve CDMO to rapidly industrialize and supply a high-volume API needed to meet urgent worldwide demand. While the project was initiated during the COVID-19 pandemic, the client's decision was based on years of successful collaboration in which Esteve CDMO demonstrated exceptional reliability, technical strength, and a highly transparent, partnership-driven way of working.

The program was launched through tight coordination between the Spain and Mexico site, while Esteve CDMO simultaneously fast-tracked an existing capacity-expansion initiative to bring a third CGMP site online. This allowed the network to absorb the additional volumes and complete the full commercial campaign. **The scale, timelines, and strategic importance of the product required an accelerated technical transfer and industrialization approach while maintaining full regulatory compliance.**

Challenges and Key Factors

Key complexities included:

1. Compressed Timelines

- Manufacturing needed to **begin within 70 days of project award date.**
- Industrialization, analytical transfer, validation, and supply chain readiness had to run in parallel.
- **Comparable commercial programs typically require 1.5–2 years to reach a similar scale.**

2. Multi-Site Commercial Execution

- A 20-metric-ton API campaign needed to be executed across three CGMP facilities on two continents followed by several other double-digit metric-ton campaigns immediately after.
- A global team operating under the same standards, quality systems, and communication model, essential to maintain alignment and avoid bottlenecks.

3. Large-Scale Supply Chain & Equipment Readiness

- High-volume raw materials and critical intermediates required global sourcing coordination during a period of heightened supply chain volatility.
- Specialized analytical and particle-size control equipment had to be acquired, installed, and qualified on an accelerated schedule.
- Maintaining speed required a mature decision-making framework and a tightly integrated cross-functional team.

Execution & Outcome

Esteve CDMO deployed a fully integrated, multi-site execution model to meet the program's accelerated requirements while maintaining full CGMP compliance.

Key components of the execution included:

Integrated Multi-Site Project Structure

- Daily cross-functional touchpoints across production, quality, engineering, analytical, and supply chain
- Direct expert-to-expert communication with the customer for rapid escalation and aligned decision-making
- Harmonized QMS enabling unified documentation, aligned deviation management, and consistent batch governance

Quality as a Strategic Enabler

- Risk-based planning allowing validation, analytical transfer, and manufacturing readiness to progress in parallel
- Quality teams acting as collaborative problem-solvers while maintaining regulatory standards
- A central success factor was the trust and collaboration established between Esteve CDMO and the customer, which enabled the adoption of a joint "lightspeed approach." Both teams aligned on a risk-based framework to determine which activities could safely run in parallel; an approach only possible within a highly transparent, trust-driven relationship.

Agile Global Procurement & Supply Chain Network

- On-the-ground procurement coverage in Europe, India, China, and North America
- Real-time supplier qualification and contingency planning to secure large-volume raw materials
- Logistics optimization, customs navigation, and accelerated import/export support
- Continuous monitoring of global constraints with proactive rerouting to avoid delays
- In parallel, Esteve CDMO also supported the customer through an Inward Processing Relief (IPR) process with Spanish authorities, mitigating the tax impact associated with high-volume imports and demonstrating the depth of our commercial and regulatory procurement capabilities.

Rapid Technical & Equipment Readiness

- Accelerated acquisition and qualification of critical equipment—including HPLCs and particle-size analyzers—in under one month
- Remote qualification and virtual FAT/SAT processes to eliminate waiting time

Commercial-Scale Delivery

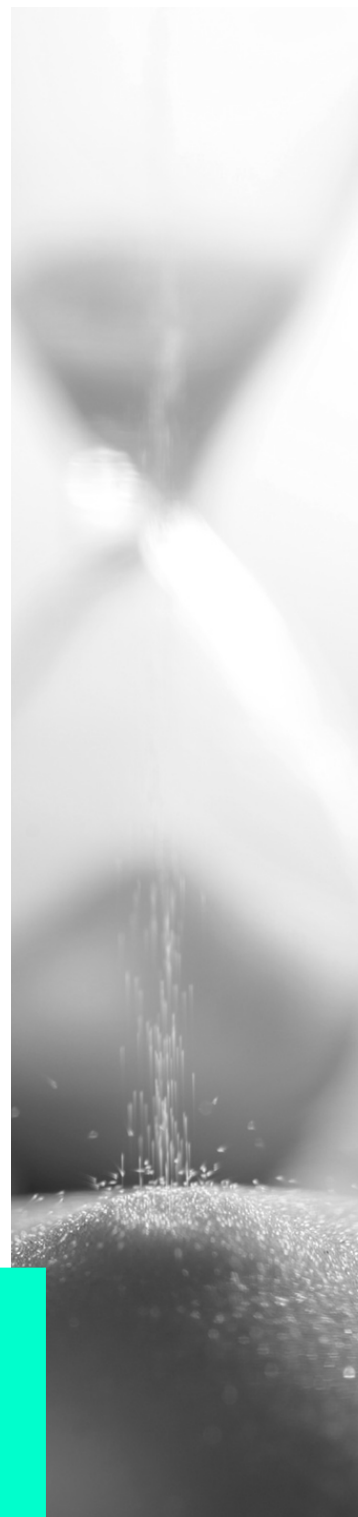
- Manufacturing initiated 70 days after program award date
- 20 MT of commercial API delivered across two sites within nine months
- Stable, high-quality supply enabling uninterrupted availability of the finished medicine
- During the 20MT lightspeed campaign, Esteve CDMO strategically acquired, revamped, and integrated a new site, ensuring capacity for validation and future scale-up for several additional double-digit multi-ton campaigns.

Outcome: Esteve CDMO delivered a large-scale, multi-site API program at unprecedented speed and quality, thanks to a highly integrated execution model, a trust-based collaboration with the customer, and resilient global quality and supply chain systems.

Summary

- **Manufacturing** began within **70 days, delivering** 20 MT of API in **9 months** across two integrated CGMP sites.
- The program succeeded through **close customer collaboration and Esteve CDMO's core capabilities:** a harmonized quality system, a mature multi-site operating model, and a resilient global supply chain.
- Esteve CDMO stands out not only for its technical expertise, but for **how we work:** transparent partnership, cross-site alignment, and robust global quality and supply chain infrastructures.
- These are exactly the capabilities companies should prioritize when choosing a CDMO, and **they are the strengths that make Esteve CDMO a trusted partner for fast, compliant, multi-site API programs.**

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



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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