



Five Reasons to Outsource API Procurement

There's a reason why DIY renovation disasters make for good television. Watching a hapless homeowner backslide from cost-conscious bravado ("I'll be my own general contractor!") into a quagmire of sunk costs and crumbling drywall feels gratifying, somehow. There's a delicious high-minded pride in knowing that we wouldn't make the same mistakes. If it came to it, we would have the good sense to call an expert and get the job done right the first time.

What does this have to do with API procurement and supply chain management? *Everything.*

INTRODUCTION

Pharmaceutical development and manufacturing is an expensive business. Owners and managers, particularly those in young, lean firms with paper-thin margins, are under tremendous pressure to lower operational costs. Under these conditions, many choose to manage their supply chain themselves ("I'll be my own API specialist!"). Sometimes, with a great expenditure of effort and time, it works. But when it doesn't, the whole house can collapse. Your supplier fails to deliver on time. Your materials spend weeks at the border, ensnared in regulatory red tape. Or they arrive, only to fail your quality control testing. Repairing this damage takes money and time you don't have, and attention you can't afford to spare.

There will always be companies that choose to accept these risks and pursue the DIY approach. That's fine—let them at it. But for those of you who got into this business for the science, not the paperwork, there's an alternative way forward: partnering with API procurement and supply chain specialists. They work in the midst of complex and evolving global regulations to ensure door-to-door delivery of your materials while you remain focused on innovation and growth.

Here are five reasons to outsource API procurement and supply chain management to a trusted and experienced specialist:

1

You'll get VIP access to API manufacturers.

Because the best procurement specialists enjoy a pristine reputation in the industry, high-profile API manufacturers lift the velvet rope to give them access to services that simply aren't available to most lone companies.

Phone calls are answered. Meetings are prompt and successful. Requests for special arrangements, like small or large quantities or materials with different specifications, are swiftly and creatively accommodated. By partnering with a procurement specialist, even a small biotech startup can negotiate with the influence of a much larger and more mature pharmaceutical company, leading to better pricing, tighter timelines, and more flexibility.

2

You'll be introduced to the perfect supplier (who you didn't know existed).

Access to the big players in the API supply chain is one thing. But many companies need services of a different sort, the kind that only niche API manufacturers with a modest customer list can provide. These suppliers, less well-known but no less qualified, have the agility and bandwidth to partner with biotech firms looking to control their costs (through API lifecycle management, for example) or develop unique formulations (requiring modifications to approved ingredients). In a crowded market, these innovative suppliers can be hard to find. Once found, they can be hard to distinguish from less reliable lookalikes.

A procurement specialist can help. They've done that vetting already, pruning their digital rolodex to include only suppliers with spotless reputations and modern, compliant CGMP operations. The most diligent of these specialists will personally approve manufacturing facilities in their annual "boots on the ground" inspections. This means you get connected with suppliers nimble enough to meet your project's needs, yet small enough that you're treated not as one customer among many, but as a priority partner with important objectives.

3

Your supply chain will deliver at hyperspeed.

Due diligence. These two simple words conceal the immense regulatory complexity of the pharmaceutical supply chain: tariff classifications, FDA notifications, licensing, certifications of suitability, end-use letters — the list goes on.

An experienced procurement specialist knows how to maneuver your APIs through this deluge and into your lab smoothly and quickly, streamlining your entire supply chain like the Amazon of pharmaceuticals. Simply place your order and a specialist will help move your sensitive materials from the manufacturing site through customs clearance to your facility, securely and according to product specifications.

4

You'll be compliant. Always.

There's a trick to ensuring that your operations and materials comply with regulators' expectations, even in today's world of intense scrutiny and rapid change: leave it to an API procurement specialist.

They've mastered the high-wire act of preparing, managing, and maintaining their customers' regulatory submissions throughout the development lifecycle. As the FDA turns more attention to traceability issues and API chain of custody, so too are the most advanced procurement specialists devoting substantial expertise to ensuring the quality and compliance of their clients' documentation. These specialists are fluent in the opaque language of Active Substance and US-Drug Master Files (ASMF and DMF), Quality Overall Summary (QOS), and Certificates of Suitability (CEP). Are you looking to accelerate a new drug approval under the 505(b)(2) pathway? Or do you need to comprehensively identify and resolve compliance gaps in your existing supply chain? A procurement specialist will consult with you to develop an API source tailored to meet your objectives, whatever they are.

5

You'll gain the insights and connections you need to plan for the future.

The most experienced API specialists know the manufacturing industry so well that they're able to confidently predict future trends and opportunities, helping you to map your individual business objectives to the movements of the global marketplace. It's not clairvoyance, although it looks that way sometimes. While you focus on innovation, your procurement specialist is focused on the global API market and how to make it work for you.

In this way, such a specialist is more partner than vendor. They have access to intelligence databases that keep them in the know about API pricing and importing activities, which helps them negotiate the best prices for you. Some have global offices to give you first-in-line access to facilities in India and China. The best of them attend relevant trade shows and events to continuously strengthen their worldwide network, cultivating flexible supplier relationships that traditional brokers simply can't offer.

These are the relationships that a good procurement specialist can call on when you need customized APIs, or a difficult-to-find molecule, or new chemical entities (NCEs) to meet your drug development needs. Some specialists don't stop at APIs, either. Need someone who can provide a reliable, pre-qualified fill finish service for your injectables? A good procurement specialist can make that introduction. Need off-site storage to keep you mobilized for rapid growth? Look for a specialist with available warehousing and the logistical solutions to ensure your materials are available on demand.

Toward a more secure supply chain.

You're an entrepreneur. An innovator. DIY is coded in your DNA. This is one of your strengths, but it also creates pressure to operate beyond the scope of your experience or interests — especially if you're required to cut costs.

Some companies do find an API manufacturer who answers their calls and provides the materials they need. But without a procurement department on-staff, this effort represents a colossal investment of time for front-line employees—time not spent at the lab bench, moving products toward commercialization. Does this represent procurement success? In a way, yes. But it's a meager success, with a heavy price. It nibbles at that company's bottom line, limits their velocity, and builds risk into their supply chain.

LGM Pharma represents another way forward. We are leaders in API procurement and supply chain management with a history of tailored service for clients large and small, from major pharmaceutical companies to lean biotech startups. If you already have a procurement team, we can extend its reach and strengthen its negotiating power. If you don't, we can become that team. We'll help you drive innovation by giving you access to the best prices, the greatest flexibility, and the highest quality of API ingredients, right-sized for your project and documented according to the latest regulations and customs requirements.

For smooth door-to-door API procurement services, without DIY headaches, call us at 1-800-881-8210 or email info@lgmpharma.com.

LGM Pharma provides pharmaceutical, biotechnology, and compounding pharmacy clients with expert API sourcing and CDMO services for complete supply chain management across all phases of drug development. With a long-established positive regulatory track record, we are trusted advisors for regulatory and market intelligence. We focus on quality, exceptional customer service, and custom solutions, to give our clients a comprehensive, one-stop solution that reduces risk, increases efficiency, and accelerates a smooth path to commercialization. Partner with LGM Pharma. Now that's smart.

