

# Should you Use an Overseas Partner When Manufacturing Controlled Substances?

## Key Considerations for Selecting a CMO

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Many bio/pharma companies turn to overseas Contract Manufacturing Organizations (CMOs) for the development of their controlled substance pharma products, often because manufacturers there can provide low-cost production facilities and labor. While using CMOs in places like India or China can make sense in some instances, this article outlines how sometimes the risk can outweigh the benefits.

## When Does It Make Good Business Sense?

For sponsors developing a new drug product, and being strictly in the development stages when large batches are not yet required, partnering with an overseas firm that is already commercially manufacturing the material can provide a big boost to your product timetable and eliminate lots of developmental steps.

For example, certain controlled substances such as Ritalin or Adderall already have established suppliers in foreign countries with permission to ship to the U.S. market. In a situation like this it would not make sense to manufacture it on your own - there really would be no need to reinvent the wheel.

However, when you are working with a new compound classified as a controlled substance, it's a different story: in that case you should almost always work with a CMO in North America.

## What are the Challenges of Overseas Manufacturing?

Importing controlled substances to the U.S. is never easy, given the logistical challenges, regulatory controls and time difference. And with controlled substances, the involvement of the DEA only compounds the regulatory requirements.

Regulatory Environment. For many years the facilities of manufacturers in India and China, for example, were not inspected. But the advent of stricter inspection policies enabled by the Generic Drug User Fee Amendments (GDUFA) increased the FDA's ability to fully inspect offshore facilities more closely to ensure that they are strictly following Good Manufacturing Practices (GMP), as well as Western standards. This closer scrutiny has often resulted in failed inspections and

subsequently banned imports. While costs can most certainly be cut when inspections go right, failed inspections often result in costs doubling or tripling when production needs to begin all over again in Western facilities.

Time-Zone, Cultural Barriers. Another issue has been the difference in time zones, language and cultural barriers. Most controlled substance projects are complicated, with lots of moving parts and regulatory activity. This type of complexity requires a close partnership and regular, open dialogue between a sponsor and its CMO. When a CMO is maybe 6-13 hours ahead of the U.S., it can take more than a day to be able to connect.

Litigation Challenges. If any issues arise regarding intellectual property (IP), litigation can be extremely challenging when addressing them from abroad. This is particularly true given that the laws in other countries do not necessarily provide the same IP protections as in the U.S. If you do work with a CMO in another country, it is often helpful to work with a broker or agent on the ground who can advocate for you when needed.

If you do, however, go the overseas route in your controlled substance manufacturing project, make sure to ask the following questions:

1. What percentage of your business is with U.S. companies? The answer will give you a good idea of how experienced the company is in terms of navigating FDA and DEA guidelines and policies, as well as how they are able to assimilate the U.S. business culture and time-zone barriers.
2. How do you address security? Inquire about the security measures they have put in place to be able to effectively handle controlled substances. Do they have authorized access entry to labs and plants for specific personnel? Do they require employee drug testing? Do they have 24-hour surveillance of vaults containing the controlled substances?
3. What are the local regulations for exporting controlled substances? Inquire about their country's regulations for importing controlled substances, as well as the U.S. regulations for receiving them.
4. Can you give me references? Speaking with U.S. customers for whom the CMO has manufactured controlled substances is one of the most important steps you can do to vet a CMO partner.

Since a major contributor to successful commercialization of controlled substances is having the right partners in place to make them a reality, companies need to do their homework when it comes to selecting a CMO – whether overseas or in the U.S. Cost or convenience should not be the watch words, but a successful partnership should involve collaboration, experience and an acute understanding of the requirements of controlled substances.

To learn more about our insights into controlled substances check out our blog article, [Generics for Controlled Substances](#). And please feel to call us (978) 462-5555.