How To Select An API Partner For Strategic Success

A strategic partner should always seek ways to innovate and improve your compound or product's value, and do it with the dedication of a partner, not a supplier. With the growing importance of contract services and plenty of providers, it is more critical than ever to make the right choice.

1. Skill in accelerating route to market

The more directly and succinctly a drug developer can manage a drug's critical timelines on the way to market, the more successful the product will be financially, both in the short and long term. Early, intensive synthesis analysis for safe and scalable chemistry is one way how an API partner can add value.

2. Drive for continuous improvement

If your chosen small molecule API manufacturer is not constantly focused on continuous process improvement, they may not be the perfect partner for strategic drug supply. CDMOs with experience and vision are able to bring an intelligent, collaborative approach and the insight needed for innovative solutions.

3. Consistent supply chain

Reliable access to a well-executed quality supply chain is a vital attribute of any strategically important supplier. How well the API supplier manages its own raw material supply chain is a leading indicator. Any disruptions to your supplier's supply chain and your API delivery may be delayed.

4. Focus on sustainable industrial processes

Those CDMOs that live core sustainability principles of reuse, recycle and reduce, not only deliver environmental benefits but are likely to be the most cost-efficient processors. CDMOs that put an emphasis on delivering cleaner chemistries that reduce their impact on the environment through best-practice operations and technical mastery are better able to deliver project economies.

Suppliers that can provide more stable chemistries and efficient batching are more effective. Those with experience optimizing processing methods that reduce or recycle intermediates and other hazardous by-products, are worth considering.

5. Expertise and experience in robust process development

Drug development routes are getting more complicated and the APIs in high therapeutic demand are getting harder to make. Robust process development is paramount, but it must be matched with deep science and process engineering acumen. This clearly extends to troubleshooting and refining synthesis to find new or better production and cost economies, as well as creating more robust and effective processes that increase quality and reliability.

6. Quality systems and operational excellence

Achieving critical quality attributes (CQAs) with consistency and transparency is certainly a prerequisite for any strategic supply relationship. But for pharma, it is a fundamental requirement and a key performance indicator when assessing the potential for long-term reliability and quality.

For APIs of every kind, one common CQA denominator is the ability of your API partner to effectively control contaminants or impurities during all primary and intermediary processing steps.

Another KPI is the ability to control and manipulate an API's physical properties effectively. A supplier that can accurately engineer API attributes to meet drug formulation and drug product (DP) targets early in a small molecule API program can often yield efficiencies to leverage later in the journey to market.

Lastly, when combined with a robust and repeatable process, "small molecule" API becomes "commercial-ready" API with a validated process, proven and ready to go the distance over the drug product's life cycle.

Final thoughts

Contract developers and manufacturers of APIs are now playing an even more important role in drug development strategies. Success of a drug might hinge on the partner's technical and operational capabilities and their experience synthesizing the target compound. Considering the above attributes might create the perfect chemistry between you and your API partner.

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