Eight criteria for a more successful API partnership

Outsourcing API development can save time and money. Or it can waste them. Since the difference between these outcomes stems from your choice of a development partner, careful consideration of these eight critical areas is required to help ensure a fast, smooth API development process.







Scientific capabilities:

your partner should have the breadth and depth of experience that comes from having developed thousands of chemical transformations and can guide you to a successful outcome.



Toxicology expertise:

it's essential that your partner has in depth knowledge and expertise in the toxicology of compounds to ensure the protection of people, other products, and the environmentlf your product is packaged in a different facility, will your provider have sufficient capacity to store your product at the right temperature until they are ready to run the job?



Drug product perspective:

The connection between drug substance and drug product formulation is critical. Your partner, having an integration between chemical synthesis and formulation, can manufacture a formulation enabling API to ensure a more successful product development process.



Supply chain:

if starting materials aren't ready and can't be purchased off the shelf, does your partner have experience finding them at required quality, or have access to a qualified supplier network? Establishing such a network is a long-term process that requires supplier visits and auditing.



Experience:

do the scientists at your API partner have sufficient knowledge and experience? A proven track record of predicting roadblocks and solving challenges will ensure your development timelines are achieved with robust processes.



Culture:

The transparency of your API partner and their proactive commitment to your success is a major factor. How well do they collaborate and react to your changing needs? Culture also affects tenure: if none of your team members from your last project are still around, what does it say about the culture?



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Lifecycle management:

Your partner should help strike the balance with an API that is neither over-engineered nor neglected for the intended use and phase it is currently in. Your ideal partner also should give you a view on early and late-occurring factors that can ensure success.



Financial strength:

This directly affects your API partner's ability to invest in state-of-the-art equipment and continue to operate to ensure you will always have a partner to take care of your manufacturing needs.