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**To Outsource
Or Not**
That is the question

by Michael Ruberto, Miles Hutchings and Dean Hamel

To Outsource Or Not: That Is the Question

When to look out of house

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MANY PHARMACEUTICAL COMPANIES view outsourcing in one of two ways: a complementary partnership that hastens a new product's journey to market, or an uncomfortable process that raises issues of control and confidentiality. Can a sponsor create favorable odds for a positive Contract Service Organization (CSO) experience? Whether you're looking for toxicological analysis, contract synthesis, Environmental Health & Safety (EH&S) testing & auditing or regulatory services, it's all a matter of asking the right questions.

The first question for a potential sponsor to ask upfront is: Do we really need to outsource? Some pharmaceutical companies have impressive in-house capabilities that allow them to analyze and test their own products—but they sometimes encounter roadblocks when investigating elements outside their sphere of expertise. Others recognize that the ability to concentrate effectively on their core competencies—innovating new drugs, producing and bringing them to market—requires that they outsource non-core competencies to a credible CSO. This is where the situation can get tricky. The first impulse may be to use a consultant employed in the past for general services. While familiarity may initially provide a level of comfort, it begs the second question . . .

What Are the CSO's Credentials?

If you don't have the necessary resources, knowledge and analytical capabilities in-house, your chosen Contract

Services Organization must have them. A medical device company, for example, should look for a CSO with a clear history of working with polymers, pigments and stabilizers,

A pharmaceutical company's core competencies lie in drug research, development, production and marketing.

Does it make sense for them to conduct complex analytical testing as well for the plastics used in drug delivery or the packaging of their drugs?

under GLP/GMP-compliant conditions. However, many CSOs will delegate studies to technician-level staff, so it's vital to know the specific qualifications and expertise of the

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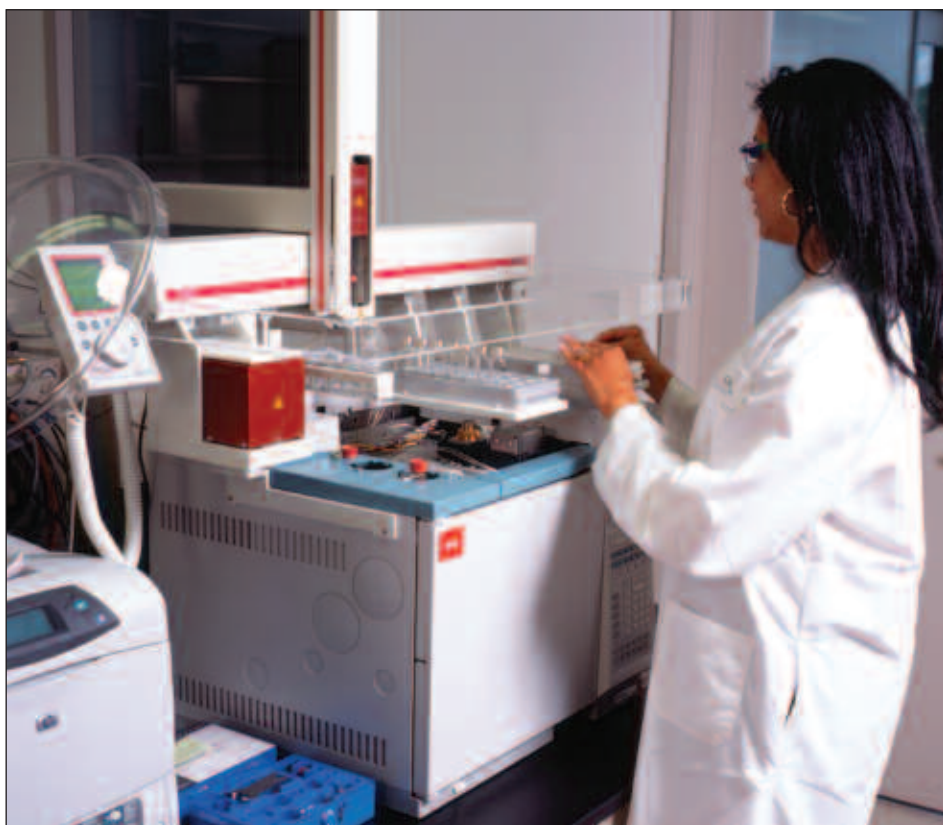
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staff that will be doing the actual work for your company. What is their experience with regard to packaging, drug delivery systems, toxicology risk assessment? Can they perform leachables and extractables studies, impurity profiling, complex formulation identification, method development and validation? What kind of interaction exists between the CSO's regulatory group and analytical staff? Because it's necessary to take a double-barreled approach to problem-solving, these two groups have to understand the overlap between regulatory and analytical issues, and the importance of a good working relationship.

Knowledge-specific CSO services have enabled sponsors to cut their testing time considerably. In fact, one pharmaceutical company took nearly a year to identify an unknown component detected in a leachables and extractables study performed on a newly developed medical device. This company decided to confirm its finding by partnering with a CSO that had extensive experience in the analysis of the plastic and rubber components often used in medical devices. Company executives quickly realized that they could have saved a significant amount of time (almost a year) by outsourcing this study. Why? Well the CSO had already identified this component many years ago and already had a characterized standard of the compound. By having the standards for that component in its lab, the CSO could have literally done the same work in less than a day.

Location, Location, Location

Real estate's "Golden Rule" could just as easily apply to hiring the right CRO for your needs. Companies looking for more productivity without increasing headcount will find it far more convenient to interact with and ship samples to a CSO located close to them. The fact is, face-to-face discussions are always preferable to the electronic kind, especially with so much at stake. It's also advisable for companies with a global presence to ask if the CSO also has geographically desirable lab facilities both domestically and overseas. This allows companies with multiple locations worldwide to enjoy easier inter-lab transfers of analytical methods and on-site consulting while dealing with only one CSO partner for all its locations. During vacation and other periods, overflow work can be conveniently assigned when the CSO has a lab in the "neighborhood"—wherever that may be.



Staying Power

It goes without saying that any pharmaceutical/medical device outsourcing should avoid CSOs that have the equivalent of a "garage" operation. But just as important as state-of-the-art facilities and sophisticated instrumentation is the CSO's past and present commitment to pharmaceutical research, and its ability to continue that commitment well into the future. With sensitive Pharma applications, you want to be confident that this resource will be around for a long time.

Safety Advisor or Chemical Practitioner?

The preclinical studies have been done, approvals received, and you're now preparing for pilot plant or large-scale manufacturing. In producing larger volumes of powders, unless you are proficient in electrostatics and dust explosion technology, you will want to engage the services of an EH&S consultant. While you can work with an analytical CSO by sending materials to their lab, in the case of an EH&S CSO, the "lab" must come to your site. This CSO will audit your safety and environmental procedures on site and develop protocols and processes customized for the safe handling of powders in your manufacturing operations.

Many EH&S consultants can provide safety auditing, but they don't actually manufacture chemicals themselves. They can make safety and compliance recommendations but may not have experience working in a GMP/GLP regulated environment. Finally, they can provide test data, but sponsors may

be left to figure out how to apply this information in a manufacturing environment. For these reasons, it makes sense to seek out a CSO that is also a practitioner, one that needs to insure the safe production of chemicals in its own manufacturing plants. Such practical “real world” experience makes this type of CSO particularly well-qualified to do the same for the sponsor’s plants and products.

The Confidentiality Issue

The growing trend toward outsourcing to other countries has been fueled, in part, by cost considerations. However, the fact that outsourcing costs may be lower in countries such as China and India is balanced by the concern that patent laws



may not be protected. Of course, protecting and assuring your intellectual property can be an issue when working with any service provider, regardless of their location. If a CSO makes contributions to any part of a product’s journey to market, there may be concern that it will also make claims on drug discovery. Certainly the signing of confidentiality agreements is an essential first step. However, in the long run, it’s the history, credibility and reputation of the CSO you hire that will vouch for its honesty and reliability. So, while it’s wise to implement the usual safeguards, it really comes down to trust. The goal of a CSO is to make your business more successful, and one with a long history and unblemished reputation for honesty will know that any compromise of a secrecy agreement or intellectual property will severely impact their relationship with sponsors – something that’s not in the best interests of anyone.

Wanted: A “Good Fit”

What kind of “company culture” does your potential CSO cultivate? An outsourcing arrangement will most likely have a better chance of success if the CSO’s “culture” is similar to yours. It’s a bit like a company making an acquisition to fill a need. Acquisitions usually involve a good “business fit,” but there are still two distinct company cultures. Participants can work through and resolve the differences to reach their goals, but it may take longer to see the results of the collaboration and business synergy. In the case of outsourcing, a CSO should be considered an extension of your company, a real member of your team, and this is still much easier to accomplish if you share similar cultures and work processes.

The Downside of “Do-It-Yourself”

Recently, a well-known Pharma company preparing to launch a new drug product that used a plastic medical device found itself in need of some “non-routine” expertise. The company’s new drug had already been proven safe and effective in clinical trials, but some unknown substance appeared to be leaching out of the polymeric component of the medical device. In seeking FDA approval, the company couldn’t say, “We have no idea what this is.” Going the DIY route, this company worked for the next couple of years with its plastics suppliers to solve the mystery—but to no avail. Finally an appropriately-experienced CSO was brought in who, within months, had not only identified the substance but its commercial trade name as well. The Pharma company was now able to perform the necessary health and safety evaluations of the substance so it could finally make its case to the FDA. In the end the company’s drug was notified—but the fact that it took far longer than it might have was the downside that could have been avoided by seeking out a CSO with the specific expertise required.

Getting The Most Out Of Your CSO Experience

Finally, ask a potential Contract Service Organization about “extras.” Some CSOs will provide sponsors with flexible training in-house or at a CSO site. Sponsors may also be able to obtain a service contract that includes access to any updates to test methods and any in-house standards used for quantification purposes, plus additional training and free access to the CSO experts for any additional questions they may have.

So, before you hire a Contract Service Organization, ask the right questions. The right answers can lead to a truly productive outsourcing partnership, one that can deliver shorter plant downtime, a shorter time getting to market, and, above all, the most accurate and scientifically documented results possible. ■