

## **Sample report**

**Title: Guide to Pharmaceutical Outsourcing in China: A Handbook for  
Pharmaceutical and Biotechnology Companies Planning to Outsource  
to China**

of these scientists also have work experience with multinational companies that have divisions in China. Some of them are returnees from overseas countries after having received education abroad or gained direct experience through working with a Western company. The percentage of Ph.D.-level scientists in the second tier CROs is slightly lower, about 10-15%. However, most of these second tier CROs have the same level of scientific staff with a Master's degree. Therefore, they are often a good choice for offsetting the high FTE rate offered by the first tier CROs.

The typical structure of a project team is composed of one senior scientist (Ph.D. level) surrounded by a group of junior level scientists (mostly with a master's degree in chemistry. This type of structure of a project team is very similar to that in a major Western pharma company!). In the first tier CROs it is possible to have two Ph.D.-level team members for one project if the project has a decent size (such as more than 6-8 FTEs). The senior (Ph.D.) scientist is generally also the project manager who is the main contact person on a daily basis for the outsourcing company. Almost all these project managers are returnees, that is, they possess foreign education background. Some of them even have direct industry experience gained through working with a US or European pharma or biotech company. All lab notebooks are recorded in English. All reports including PowerPoint slides are written and presented in English. All teleconferences (either video or phone conferences) with international customers are conducted in English.

## **II. How to effectively manage your outsourced projects in China**

*The ultimate goal of the outsourcing effort is to achieve the expected objectives for a specific project in a timely fashion besides achieving cost saving at the same time. The outsourcing companies should set up project goals at the very beginning. Specific deliverable goals, such as the number of target compounds to be delivered and their delivery time frames, quantity and other specifications (such as Certificate of Analysis, or COFA), should also be set up as early and detailedly as possible. The deliverables also need to be updated frequently as project proceeds forward. All these will make the service provider aware of what they are expected by their clients at any stages of the outsourcing process.*

Besides, establishing an open and effective communication channel is another key element to ensure the success of your

outsourcing effort. It is recommended that the outsourcing companies identify the managing personnel at the service provider side and designate their internal personnel (or a consulting firm) that have experience managing contract research projects to conduct communications on a regular basis with the project manager of the service provider. In detail, this should include research updates (such as research reports) on a regular basis (such as on a weekly or biweekly basis). Also, it is necessary to have teleconferences (either video or phone conferences) with the service provider on a regular basis to discuss any issues related to the project. In addition, the outsourcing companies should insist to the service provider that they be informed immediately with any issues related to the project.

### **III. Pay attentions to establishing a good relationship**

*A good relationship, including mutual understanding and trust, is very important in almost every aspect of business conduct in every place of the world. This is especially important when doing business in China. Establishing a good relationship with a Chinese service provider at the very beginning is as important as ensuring the absolute success of your outsourced project later on. However, as a Rule of Thumb, the Western companies should choose their partners (either collaborators or service providers) carefully in the first step. Only those CROs that have a relatively long service history and excellent reputation in this industry can be considered (This is the same criteria for every type of business outsourcing!). It is better to obtain this information through the recommendations from someone who did the outsourcing in China before.*

Once the preliminary relationship is established, the Western companies need to make sure that there are designated internal personnel that cultivate the relationship from time to time. For large companies it is usually someone who is familiar with the Chinese culture and business conduct principles to manage the project. For small companies this can be done through a consulting firm that specializes in managing outsourcing projects in China. The relation cultivation can be done through frequent contacts, either phone contacts or on-site visits. This is also necessary to ensure that your project moves forward smoothly and as expected.

**Chapter 7.**  
**Evaluation of the possibility of**  
**small biotech companies to outsource to China**

## **I. Necessity of small-sized biotech companies to outsource to China**

*In fact, smaller biotech companies have more reasons to outsource their costly drug R&D to the low cost areas such as China in order to save money for their tight budget because it is generally more difficult for them to raise funding or get big investments. All small companies have the following common difficulties:*

1. Lack of a full scope of expertise. Generally the small companies started by one or a couple of founders who possess expertise only in one or a couple of areas. They do not have expertise in all areas that are required by the complex drug discovery and development process. They desperately need outside expertise complimentary to their internal resources. This is the key fact that determines their need for outsourcing. Furthermore, many biotech startups are founded by professors and/or scientists that specialize in the medical research only, or by executives who most likely are experts only in the management and/or administration, but definitely not in the drug discovery and development. They need outside expertise in such areas as the selection of druglike compounds from a huge compound library, rational drug design for the selected target(s), optimization of potency for discovered lead compounds as well as the optimization of pharmacological properties (PK and PD) in order to make the lead compounds more druggable, etc.

2. Lack of a full-scale facility to conduct all steps of drug R&D. Due to the limitations in funding and expertise, small biotech companies generally only have limited inhouse facilities such as an in-house small laboratory for biological testing or a small scale chemistry laboratory for medicinal chemistry research. Either type of facility is only able to conduct a small part of the entire lengthy drug R&D process. This fact also determines the need for these companies to outsource part of their drug R&D. Nowadays there are many virtual biotech companies that generally have only a management office. All real research activities are outsourced to a series of CROs. These companies generally need help from outside with a strong experience in contract project management.

3. Lack of sufficient funding. Most of small biotech companies are in their early stage of development. The

ease to raise funding totally depends on the achievement of positive research results. Whereas good results take both money and time to achieve. So it is a chain reaction. That determines the difficulty for those startups that have not achieved a substantial amount of positive data to raise a sufficient amount of funding. These companies definitely need to live on their tight budget. Outsourcing to a low cost area would be a perfect solution to solve their dilemma as long as there are practical procedures to protect their intellectual properties.

## **II. Advices for small-sized biotech companies planning to outsource to China**

*The real risk for these small companies to conduct outsourcing is the possible loss of IP. This is understandable because the intellectual properties are their whole asset and the key element for survival. This is also the key reason that makes them unwilling to outsource to a low cost area which is generally also a developing country where the IP protection and law enforcement could be weak. So there are not many choices remaining to them. Generally, the only choice they could have is to outsource to a local CRO or at least in the same country. They are certainly aware that this will cost them a lot, many times even their whole fortune, and that there are still no any guarantees for them to achieve positive results.*

On the other hand, these companies still possibly face losing IP even though they choose a local CRO or a CRO in the same country for outsourcing. This is because many Western CROs are also conducting their own internal drug R&D. Although all of them claim that they will not work in the same field or on the same idea as their client companies do, ideas and protocols generated during the outsourcing collaborations can always be released within the CRO company and can be utilized by their internal research. Also, there are many scientific staff turnovers happening in every Western CRO. Scientists who worked on a customer project and then left the CRO join a drug discovery company that may work in the same therapeutic area. Therefore there is no absolute guarantee for the IP protection even though the small biotech companies outsource their R&D to a local CRO in the same country. The only assurance they can get is they will know who have breached the contract. But generally it is too late to chase them down. Also, law suit in the West is both time- and money-consuming.