



# Development Game Plan

**Peter Soelkner at Vetter Pharma International highlights points to consider when choosing a suitable contract manufacturer to guide biotech companies through the early clinical development period**

Imagine a major game designer developing a new video game for release to the market that is comprised of pitfalls and complexities so numerous and difficult that only a very small percentage of players ever reach the midpoint, and an even smaller number of players complete the game successfully. Today, in the world of biotechnology, many companies face such a scenario on a regular basis. Therefore, they must do everything they can to increase their odds of successful completion of the ‘development game’ and reduce their risks of future elimination. The risks and rewards of playing this game are high and few can afford to fail, even once.

Like video games, biotechnology projects are complex and subject to many levels of risk during the early clinical phases. Only a few products ever make it to Phase III, and even fewer make it through approval and to commercial manufacturing. In addition, globalisation and other recent developments, such as stricter quality control criteria, evolving technologies and the

increasing stringency of regulatory standards, to name just a few, have imposed enormous pressures on an already difficult task. Small biotechnology companies by definition are extremely sensitive to any risk in early clinical phases. Unlike the large, well financed biopharmaceutical company, the small biotechnology company typically has less resources in both finances and personnel. Their primary concern in most instances is to maximise the value of their compound in the earliest stages of development, adding value that will assist in attracting investors, provide out-licensing opportunities or in some cases, even outright acquisition by a larger company. To such companies, little thought is given to the later development or commercialisation efforts that must be applied to the compound and the myriad interfaces between various partners that might be necessary as they move forward in their work. For these companies, the right selection of one or various business partners can make the difference between not just the success or failure of the project, but the very survival of the company itself.

## CMOs CAN HELP YOU WIN

To improve a company's chances of winning the 'game of drug development', efficiency of time and judicious expenditures of capital during the early clinical phases has become all the more important. In this regard, a contract manufacturer can be of vital support to smaller organisations in helping them manage processes and facilitate decision-making during the early development period. However, finding the right partner means that time intensive, careful screening takes place. To help in this process, the following are recommendations that should be considered when beginning the selection process for the partner that best fits the small biotechnology company.

### TO PARTNER OR NOT TO PARTNER?

For the small biotechnology company, there really is no question. Given their limitations in resources and equipment, they must consider partnering. The choice is to either partner with several companies that can help them achieve their early goals via a step-by-step process, or partner with a full service CMO who can help them bring their compound through all phases of clinical development into commercial manufacturing. Developing and manufacturing innovative compounds, such as monoclonal antibodies and other 'high value' substances, involves considerable risks, particularly financial ones. For many, finding a suitable partner can free up the company to concentrate its efforts and money on its core competencies like research and development.

Additionally, if out-licensing is part of the overall strategy of the company, a CMO which has already positioned itself as preferred partner for biotechnology companies can add a significant degree of perceived and real value, not only to the compound at hand by helping to raise investment capital, but also to the company itself, which will help attract future investors and licensing opportunities. The CMO, then, is given the task of managing the filing of clinical trial material, including process development, biopharmaceutical analysis and packaging. Outsourcing should be scheduled early in the strategic planning of a drug's life cycle. During the early development process, which can last several years, a partner with the necessary capacity, expertise and experience can be identified and brought onboard.

Thus, a partnering relationship with a CMO is beneficial. How to select the right CMO for your company, however, is not as simple as it may seem.

### FINDING A SUITABLE CONTRACT MANUFACTURER

If your company has decided to partner with a CMO, you may be wondering how to proceed to help ensure the success of your project. To assist in your selection, consider the following:

#### Are They Experienced?

The first consideration for choosing a CMO should be the level of expertise and experience. Some questions to ask include:



An employee carefully prepares a solution for use in future experiments

Source: Vetter-Pharma International GmbH

- ◆ How long has the CMO been in business and what kinds of work has the company done?
- ◆ Is their work history consistent with the current project(s) you have underway now and for those planned for the future?
- ◆ Do they have experience in supporting your drug development steps, including realising the clinical filing as well as the later commercial manufacturing and market supply?
- ◆ Do they have relationships with regulators and how extensive is their knowledge of domestic and international regulations?

Generally speaking, the more experienced the CMO, the greater the likelihood of success and the smoother the collaboration. Additionally, having well trained teams of scientists and engineers is an essential method of ensuring a competent and creative approach to solving any problems that might arise. It can also contribute to speeding up time-to-clinic. A well versed team can work more efficiently, since they will have comprehensive expertise about possible challenges in all processes and support the organisation of each and every step, so that the project can make optimal use of budget, time and human resources.

Also, consider for later commercial stages how well positioned the CMO is internationally. Each country has its own regulatory systems and national specifications for approval. If a CMO has already supported companies in international approvals, it is safe to assume that it has developed a significant body of experience that has been integrated into its processes. Furthermore, it will already have established a solid working relationship with regulatory agencies such as the FDA

and EMA. It is just one more element in reducing the overall time-to-market.

### Are They Nimble and Flexible?

Early development by its very nature often presents surprises. New drug products must often be adjusted, dictated by the results of early clinical testing. Can the CMO act quickly to update project specifications under tight timeframes?

### Do They Have Experienced Project Managers?

In your search for the right CMO, make every effort to understand how your business will be handled and how you integrate project management. This is essential in making sure that each project is being handled properly and communication channels are open. Regular team sessions with technical experts from all involved areas should be part of every relationship to help ensure that each party is fully informed of any potential roadblocks. Every process carried out must be carefully documented for future reference. The best way to keep track of a project's progress is to jointly establish performance measures that can be easily quantified using objective data. Because small biotechnology companies often have less experience in assembling their own project management teams, the CMO and its designated project manager are critical and will create a team that suits each project's specific needs, keeping in mind that small biotech staff members can then focus their efforts on areas where their expertise is best applied. Ultimately, however, a company outsourcing production processes will be dependent on its partner to a great extent. You must feel confident that knowledge and information is shared. In the end, the true core of any partnership is trust.

### Do Their Services Meet International Quality Standards?

Today, aseptic manufacturing is becoming increasingly more rigorous and demanding. Ever-increasing quality standards are being enforced by regulatory bodies in Europe, Japan and the US and demand that CMOs keep up to date with new and emerging rules and regulations. Of course, these rigorous standards also mean that the technology for the facility itself must remain cutting edge. Providing high quality yield of valuable product is a must.

### Are They Creative and Able to Offer Solutions?

The CMO under consideration should offer a range of services that will have the necessary flexibility to address the changing needs of the market. A basic portfolio should include single chamber syringes, vials and cartridges. Life cycle management is another important consideration if you think about later commercial filling. If a drug is to hit the clinic fast in a first cycle, it will probably be in a vial. For the later clinical phases – depending on the drug – the company may opt for a syringe. When entering the market, a more patient-friendly system such as a dual-chamber syringe or an auto-injector may be the best drug-delivery system. A viable CMO will have these capabilities and, because of their expertise and dedicated staff, be able to offer proactive approaches to the different challenges in each stage. Life cycle management, if planned early enough, can mean the real success of a drug in the face of upcoming competition.

### Are They Financially Stable?

Manufacturing a drug is not a one-off event, nor is it a brief one. Because a drug can take an extended period of time from process development to commercial manufacturing, the relationship you are developing with the CMO is a long term one. So be certain that the CMO is able to demonstrate that it has independent financial standing. A CMO with a history of organic, consistent growth will prove to be a strong ally. If and when something goes wrong, you want to know they have the financial strength to deal with the situation.

### Are You Playing the Same 'Game'?

Developing a solid working relationship with the right CMO can lead to a win-win situation, but it requires investment by both parties, particularly in the area of communications. Good communication among team members and peers is not always easy to achieve. Differences in corporate cultures and business models, varying levels of knowledge and experience at all levels are just a few of the issues that can make communication among parties more difficult.

Finally, a good contract manufacturer will be there throughout all stages of a drug's development and lifecycle, providing necessary support at all times. This will provide you with valuable time and resources to concentrate on research and development.

## CONCLUSION

These suggestions and recommendations will help you select a partner who is able to help you meet your business needs and navigate the 'development game', today and in the future. To meet the growing number of challenges facing the biopharmaceutical industry, outsourcing has become the critical strategic element. With whom to partner is a fundamental decision that must be made in the early phases of a drug's development, when time is sufficient to find the right partner and develop a strong relationship. The partner you choose will strongly influence the way you play the game. If done correctly, everybody wins.

### About the author



**Peter Soelkner** has been a Managing Director of Vetter Pharma-Fertigung GmbH & Co KG since June 2008. In 2009, he was also appointed Managing Director of Vetter Pharma International GmbH, the company's marketing and sales organisation. Peter graduated from the University of Dortmund, Germany in 1992 with a degree in Chemical Engineering and earned an MBA from Columbia University, New York, US in 2001. Before joining Vetter, he held positions in Germany and North America at Sartorius AG and Sartorius North America Inc, in R&D, marketing, key account management and general management roles. At Vetter, from 2003 to 2007, Peter managed the company's key account programme and global supply chain. He left the company for a year to serve as Vice President of global key account management at Sartorius Stedim Biotech, US, before returning to Vetter in 2008. **Email:** info@vetter-pharma.com