



Contract Pharma Services

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## Outsourcing in the Pharma Industry – Experience, Expertise and Enthusiasm

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**Key success factors in fostering and  
maintaining a long-term strategic partnership**

## Introduction

2012 will be regarded by many commentators as one of the most challenging years in the pharmaceutical industry's history, due in no small part to numerous products facing patent expirations and increased global competition. It is now considered a sound strategic move by pharmaceutical companies, from big pharma to smaller players, to increasingly rely on outsourcing service providers to fulfil specific tasks, solve problems and improve efficiency and productivity. One of the growing trends is the outsourcing of late-stage scale-up and commercial manufacturing activities, evidenced by the fact that in the last three years, more than 100 manufacturing facilities owned by pharmaceutical companies closed their doors for business in the U.S. alone<sup>1</sup>. The global pharma contract manufacturing market is expected to reach \$40.7 billion by 2015<sup>2</sup>, according to a recent report by Global Industry Analysts, Inc.

## Strategic not tactical, partners not clients

While engaging in an outsourcing solution may make good commercial sense to a pharma company seeking efficiencies in their business, handing over an important step in the drug commercialization process does not come without risk and should be carefully considered. In a recent outsourcing survey conducted by contractpharma.com, 75% of respondents said that they would use the word 'partnership' to describe their relationship with their contract service provider(s)<sup>3</sup>. Further evidence of the practice of selecting a few reliable partners was shown with the majority of survey respondents saying they engage in only a handful (one to five strategic vendor relationships) of partnership arrangements for their outsourcing needs. With so much at stake, engaging in an outsourcing solution is no longer a tactical decision, but rather is considered a partner-driven strategic activity.

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**75% of pharma outsourcing arrangements are classed as 'partnerships'**

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1. Sugarland Industrial Information Resources report 2010
2. [http://www.strategyr.com/Pharmaceutical\\_Contract\\_Manufacturing\\_Market\\_Report.asp](http://www.strategyr.com/Pharmaceutical_Contract_Manufacturing_Market_Report.asp)
3. 2011 Contract Pharma Outsourcing Survey [www.contractpharma.com](http://www.contractpharma.com)

## Initial check-list

### Look for experience and expertise

Selecting a preferred partner to form a strategic outsourcing partnership for product manufacturing is a complex process. Developing the right relationship and vision from the start is vital to success. There are many approaches undertaken to get to know a prospective outsourcing partner, but in essence, the key considerations revolve around experience and expertise as they relate to commercial scale-up and manufacturing activities.

Initial checklist to consider when viewing a potential manufacturing partner

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**Key considerations in partner selection include evaluation of experience and expertise on offer**

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- How long has the Contract Manufacturing Organization (CMO) been in business and have they done work similar to the assignment you want them to undertake?
- Does the CMO have experience with complex drug compounds?
- Does the CMO have experience supporting tech-transfer, scale-up and manufacturing for multiple contracts?
- Does the CMO have established relationships with regulators? Do they have extensive knowledge of regulatory agencies worldwide and in particular to the countries in which your product will be exported?
- Does the CMO have well-trained teams of scientists and engineers?
- Does the CMO have designated project managers who will be given project-specific goals to ensure the success of your project?
- Can the CMO demonstrate that it has expertise and dedicated staff to offer proactive approaches to challenges that may evolve throughout the life of the commercial arrangement?
- Is the CMO financially stable? As the relationship is anticipated to be a long term one, a consistent history of financial stability and growth will be the sign of a strong partner.
- What is the CMOs historical position with the FDA, EMA and other key regulatory agencies?
- Has the CMO been validated by external agencies other than the regulatory authorities? Have any awards or accolades been won by key groups involved in the manufacturing of product which would signal excellence initiatives?
- Is there an Operational Excellence culture in place at the CMO where commitment to quality and continuous improvement is embedded in the organization?

Though significant reassurances can be taken from obtaining positive responses to the initial check-list questions outlined above, this should be considered only the start of the evaluation and intelligence gathering process for selecting a CMO. Referrals, face-to-face meetings at industry events and reviewing marketing collateral all help to gain more knowledge of the company and are considered key sources of intelligence gathering used in the initial assessment process. By focusing on the above checklist and visiting a prospective partner, a clear picture should emerge on their overall approach to their contracting relationships. Scoring positively on these activities provides color on the business' stability, dependability and ability to fulfil projects.

## Executing an effective partnership

### **Don't forget enthusiasm**

After initial qualification of the CMO, visiting the site where potentially your product will be manufactured is an important step to gain more comprehensive insight about the 'fit' between both parties. As a contract manufacturing service provider, Alkermes Contract Pharma Services encourages its prospective partners to spend time on site, examine various aspects of our scale-up and manufacturing capabilities, meet the people who will be deeply involved in the project and see how committed we are to a partner-driven approach.

### **Experience, Expertise and Enthusiasm**

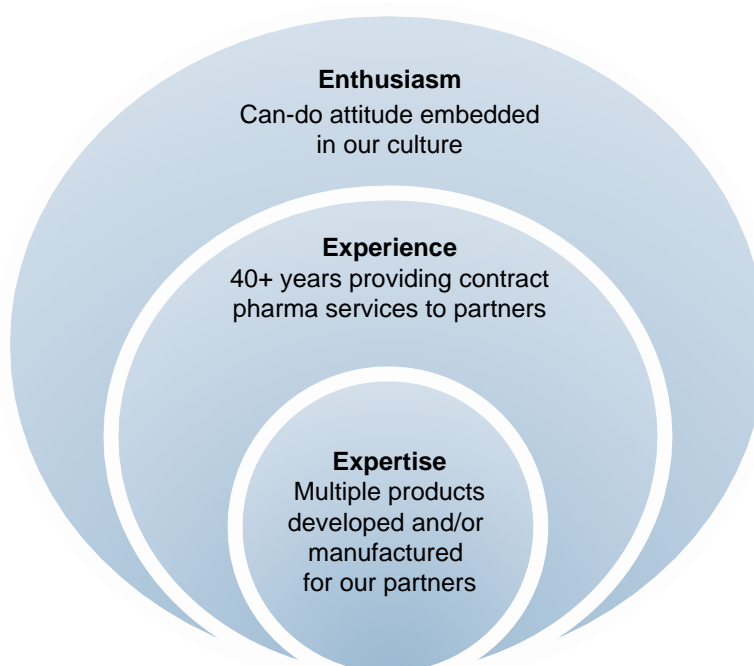
Three elements considered to be essential by Alkermes Contract Pharma Services to foster and maintain long-term relationships are: experience, expertise and enthusiasm. Alkermes Contract Pharma Services has been in the pharmaceutical manufacturing business for over 40 years and successfully manufactures products for a blue-chip client list including seven of the top ten pharma companies in the world. While experience and expertise are relatively easy to assess based on the track-record of past performance, measuring enthusiasm can only truly be appreciated through the meeting people who will potentially be deeply involved in the partnership arrangement.

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**An enthusiastic, 'can-do' approach is necessary for successful execution, especially for the more challenging projects**

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## Alkermes Contract Pharma Services' partner-driven approach



### **Experience**

Critical for a company partnering their drug for commercial manufacture.

- A successful track-record in product manufacturing is a cornerstone for gaining a company's trust for a long-term outsourcing relationship.

### **Expertise**

Relevant and extensive expertise to solve present and future problems is critically important, including:

- tech transfer skills for seamless evolution to full scale production;
- regulatory expertise is a critical asset, particularly for smaller pharma partners and;
- delivering service that creates value and achieves the partner's goals.

### **Enthusiasm**

Enthusiasm is an essential element for successfully executing outsourced manufacturing projects. It is particularly important to have an enthusiastic 'can do' approach for anticipating and addressing problems and for building a commitment as a long-term partner.

- An enthusiastic culture creates a drive to always look at ways to improve the service to the partner (OE initiatives);
- Enthusiasm is necessary in establishing strong long-term strategic relationships with partners and building customer loyalty.

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**An open and transparent culture is vital for long term success**

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Cultural alignment of companies is often ignored but is important in establishing long-term, high-value relationships. The more culturally aligned the organizations are, the more likely strong relationships are developed and maintained.

**Communication – vital for long-term success**

Once both parties enter into a contracting arrangement, it is valuable to create an open and transparent approach to communication from the start, so that any idea and issues can be shared. Open communication enables a partnership to flourish so that new approaches can be surfaced and solutions are arrived at quickly. Reports and project dashboards are tools that can facilitate communication so that information can be displayed in real time to assess performance across the value chain and communicated regularly to all parties involved. Key performance indicators (KPIs) should be agreed upon, and customized where appropriate, by both partners. In addition, it is helpful to distribute general indicators, such as On-Time-In-Full (OTIF) and Right First Time (RFT), as these are valuable metrics to regularly assess product manufacturing, while other Critical Process Parameters (CPPs) can also be selected and included in regular reporting.



Right First Time



OTIF



Cycle Times

*Measurement Metrics routinely used at Alkermes Contract Pharma Services*

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**What gets measured gets done – performance metrics need to be put in place**

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## Performance metrics used in partnerships

Based on a long track record for providing contract manufacturing services, Alkermes Contract Pharma Services also provides the following initiatives as part of its service offering:

- Inspection Ready Status and Continuous Quality Improvement strategies which are reinforced by an extensive self-inspection program and a Corrective And Preventative Action (CAPA) database
- Operational Excellence (OE) initiatives where a process improvement culture is enthusiastically encouraged within our manufacturing facilities, with a focus on reducing variability and eliminating waste
- Problem solving throughout the organization is approached in a collaborative and professional manner by focusing on the specific (and often unique) needs of our partner projects, empowering employees, and optimizing existing activities in our development, scale-up and manufacturing processes
- A systematic training program which has created highly skilled problem solvers (black belts, green belts and yellow belts) that can anticipate, overcome and improve workflow challenges of partner products
- Our highly qualified chemists and scientific staff which operate in fully equipped, best-in-class facilities that include: raw materials, in-process and finished product release testing laboratories, microbiology laboratories, bioanalytical laboratories, stability incubators and testing facilities, method development laboratories and method validation laboratories
- Dedicated project management staff and resources including secure intranet-portal access for partners.

## Conclusion

Engaging with a CMO can provide many strategic advantages to a pharmaceutical company, including lower manufacturing scale-up costs, easier access to core competencies in specialized processes and equipment, and improved efficiency and productivity. The value of partnering with an outsourced manufacturing partner can impact a pharma company's bottom line by alleviating capacity constraints, reducing capital spending and improving supply chain predictability. Building a solid relationship based on experience and expertise, with an enthusiasm to successfully execute on a project, has the power to turn a third party arrangement into a long-term, strategic, win-win partnership for all parties concerned.

### **About Alkermes Contract Pharma Services**

Alkermes Contract Pharma Services is a leading provider of solid dosage form scale-up and manufacturing services for the pharmaceutical market and is an operation within the global biopharmaceutical company, Alkermes plc. With over 40 years experience and innovation, previously as Elan Drug Technologies, we are the outsourcing partner of choice for over 30 leading pharmaceutical companies. All the services we offer to our partners are provided with the greatest attention to quality and customer service. Our manufacturing business is driven by 'excellence in everything we do', which gives our partners the reassurance that their product will be guided through our facilities to exacting specifications. Alkermes Contract Pharma Services has extensive capabilities including tech-transfer, scale-up and manufacturing facilities in the U.S. and Europe.

For more information visit **[www.alkermes.com/contract](http://www.alkermes.com/contract)**  
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June 2012 © Alkermes plc