

The Future Of The Pharma Outsourcing Industry After The Financial Crisis

Life Science Leader, April 2010

Written by: Jim Zhang, Ph.D.

It is widely accepted that the current financial crisis has dramatically changed the landscape of the global biotech industry. Having also been affected by the poor economy, major pharma companies are now using this time to address existing and new issues within their own organizations. As a result, new operation models are likely going to evolve within both industries. Outsourcing service providers, both CROs and CMOs, have to get prepared to face the changes.

Challenges Facing Global Drug Companies

Most major pharma companies have been running at low R&D productivity for a number of years. The increasing difficulty to discover a new drug is one factor to blame. The gradually raised regulatory bar due to safety concerns is another factor. Meanwhile, to many of those R&D-focused small biotech companies, the significant reduction in venture capital has become the major threat to their continual operation. However, no matter what type of drug company, the key challenge, both at present and in near future, is how to speed up R&D while still maintaining the overall operation budget.

New Strategies To Implement In Near Future

On one hand, to improve R&D productivity, many pharma and biotech companies are going to restructure their R&D divisions into smaller organizations. For example, Pfizer is planning to reorganize its R&D divisions into numerous smaller R&D centers, each focusing on only one therapeutic area and containing 100 to 150 researchers. On the other hand, many companies are going to increasingly implement the new R&D model of the Networked Partnership (NP). For example, Lilly has set up an independent operation group called "Chorus" in its Indianapolis headquarters. Chorus focuses on handling all collaborations with its partners worldwide. It also has a similar operation group in its Shanghai R&D center, though much smaller in size.

To speed up their R&D progress, pharma companies also are likely to increase in-licensing of drug candidates from many drug companies around the world. For example, sanofi-aventis is planning to reduce its efforts and R&D spending in early stage research. It will focus on only the late-stage development and registration.

How Will The Pharma Outsourcing Industry Likely Be Affected?

In the value chain of the series of changes, the outsourcing service sector is, unfortunately, in the downstream. How the future global pharma outsourcing industry will likely develop is entirely dependent upon the actions taken by both pharma and biotech industries to address the existing issues within their own area. Figure 1 depicts a series of strategies that will likely be implemented by both industries.

To major pharma companies, their ultimate goal is to have a steady flow of drug products in their pipelines. To have a product pipeline filled with innovative drugs, pharma companies need to focus on improving productivity so as to make drug discovery and development faster. To speed up that progress, they will have to enhance collaborations with as many companies or organizations and on as many aspects of a drug R&D program as possible. Simultaneously, they also will have to look all over the world to in-license appropriate drug candidates.

To speed up their drug R&D progress, both major pharma and small biotech companies need to have more accurate therapeutic targets and know more about the mechanism of action (MOA) of a drug compound. They also need to quickly identify lead compounds and get them optimized more rapidly. In addition, they need quick results of efficacy and safety testing, and they need to address the manufacturing cost for both developmental and marketed drugs. All these operations must be organized in an efficient way.

To realize these goals, drug companies are going to conduct broader and more extensive research on genomics and proteomics, including the development of disease/animal models, more effective diagnostic and imaging methods, and better biomarkers. They will also need large, readily available compound libraries that possess special structural features so they can be readily screened against the selected targets. They will also rely on faster, more accurate high-throughput screening systems to screen the compound libraries. A big portion of such heavy research work will be fulfilled in the manner of collaborations with either academic research institutions (for target identification/validation and elucidation of action mechanism) or professional service providers (for discovery, development, and manufacturing). On the other hand, they will also likely want to have more control themselves over the late-stage development as well as drug registration.

Based on these analyses, we reached the following conclusions regarding how outsourcing demands by both pharma and biotech industries will likely change in the

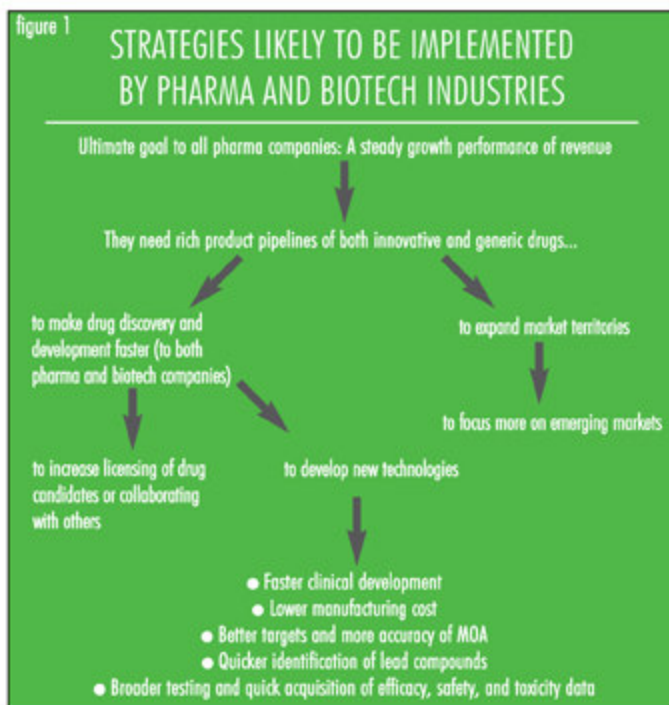
near future.

a. Outsourcing demands by major pharma companies will likely still remain strong in following areas:

- Research in genomics and proteomics: Major pharma companies are in desperate need to develop better drugs with high success rates. To meet that end, they must have more accurate therapeutic targets and understand more about the MOA and the causes of side effects. To accomplish these tasks, they need to increase their focus on the basic research in genomics and proteomics.
- Compound libraries with special structural features: Outsourcing of large, structurally diverse, more natural, product-like compound libraries will still remain strong. Wide R&D collaborations between drug companies and those technically capable professional CROs are expected.
- Preclinical research: Many special techniques, such as the good animal/disease models, better in vivo bio-imaging techniques, and more effective molecular diagnostic tools, have been developed in recent years. Major pharma companies will rely more on those companies possessing the specialty techniques to fulfill their tasks. In fact, in the future, more specialty biotech companies will become outsourcing service providers.
- Manufacturing: All pharma companies will still outsource a large portion of manufacturing work for both developmental and approved drugs, including generics. They may only keep a couple of key steps in-house, such as those chemical transformations requiring special techniques.

b. Outsourcing demands by major pharma will likely become weak in the following areas:

- Rational drug design and optimization of lead



compounds: As drug discovery and potency optimization are considered the core part of drug R&D (they are also highly IP-sensitive), the major pharma companies will likely still keep the most part of this type of research in-house.

- Late-stage (such as phase 3) clinical trials: As this stage is so critical in the lengthy process of drug R&D, many major pharma companies will still want to have more control. Plus, they have strength and expertise in this area, including the drug registration.
- Formulations: As this is the tech-rich stage in a drug manufacturing process and also the last stage directly related to the product quality, very likely most parts of this type of work will be kept in-house by major pharma companies.

c. New outsourcing strategies likely to be implemented by major pharma in selecting their service partners:

Major pharma companies will become more careful and pickier when selecting ideal outsourcing service partners in the future. They will prefer more of the major CROs/CMOs that are well- equipped and capable of conducting a wide range of drug R&D and/or manufacturing work. Meanwhile, they also will look for those CROs/CMOs that possess specialty techniques, such as the quick and effective detections of toxicity, bio-imaging, new drug delivery, etc. On the other hand, to more effectively control cost, they will still outsource to low-cost regions but, with the same reasons, will prefer choosing those technically capable CROs/CMOs.

d. Outsourcing demands by those R&D-focused small biotech companies will likely still remain strong in the following areas:

- late-stage clinical trials (phase 2b and after)
- large-scale cGMP production of APIs to support the late-stage clinical trials
- development of special techniques such as drug delivery, biomarkers, diagnostics/bio-imaging, etc.

e. Outsourcing demands by these small biotech companies will become weak in the following areas:

Mainly due to the dramatic change in the landscape of the global biotech industry by the financial crisis, in the near future there will be significantly fewer biotech start-ups, early-stage companies, and early-stage drug R&D programs. A significant reduction in outsourcing demand by the biotech sector is thus expected to occur in such areas as

drug discovery, small-scale production (such as kilo lab work), and early-stage development, including preclinical and phase 1 clinical trials.

What Should Outsourcing Service Providers Do To Face These Challenges?

The increasingly complex outsourcing demands require outsourcing service providers that possess either strong service capabilities spanning a wider range of the drug R&D and manufacturing process or special techniques that can help speed up any part of an R&D project. The former will become favored outsourcing partners and thus able to secure large, long-term projects that may include milestones and royalties. The latter will become favored specialists of the industry to solve special technical difficulties.

The following are only two examples to illustrate the importance of special techniques urgently needed by the entire pharma industry:

- New techniques to detect, identify, and even reduce toxicity of a drug compound. At present >50% of drug candidates fail in clinical trials mainly because of their severe toxicity or side effects.
- New, effective drug delivery techniques. The other factor that also attributes to the high failure rate of clinical trials includes the low in vivo efficacy of tested drugs. In many cases the drug molecules are unable to enter the cells, or they are dissected even before reaching the target cells. An ideal delivery tool will certainly enhance the success rate. Also, new delivery techniques are highly desirable to biologic drugs, as they are all large molecule drugs which render extreme difficulty for their effective delivery. At present, the only delivery vehicle for biologic drugs is injection, which is not favorable to patients.

In summary, outsourcing service providers have to get prepared to face the widespread pharma industry changes that are currently occurring. The keys to success in the new wave of outsourcing are to have a broader service scope, better service capability and quality, special techniques in any part of the drug R&D and manufacturing value chain, and cost-effective services.

[Back to top](#)