

# The Outsourcing Relationship

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Today's economic environment has driven biopharmaceutical manufacturers to focus heavily on productivity, processes, and quality. These pressures have, in turn, affected the relationships companies have with their outsourcing contractors, according to our 9th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production.

In the study, we identified a number of critical issues that CMOs experience with their clients. Expressed in terms of common mistakes made by their clients, the study quantifies problem trends that are pervasive in relationships. We found that, among the 10 areas cited, three problem areas from the CMO perspective stood out, each cited by over 86 percent of as either a "very common problem" or a "somewhat common problem" include:

- 'Clients don't communicate with us effectively;'
- 'Clients don't build in sufficient time for the project (unrealistic timeframes);' and
- 'Clients want to contain cost by doing limited development runs, but still expect successful full scale manufacturing.'

The top factor again this year centers on communication problems. Technical organizations often experience difficulties in this area, and numerous texts on the topic support research into solutions<sup>2</sup>. The fact that both clients and their CMOs point to difficulties in relationship building and communication indicates a systemic problem, which requires a systems approach to reach a solution.

In fact, the second issue involving unrealistic timeframes are also a symptom of communication problems — and may be more significant among smaller companies that have unrealistic preconceptions, or simply do not understand issues such as how to achieve high-performance processes, advance from small scale to clinical manufacturing, or how to release clinical grade material. While some of the blame for unrealistic timeframes can be passed to the client, CMOs may need to take more responsibility. Experienced CMOs should know what is possible — from prior experience — and can work on managing expectations and optimizing their communication with the client on this issue. Communication problems between client and contractor are often a matter of how effectively the client's "project management" is set up and managed, and how well the client and CMO can coordinate the exchange of information in a controlled way. Some of this CMOs can have a direct influence on, but this partly lies in the hands of the client. Even so, even if a CMO has a strong reputation for resolving issues, they need to be careful

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not to overpromise.

Some other common problems indicated by CMOs include clients not recognizing the variability in process development (83.3 percent) and clients not appreciating the differences between small scale and full scale manufacturing (75 percent). Good communication between client and contractor should temper some of these problems before they become critical.

In the study, we also solicited comments regarding the client-CMO relationship. Some representative comments include:

- As a CMO, I find many clients: have limited comprehension as to why GMP manufacturing costs are “too high;” have unrealistic timelines for approving GMP documentation and the review/approval of executed GMO documentation
- Clients don’t devote the proper amount to process development work prior to the GMP manufacturing. They have no in-house QA QC expertise and expect their CMO to make regulatory decisions regarding their product.
- Clients sometimes don’t provide enough information regarding their raw materials, cell lines, etc.
- Clients do not appreciate the need to create a comprehensive contract specifying roles and responsibilities of each party to deal with worst case scenarios.

### Problems Have Shifted Over Time

We evaluated how the trends in client-CMO relationships have evolved from 2010-2012. We found that CMO relationships have continued to involve problems, with these problems remaining rather high — and steady — in recent years.

The good news is that after a big jump between 2010 and 2011, some of the more common problems have declined in prevalence from last year. For example, unrealistic timeframes and cost containment expectations, both of which topped the list this year at 86.1 percent of respondents, are each down from 92 percent last year (though they remain up from 2010’s 82.1 percent and 78.6 percent, respectively). Similarly, complaints about clients not planning their tech transfer process have declined to 83.3 percent of respondents this year, from 88 percent last year, while the issue of clients expecting CMOs to resolve the most difficult problems has seen a sharp downward swing, from 90 percent of respondents last year to 72.2 percent this year.

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"Very Common" or "Somewhat Common Problem"	2012	2011	2010
Clients don't build in sufficient time for the project (unrealistic timeframes)	86.1%	92.0%	82.1%
Clients want to contain cost by doing limited development runs, but still expect successful full scale manufacturing	86.1%	92.0%	78.6%
Clients don't communicate with us effectively	86.1%	84.0%	80.4%

*Fig. 1: Selected Common Mistakes Biopharmaceutical Sponsors Make With Their CMOs, 2010-2012. Source: 9th Annual Report and Survey, Biopharmaceutical Manufacturing and Capacity, [www.BioPlanAssociates.com](http://www.BioPlanAssociates.com), April 2012*

Tempering this good news is our finding that some of the less common issues are becoming increasingly widespread. This year 69.4 percent indicated that 'clients don't understand their role in regulatory submissions,' up from 66 percent last year and 53.6 percent the year before. The problem of 'clients just handing off a project without planning for on-going interactions' has risen to 66.7 percent of respondents, up from 66 percent last year and 53.6 percent in 2010. And more CMOs are saying that clients want them to use cell lines or processes that are not suitable for GMP manufacturing (61.1 percent this year, vs. 58 percent in 2011 and 51.8 percent in 2010).

Perhaps most worrisome, the proportion of CMOs who say that clients are not communicating effectively with them is either a very or somewhat common problem is also now on a 2-year upward trend, from 80.4 percent in 2010 to 86.1 percent this year.

The results suggest that while some of the most common problems have stabilized over the past year, other less common ones are coming to the fore. This may simply be a reflection of increased outsourcing activity and increased complexity of those activities, or an indication that in focusing on resolving some problems, clients and CMOs have left themselves more open to others.

### The Client Perspective

Of course, clients have their own perspective on what constitutes an ideal CMO to work with, and predictably, one with which they can establish a good relationship is at the forefront of their considerations. Separately in the study, when we asked biopharmaceutical developers to identify the issues they consider when outsourcing to a CMO, the issue they most commonly cited as either "important" or "very important" was establishing a good working relationship, by 96.8% of respondents, up from 93.2 percent last year. Next on the list were 'comply with my company's quality standards,' and 'effectively handle cross-contamination issues'.

When we sort the responses by "very important" only, the rankings change, with quality standard compliance and cross-contamination handling tying for the top spot. Establish a good working relationship — while the most common issue considered — is less critical, indicated by 58.7 percent of respondents to be a "very

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important” issue. Rounding out the top “very important” attributes are ‘protect intellectual property’ (57.1 percent), followed by ‘stick to a schedule’ and ‘have capacity enough to meet my sales demand,’ each cited by 44.4 percent of clients.

### Summary

Client-contractor relationships are full of potential pitfalls. Large sums of money are at stake, timing is of the essence, and both sides are under internal and external pressure. Yet there are concrete steps that both sides can take to make the relationship healthier, and by extension, more rewarding. With communication issues consistently topping the list of attributes — and complaints — both clients and CMOs need to continue to focus their efforts on establishing better relationships. With better communication, the CMO-client relationship can reduce concerns before they become actual problems.

### References:

1. 9th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production, April 2012, Rockville, MD [www.bioplanassociates.com](http://www.bioplanassociates.com)

2 Technimanagement: The Human Side of the Organization, Brown, D. 1997, Pub: BioPlan Associates, Inc.

*For more information, please visit [www.bioplanassociates.com](http://www.bioplanassociates.com) [1].*

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