

# The Sting: scope-changing CDMOs

In 1973, a movie entitled 'The Sting' was released. The title phrase refers to the moment when a con artist finishes the 'play' and takes a person's money. If a con is successful, the person does not realise they have been cheated until the con men are long gone, if at all.  
By Kenneth Drew, Ph.D.\*

**T**he movie won seven Oscars at the 46th Academy Awards and is a very good watch.

Unfortunately, the plot of this movie is being played out in today's pharmaceutical world. Unknowingly, there are innovator drug companies being subjected to this sort of 'play' when they look to source their compounds. While it is not as elaborate as in the movies, it is still very painful to the company (or the 'mark') that is targeted. The goal of this article is to shine a light on this common practice taking place today and, hopefully, educate those in charge of sourcing their drug substance.

## The process

If you are a pharmaceutical company that is developing a drug, you will need a CDMO to be part of your project. Typically, you will send a Request for Proposal (RFP) to a variety of CDMOs to allow you to compare and contrast the costs from these vendors with the goal to stay within a specific budget set forth by management.

One of the biggest issues in the selection of a CDMO is relying on unrealistic budgets that are set forth from management. Perhaps, the management is inexperienced or has limited funds in which to complete their project. Nonetheless, this has a profound effect on the project cost and the timelines associated with it.

Another perplexing issue is that every CDMO has a different

format for proposals. This makes it difficult for the CMC team in charge of outsourcing to compare apples to apples. This can lead to confusion during the selection process as some quotes may give them a case of sticker shock.

## The Sting

It has become a common practice for many CDMOs to deliberately underbid in hopes to gain the business. Some CDMOs purposely provide quotes using the same template for any project. These proposals are set up to be knowingly vague with a lower cost. Once they gain the purchase order (PO), they begin to work by following a timeline that they provided to the customer. After several months, the nefarious CDMO will knowingly institute huge, costly scope changes as the project moves to a stage where the customer has no choice but to stay with the CDMO since changing CDMOs would now cause larger problems with their timelines.

At this point, the customer has no option but to stay put. They must speak to their management team to acquire extra funding for the project. As the project continues, the cost suddenly exceeds the costs of some of the other initial proposals that were part of the selection process, but dismissed as they were deemed too expensive. Some of these proposals may have been very detailed and complete yet they were not reviewed in enough

detail to be considered. This is consistently happening today because these individuals are now in charge of a project that will come in over budget and will also be late. Why? Because they made the decision to not push back on management and fight to work with a CDMO that initially provided a very detailed proposal that lined out the breakdown of the raw materials, as well as the estimated time to do the necessary process and analytical development.

## Advice

It is advisable to budget more money than you need for your project initially. You will find it much easier to tell the finance team that you did not spend all the allotted money rather than having to ask for more due to unenviable scope changes that occur.

When sourcing a project, ask for transparency to allow you to compare proposals properly. Raw material tables are a must with a breakdown of not only the cost, but the % impact to the project. This allows one to hone in on problematic materials and possibly consider potential options to avoid high costing raw materials. An overview of the resources needed, as well as a Gantt chart should be included.

Do not mislead yourself, scope changes will happen. The goal is to minimise these. Finding a CDMO that speaks to potential issues up front in their proposal is a good indicator of a CDMO willing to not only work with



you, but for you as a true partner. This is much better than waiting until you are three to six months into the project and the nefarious CDMO tells you that the project will cost more and be significantly late.

A recent survey<sup>1</sup> found that many drug developers do not formally budget for the CDMO selection process. It is well worth it to provide some upfront funding to allow for visits to potential CDMOs. There is something to be said for actually meeting a team in person and understanding what type of company you consider working with. Also, do not be afraid to speak to those in your professional network.

I have found that seasoned CMC professionals are able to focus on a combination of service, reputation, experience, timeline and price together while inexperienced CMC professionals tend to solely focus on price and timeline. It is the inexperienced CMC professional that ends up being 'the mark' that the nefarious CDMOs look for. Don't get stung.....

1. <https://www.lifescienceleader.com/doc/outsourcers-who-most-heavily-rely-on-cdmos-often-lack-cdmo-selection-resources-0001>.

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