Built To Fail: How Today's Manufacturing Options Leave Pharma At Risk

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When planning for the development of a new product, a pharmaceutical manufacturer must determine very early in the process what a product's anticipated demand will be at the time of launch.

Because of the arduous road manufacturers must follow to bring a drug to market, forecasting this demand is often done three to four years ahead of time when the company has no real idea if a product will be a success. There is also a limited understanding at this time of the market uptake as well as the competitive landscape the product will face once it is launched. There is no exact science to making an accurate prediction, which often leads to under- and over-forecasting.

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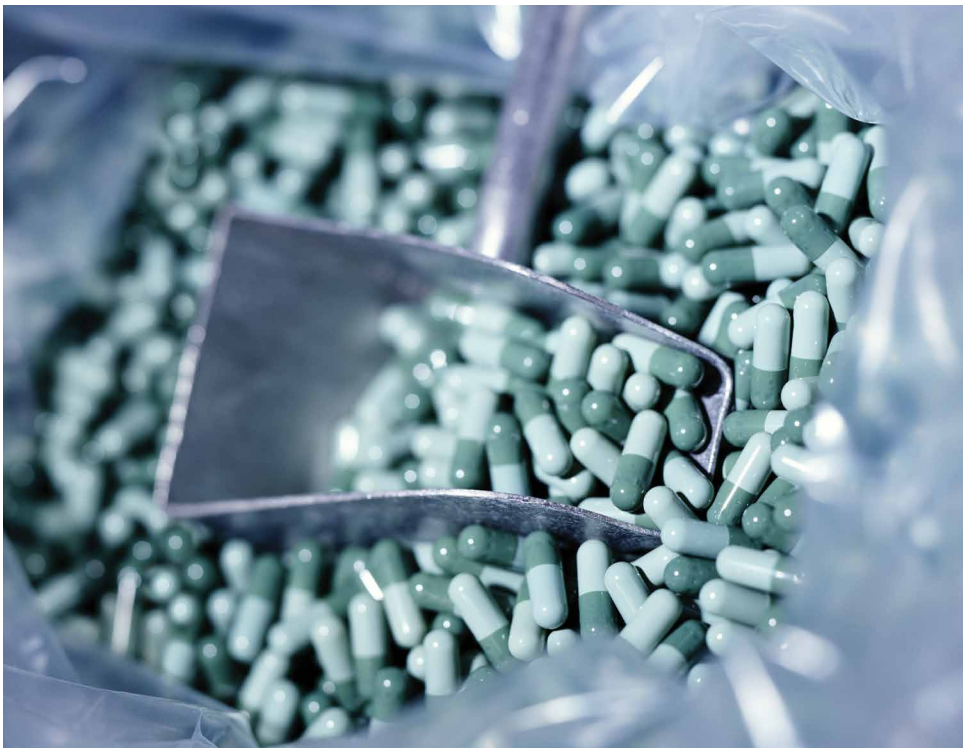
Though pharma companies do their best to understand the environment, it can be very difficult to predict demand, and the consequences of incorrect forecasts can be very costly in a number of ways. Underestimating demand can result in a loss of sales, product risk, and overworked employees, while overestimating can result in a misappropriation of capital. For example, a typical biologics facility requires an investment of $400 to $500 million and can take three to five years to actually produce. If you are basing a capital expense of that magnitude on a demand that is forecasted, then you are looking at the very real possibility of making a huge capital investment that could wind up being empty or half-empty, because you really don't have a firm handle on the amount you need. The converse is also true. If you do not procure enough capacity, then you end up short-stocking the market and patients do not get product. In addition to lost revenue, you are also faced with a situation of denying patients the medicine they need—a scenario no one wants.

In a recent study from ORC International, it was found that a majority of companies are over- or underestimating demand by up to 25%, though instances of over 50% were reported. In the cases of overestimating, respondents pointed to market volatility or to being overly optimistic as the cause, while a lack of background data to support forecasting information was often the cause for underestimating. Beyond the serious consequences that over- and underestimating demand has to internal operations, it can also have a negative impact on a company's reputation. Whether it is an inability to supply drugs to the patients who need them or a competitor bolstering their own reputation at the expense of another's shortcomings, the long-term damage of these misjudgments can cause a company to face backlash for years to come. This leaves pharmaceutical manufacturers with some very difficult decisions to make when it comes to preparing manufacturing capacity, starting with one important question – build or buy?



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If you build it…will they come?

Insourcing is a long process, and having the capacity necessary for demand is the first hurdle to address. If enough capacity exists for the predicted demand, the task of preparing for a new drug is a bit easier and the investment is likely not as significant. However, if you need to plan for new capacity, engineering studies and plans must be completed, facilities must be built or modified, and equipment must be ordered, installed, and qualified, which can all take years to complete. As already stated, this comes with a hefty price tag.

There are also many decisions that need to be made when planning a new build, such as the scale of the facility, how many platforms the facility will be for, the location, the tax strategy, and many more. The goal is to build a facility that accommodates whatever demand is projected, but again, you are counting on an unreliable forecast to eventually justify the investment. Based on what the forecast indicates in terms of the amount of material that will be needed, each company will need to have its own risk profile—should they stick to the forecast or are they going to hedge their bets and procure a little extra? There is no universal approach to risk mitigation, and some companies are risk tolerant while others are extremely conservative and will over-procure materials to make sure they have enough.

Forecasting uncertainty drives outsourcing

The alternative, of course, is to outsource capacity. In this case, capacity can be secured at shorter notice, but it has historically offered little flexibility to move with actual demand. There is also the task of identifying the right CDMO for your project, and if special capabilities are required, the CDMO must then examine its engineering and capital investment program. Contracts will need to be negotiated, and in what has become a commercial norm for the industry, take-or-pay contracts are often executed by CDMOs looking to safeguard their investment. Understandably, pharma companies do not like take-or-pay contracts, while suppliers see them as necessary to protect lost revenues. This has represented the approach for years. Underestimating means the company must procure additional capacity (typically externally), unless they have an abundance of capacity, and again, the same theme presents itself. Finally, processes will need to be transferred and validated, with stability batches manufactured. This all requires an extended manufacturing and supply chain planning cycle.

Because of these significant investments combined with the multiple variables that can change a sales outlook over the course of a manufacturing timeline, supplier business models that can provide flexible manufacturing options with the ability to move in concert with real demand offer a number of advantages. They include, but are not limited to, a reduction of complexity in supply chain management, elimination of redundant activities repeated with supplier handoffs, and above all, increased speed. Forecasting will always be required and pharma companies continue to work on improving forecast accuracy; however, the solution lies in a business model that can absorb the ebbs and flows of real demand in real time.

Flexibility in the face of unpredictability

Without the ability to predict capacity needs with 100% accuracy, pharma must come up with an effective way to eliminate demand risks. Today's traditional approaches cannot provide the flexibility and scalability necessary to grow and advance in an industry that continues to offer exciting innovations often coupled with new challenges. Advances in technology, such as single-use bioreactors and continuous manufacturing trains, offer CDMOs the ability to run multiple scenarios that establish broad parameters rather than the single-point estimates of traditional forecasts. This allows for the flexibility necessary to adapt to a wide range of possible launch outcomes. By moving beyond the traditional one-size-fits-all solution, which relies on multiple clients sharing the same tightly scheduled production train, CDMOs open themselves and their clients up to new solutions to supply chain management.

For example, if the predictions for forecast are made up to five years ahead of the launch and the client has the good fortune that the uptake of the product, once it hit the market, is wildly ahead of their expectations, a CDMO working through a flexible model can construct business models that provide the capacity for these surges. Conversely, if the product is being taken up more slowly in the market, the business model can be adjusted to allow the clients the option of releasing some of that capacity. However, in order to provide this flexibility, a CDMO must have a geographic footprint, proper scale, and the skillset to manage this type of project.

Overall, there are countless factors that influence and contribute to the unpredictability of drug development. By mitigating the risks of the unknown with a strategy that is both flexible and scalable, you will be better prepared for the growing challenges in a new era of pharmaceutical manufacturing.

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Published 03/19 PATH0690

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