Contract Manufacturing in Biotech: Turning Your Supply Chain into a Competitive Differentiator

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Executive Synopsis

Global supply chains are often underutilized assets. By embracing the concept of variabilization- transforming fixed costs to variable costs, biotech companies can significantly leverage their supply chain, thereby freeing up valuable resources for new product launches or other priority initiatives. Key to this strategy is finding and engaging a knowledgeable and dependable contract manufacturer. Potential contract manufacturers must keep intellectual property (IP) safe, meet necessary regulatory requirements, and provide excellent cost effective client support. The first step in leveraging the supply chain is bringing together the contract manufacturer with operational and change-management leaders. By starting on a project where all parties are confident of success, a firm base is established for improving supply chain leverage.

Contract Manufacturing in Biotech

Contract manufacturing in the life-sciences industry is gaining a strategic role in the supply chains of some of the most successful companies. Once considered just a capacity alternative to the manufacturing or distribution capabilities of operations, the benefits of leveraged supply chains are increasingly recognized. Why is this transition occurring? A leveraged supply chain not only improves operating profits, it has the power to transform the global operations team into a competitive operating advantage by accelerating the company's innovation engines in new product development. This paper will explore some of the reasons companies are using leveraged supply chain models and how you can deploy this strategy in your company.

Factors Impacting the Biotech Supply Chain

Today, leaders of biotech supply chains must navigate the traditional operational challenges including planning capacity, supply chain risk management, and organizational inefficiencies, while meeting performance metrics. However, there are three additional contributing factors that are more unique, or heavily weighted in the sector today.

The operating profit squeeze – Publicly traded biotech companies continually cite the priority to improve operating profits in their quarterly reports as they navigate sector challenges. According to the annual 2016 Life Sciences outlook report from Deloitte these challenges are[1]:

- Navigating Market Dynamics
- Countering Price and Cost Pressures
- Promoting Innovation
- Adapting to an evolving regulatory and risk environment

The question for leaders is how to overcome the cost pressures sustainably, rather than taking short-lived cost cutting measures that have the desired effects to the bottom-line but often doesn't change the underlying operating norms of the company.

More emphasis on R&D execution – By definition, biotechnology companies are largely valued by their ability to innovate. This fact has never been more important than in the competitive landscape of today where biotechs allocate 8%-20% of annual revenues on research and development. Indeed, research budgets are growing at 18% YOY as revenues improve and more FDA approvals are gained[2].

In order to maintain this high level of innovation, a company's most talented people are often focused on new product introduction. However, the need to innovate and launch products can be at odds with an operations supply chain that is under constant expense and capital pressures. Companies must also find ways to free these experts up from the routine activities associated with supporting the revenue-generating legacy elements of the product portfolio.

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1 http://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2016-life-sciences-outlook.pdf

2 https://www.bdo.com/news/2015-november/biotech-fever-drives-boom-in-r-d-spending-revenue

The "silent killer" of competitive supply chains, the dreaded depreciation schedule – Year after year the capital committee reviews the forecasted capital spending plan submitted by the various elements of the business. In my experience, every year the amount of capital requested exceeds the amount allocated to capital expansion. Worse yet, is what I describe as the "silent killer effect" that capital expansion can have on the overall supply chain's competitiveness for the company when it is underutilized. Unless these capital expenses are fully utilized, they add to the burdened overhead of the operations. This has the effect of pushing the leverage any company would want from operations further and further away. Of course, there will always be obvious capital expansion requests and these are easy to justify. But more often the case for capital expansion is strategic in nature, often tied to new capabilities that will be underutilized in the beginning and is based on optimistic growth forecasts.

Leveraged Supply Chains as a Competitive Advantage

To address the squeeze on operating profits, free up resources for innovation, and avoid depreciation coming from underutilized manufacturing resources, companies are focusing on "variabilization." Variabilization can be defined as the transformation of fixed costs into variable costs within the enterprise. This transformation creates powerful leverage for a business and a competitive advantage. This is especially true when fixed costs that are underutilized can be shifted into variable costs, thereby freeing capital for other higher priority, more strategic initiatives within the company. An example will help explain:

Let's assume that a company – GenCo, has $10 million of invested capital[3] in their supply chain (Plan, Source, Make and Deliver). GenCo has revenues of $100 million from product revenues on the existing $10 million supply chain. This provides us a simple ratio of $10 dollars of revenue for every $1 dollar of invested capital (10:1). This ratio will allow us to understand the impacts of variabilization for GenCo.

Now, the enthusiastic Marketing and Sales team at GenCo has expectations to add $20 million dollars of additional revenues (at approximately the same average selling prices) due to a new product that is still in R&D but due to launch in 6 months. However, in order to support this new product, GenCo must expand its supply chain capacity at a cost of $10 million. GenCo will have $20 million in invested capital, against $120 million in revenues so its leverage has dropped from 10:1 to 6:1. A loss of 40% of leverage in the supply chain! If the $10 million dollar expansion has more capacity, or can support other new products, or if the new product has higher growth than forecasted, then

[3] This is not a calculation on a return on invested capital (ROIC) as there are different variables in that equation. This is only a simplified example.

some day GenCo may return to their 10:1 leverage ratio. Unfortunately, those are quite a few assumptions. Indeed, the risk can go higher; What if the new product has the ability to cannibalize the existing portfolio in some way? What if the new product isn't successful in the market? What happens if the macro economic environment changes? These are big risks, but GenCo is fortunate to recognize it has an alternative-variabilization.

To gain leverage, GenCo has two variabilization options.

1. It instead engages a strategic contract manufacturer for elements of its existing legacy product portfolio. This has the added advantage of making room on the factory floor while freeing up valuable resources for the new product launch.
2. Alternatively, GenCo decides to have a contract manufacturer work directly with the new product team to bring the new product to market by establishing the new product manufacturing at the contractor's site.

In these options, GenCo hasn't added fixed capital costs to their business. Simply put, GenCo is not paying for idle capacity nor is it being hit with capital depreciation. They will pay some small amount of non-recurring engineering costs to support the product and for tooling or special equipment, but GenCo would be adding this anyway. More importantly though, GenCo has increased their supply chain leverage, not reduced it. They now have $120 million in revenue supported on the same $10 million in invested capital or a ratio of 12:1. This leverage (freed capital) can be preserved or perhaps used for other innovations! Isn't this the primary objective of innovation-oriented companies?

Choosing the Right Contract Manufacturer

Selecting the right biotech contract manufacturer to work with is essential to enable a leveraged supply chain model. Here are some important characteristics to consider:

- Do they match your Quality and Regulatory requirements? Not only for today but in the future? The increasing regulatory environments in this market are here to stay.
- Are you enabling a future competitor? A product company with excess capacity for hire is not a contract manufacturing services company.
- Is your intellectual property safe? Only a 100% dedicated contract manufacturing services company can promise this.
- What expertise does the manufacturer have? Consider technical strength, operational excellence, and supply chain execution.

- Is there transparency in pricing and costs? These are essential for a healthy long-term relationship for both the client and the contract manufacturer.
- Are there demonstrated examples of accountability and agility from the contract manufacturer? Not everything in a relationship goes as planned and a good contract manufacturer will bring solutions to the table to deal with unforeseen circumstances.

Getting Started

Getting started on leveraging your supply chain begins by developing an internal team of employees who appreciate the importance of focusing on your company's core strengths. While this may sound obvious, for some people leveraging the supply chain is thinking "outside the box." Making sure your team appreciates this leverage can be a valuable company asset, one that is measurable as a competitive advantage. You will want team members who are open to new ideas and are comfortable with change, when that change makes sense for the company.

Be sure to secure sponsorship and support with your operations leaders. Adding leverage to your supply chain requires change management support as well. HR, finance, operations and product groups must be involved actively and in a positive way. Any detractors need to know that you are adding capabilities to your company. You are not taking responsibilities away or passing judgment on previous organizations capabilities.

Formulate a set of prospective projects, and set the project up for success. Start with projects that the contract manufacturer and you are confident will succeed. Build familiarity with each other, share with transparency and honesty. The first project is the wrong time in the relationship to leave important decisions to chance.

Finally, have fun and learn as you build out this new competitive advantage for your company. Like any other project you do in your business, success begets success. Set your sight on building a strong long term relationship and you will be highly satisfied.

Conclusion

Now more than ever, the Life Sciences industry is moving and maturing at an accelerated rate. The changing regulatory environment, focus on innovation and new products, combined with increasing cost and pricing pressures provide an opportune time to upgrade your operational arsenal. By adding a trusted contract manufacturer partner, you can harness the power of leverage, experienced capabilities and variabilization to transform your company's global supply chain into a competitive differentiator.

For more information on how to leverage your supply chain, call us at 1-888-834-8892 or email info@argonautms.com.