

Perspective by Todd Applebaum, Managing Director

Improving Demand & Supply Planning for Emerging Life Science Companies

Service Area: Supply Chain

Lifecycle Stage: Preclinical, Clinical, Commercial, Mature

Planning for demand and supply is crucial for all Life Science companies, especially those who are dealing with fragile or perishable treatments for chronic or life-threatening conditions. Bringing innovative therapeutics to market involves a tremendous amount of uncertainty. Supply chains are complex. Lead times are long. Clinical and regulatory outcomes are unclear until very late in the process.

This challenge is even greater for emerging life science companies because they are also establishing their processes and infrastructure for the first time. These young companies must balance ensuring that materials are always available for patients during clinical trials with ongoing product and process development, all while preparing for commercial manufacturing.

Poor planning also introduces substantial risk. For example, supply disruptions during clinical studies could lead to stockouts at clinical sites, missed dosing of patient treatments, or possible study cancelation by regulators.

Emerging companies who build and appropriately scale their planning capabilities at this stage are more likely to ensure reliable supply, maintain launch preparation timelines, avoid unnecessary write-offs, achieve more effective vendor relationships, deliver better customer service and be prepared for managing variability in the supply chain and the marketplace.

Improving the planning process empowers all organizations to do more with less money, maintain timelines more precisely, forecast cash flow and revenue expectations, and ultimately deliver patient treatments as quickly as possible.

Planning Challenges Unique to Emerging Companies

Emerging companies face a more challenging environment than life science companies at other stages of development. Demand in clinical-stage companies is based on fluctuating site recruitment and enrollment rates, as well as study protocols that are subject to change and redesign. Long manufacturing and supply lead times also mean that they must invest in commercial production batches before clinical trial data is reported, and long before reliable commercial forecasts are developed.

They must address these challenges while also dealing with regulatory, compliance, and product constraints that can impede the ability to plan or quickly respond to change. For example, supply chains for temperature-controlled products require cold chain expertise and add to transportation lead time. These aspects introduce potential points of failure into an already complex sequence.

Typical Planning Challenges for Emerging Companies

- Protocol-driven demand profiles with multiple arms & variable treatment durations
- Clinical site startup and enrollment uncertainties
- Complementary and ancillary materials
- Lack of planning experience within CMC/Technical Operations team
- Absence of defined planning process or inventory strategy
- No established supply chain organization
- Constrained personnel and financial resources
- Lack of communications and understanding of cross-functional demand and supply needs

Additionally, while emerging companies are abundant with scientific knowledge, they typically lack expertise in supply chain and forecasting, as well as the operational resources of their more established peers. Other challenges include lack of established planning tools, insufficient forecasting processes, manufacturing processes that are still in development, and unreliable service from suppliers.

Emerging companies are also frequently operating with lean teams. Consequently, there is limited ability to dedicate resources to understanding their specific demand and supply situation, let alone keeping other functional areas informed of constraints and changes. This lack of information and coordination makes it difficult to determine whether to commit to expensive production batches or when changes are needed for existing plans.

Traditional Approaches Can Be Misleading

Companies have traditionally used inventory to buffer against the planning challenges posed by demand and supply. Historically, inventory strategy for emerging biopharma has been a simple rule-of-thumb approach, calculating a blanket 24 months or more of inventory to have on hand in order to cover supply disruptions or demand variability. However, in addition to being a costly approach, companies learn that even several years' worth of inventory can fall short with the proliferation of clinical packaging configurations, regions, depots, and SKUs.

Emerging clinical-stage companies are typically operating very lean with Clinical Operations handling demand forecasting. These professionals are experts in setting up and managing activities at clinical sites, but often do not fully understand fundamental planning principles or the interdependency with supply functions.

Supply planning is generally the responsibility of a similarly lean CMC team. While CMC excel in technical expertise, they frequently lack the experience to manage demand aggregation, depot replenishment and the requirements of complementary/kitted materials.

These limitations of traditional methods call for new ways of approaching demand and supply planning for emerging and growing biopharmaceutical companies.

Stage-Appropriate Planning

A more suitable approach is to view planning through the lens of maturity, aligning key aspects of the planning process to a company's lifecycle stage. For example, work particularly with emerging life science companies led Converge consultants to develop a **Demand & Supply Planning Maturity Model** specific to this industry and stage of development.

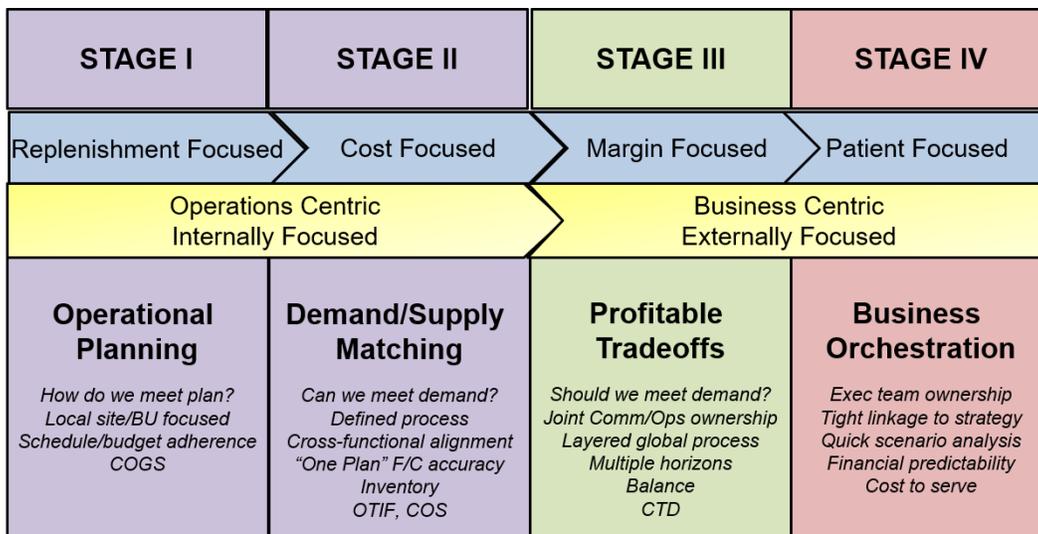


Figure 1. Demand & Supply Planning Maturity Model

The stage-appropriate activities captured in this model recognize how important it is for small, developing companies to begin with a 'lite' planning process that is more tactical in nature, but not overly resource dependent. Planning then becomes more strategic as the companies grow over time.

A key aspect of the model, however, is that it maintains core principles of S&OP - demand planning, supply planning, and alignment - even at the earliest stages. Employees from across the demand, supply and finance functions are involved in designing an iterative cycle that allows their organization to build comfort with the process as they learn and grow in capability.

It also adapts these fundamental concepts to the particular needs of emerging companies by:

- Focusing initially on cross-functional communications and alignment rather than tools and processes.
- Establishing light versions of demand & supply planning discussions to foster broader understanding.
- Incorporating education in planning principles and requirements across functions.
- Designing the process for lean organizations, where multiple roles are held by a few key players.
- Defining lighter levels of involvement from cross-functional participants.
- Utilizing inputs and KPIs that evolve as the company matures.

Using maturity models, companies can also identify where to focus financial investment based on their lifecycle stage. Stage 1 companies rarely find value from investments in complex software technology while data from pivotal trials is still in doubt. In many cases, lighter cloud-based tools or Microsoft Office applications can fulfill their planning needs.

These models accommodate the limited resources and complexity of an emerging company by providing a simplified planning approach that can be managed in a lean resource environment with very basic data. The approach becomes more robust over time as the organization and complexity of the business environment grows from a first commercial product to multiple commercial products and development programs running simultaneously. It also provides a platform for helping align organizations around the significant business decisions that must be made to balance demand, supply, and financial considerations.

Application of a Planning Maturity Model for Emerging Life Sciences Companies

In one recent engagement, a client was in the early stages of preparing for a large-scale trial. Process development staff in the Technical Operations group was conducting the planning activities. Demand forecasting was essentially a black-box number from the CRO with no visibility into their assumptions, decisions, or restocking policies.

The supply side was equally reactive with little visibility into CMO production plans and highly unreliable timing for production runs. There were no established tools or processes in place yet. As a result, the sole part-time planner was struggling to effectively determine supply requirements, let alone balance supply and demand.

The situation was brought to a breaking point when the company had to determine whether to initiate another multimillion-dollar manufacturing batch of API to support a sudden increase in the demand forecast.

Converge practitioners partnered with the client to establish a planning approach that was well-suited to their lifecycle stage, using the parameters of the Planning Maturity Model. We assessed their demand and supply dynamics, which led to setting a rational inventory target.

A very basic supply/demand model was developed to translate the demand forecast into supply requirements.

A basic Demand & Operations Planning process, or D&OP (based on core S&OP principles) was designed that required minimal resources and made judicious use of senior management time. It allows for the collection of demand requirements, development of a supply plan and then a well-informed conversation to ensure alignment and set forward-looking plans for the next 24 months. This new process relies on part-time contributions from five key employees. It highlights decisions, tradeoffs to address, and enables a forecast that can be used with vendors. It also provides visibility to plans and, more importantly, to changes throughout the organization.

Now, not only does the company understand the underlying demand and supply dynamics, but also the executive team was able to avoid that multimillion-dollar investment in additional inventory.

In Summary

Demand and supply planning is as critical a capability for emerging life science companies as it is for large mature companies. While clinical-stage firms are managing complex studies and preparing for commercial supply, they are also facing massive uncertainty in both supply and demand that should be managed in alignment with their current capabilities and long-term objectives.

Planning maturity models, such as Converge Consulting’s Planning Maturity Model, enable emerging biopharma companies to adopt the core principles of S&OP at a level aligned to their size and maturity. They enable smaller organizations to match supply with demand, driving improvements in demand and supply management. They also provide a forum for discussion of investments, risks, and tradeoff decisions, which all lead to better financial planning.

Life science companies of any size can implement sound planning principles regardless of their lifecycle stage. Successful planning models help design processes that are “fit for purpose” so they can evolve over time to adapt effectively to demand, supply and other business uncertainties as companies grow.

Todd Applebaum has a 20-year track record working with companies across the pharmaceutical, biologics, regenerative medicines, and medical device sectors. Before founding Converge, he led manufacturing, quality, supply chain, and technical services at Ovascience, Inc. as the company transitioned from research to commercial. Todd has also provided life sciences research leadership at Gartner, Inc., operations expertise at Deloitte Consulting, and co-founded Maxiom Consulting Group, which focused on operations strategies, manufacturing and supply chain, commercialization planning, and Operational Excellence. He holds a BS in Industrial Engineering, and an MBA from Carnegie Mellon University.

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Figure 2. D&OP Process Cycle

