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Supply chains should be designed early in the product development cycle and should be flexible and resilient.

Delivering on the Promise: Building an Effective Product Supply Chain

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As biopharmaceutical companies bring new products to market, they generally focus on clinical development, regulatory submissions, and preparation of the target market. Equally as critical is developing the product's commercial supply network. Thoughtful planning and design of the supply chain during product development significantly impacts not only the efficiency of commercial sup-

ply, but also the flexibility required to accommodate lifecycle changes. Ultimately, the right supply chain can help ensure the availability of critical and life-saving products to patients who need them. Conversely, an ill-planned supply chain can increase operating costs, restrict a company's flexibility, and constrain the flow of product to patients.

A supply chain allows the movement of materials, money, and related information from the suppli-

ers of key materials and components to the end customers or patients. During the years leading up to a product launch, basic strategies and best practices can be applied to plan, design, and build a product's supply infrastructure. These steps should be followed each time a supply chain is established, whether it is a company's first or tenth commercial product launch.

START EARLY WITH STRATEGIES

Developing a strategy is the first and most important step in creating a new supply chain. The strategy should identify:

- the general structure of the product's supply chain
- which capabilities will be bought or built internally
- which elements overlap with other products, either approved or in the pipeline.

The supply chain strategy sets the tone for launch-related activities throughout the organization, and helps to shape planning for other functions, including QA,

Quick Recap

- **Developing a strategy** is the first and most important step in creating a new supply chain.
- **Early planning** helps to define which activities are necessary to develop the infrastructure, and when they need to be completed.
- **Supply chain design** requires considering the product itself, requirements for market area, and regulatory strategy.

commercial operations, and finance and development.

ASSUMPTIONS ARE KEY

Early planning is an important insurance policy and helps define which activities are necessary to develop the infrastructure, and when they need to be completed.

Planning for a commercial supply chain build-out should begin roughly 24 to 30 months before the anticipated commercial launch. This may vary depending on the duration of clinical trials, and the complexity of technology transfer.

Managers in many life sciences companies hesitate to establish a plan early in the development stage because of all the unknowns surrounding key supply chain variables, such as demand patterns, manufacturing yields, and stability ranges. It is helpful to document a preliminary set of working assumptions to initiate planning and limit the degrees of uncertainty. This helps to clarify intent, communicate consistently across the organization, and allow departments to conduct their own functional planning.

In many emerging companies, supply chain expertise does not exist early on, and there is a long delay in filling key internal roles. Planning can become fragmented, with various individuals and functions developing the supply chain. Sometimes, planning is well-defined for certain parts of the supply chain, like manufacturing, but not for others, like packaging and distribution. Planners should focus on relevance over precision; they should review documents regularly, changing

them as new information becomes available throughout development and launch preparation.

DESIGNING A SUPPLY CHAIN

Developing a detailed design for the commercial supply chain should be done early and include an in-depth description of the numbers and types of organizations involved, required business processes, definitions of internal and external roles, required information flow, underlying applications, and existing constraints.

Supply chain design requires considering the product itself (storage and handling requirements), requirements for market or therapeutic area (complementary components, packaging, channels), and regulatory strategy. Flexibility and resilience should be built into the supply network to handle fluctuations and unexpected events. Companies should develop preliminary performance models to examine the behavior of the prospective supply chain along key metrics. This will provide a baseline expectation of performance that can be used for budgeting and planning, and for developing contingency plans. Such models may be spreadsheet based, but companies can also use more sophisticated modeling and optimization tools.

Supply chain design is inherently cross-functional, and highly dependent on decisions made in other areas. For example, product or process development may have designed a requirement for a proprietary manufacturing method or unique component. Sometimes, there may be only one single sup-

The supply chain can be used as a tool for managing not only product supply risks, but overall business risks as well.

plier for such a capability. As a result, the selection of the manufacturing partner has most likely already been made.

While due diligence should be conducted to ensure that development-stage partners are capable of supporting commercial production, these early stage decisions are likely to constrain the design of the supply chain. Marketing has also more than likely already established preliminary demand requirements or projections. Demand characteristics such as seasonality for drugs such as vaccines, or geographic expansion are important drivers of both manufacturing capacity and distribution capabilities.

Often the original sourcing of materials is performed by development or research personnel, and does not consider the critical nature of the component to the manufacturing process. In this regulated industry, any single-sourced component can become critical to the manufacturing process. As products mature through the life cycle, their demand typically increases, as do production requirements. The stability of the critical component supplier and its capacity become increasingly important. Although not usually required or feasible before launch, second sourcing of critical raw materials shortly afterwards is advisable to secure the supply chain.

FLEXIBILITY FOR CHANGING CONDITIONS

Design priorities for a supply chain change throughout a product's life-cycle. While more mature supply networks are fine-tuned with the intent of squeezing out inefficiencies and leveraging economies of scale, during product launch the focus is on ensuring that product can be shipped on approval and that supply can be maintained.

In preparation for launch, it is critical that the supply chain design enable enough product to be made so there are no shortages. The cost of the product compared with the margin and opportunity cost of a shortage, typically outweighs the cost of producing additional material.

These changes over time should be taken into account as supply partnerships and contracts are developed. If the correct amount of effort is put into the planning and design of the supply chain, building it should primarily be about execution.

A RISK MANAGEMENT TOOL

Whether building internal capabilities and facilities, or establishing a "virtual" chain, developing a commercial supply chain is a huge investment for most life sciences companies. By anticipating changing conditions and managing the

uncertainties explicitly, the supply chain can be used as a tool for managing not only product supply risks, but also overall business risk as well.

Building out the commercial supply chain typically includes establishing relationships with partners for all external capabilities, increasing productive capacity both internally and externally, designing the internal business processes and organization for managing supply, and implementing information technology solutions. Each of these activities will bring its own challenges.

Partnerships can play a key role in building the supply chain. While there are many reasons for outsourcing capabilities, emerging life sciences companies often partner with other organizations to secure major elements of their supply chain. This is due to a lack of sufficient expertise in a particular area, and constrained resources for investing in building the capability. Outsourcing can pose several challenges simply in understanding the appropriate requirements for making an outsourcing selection, and in defining the correct terms and expectations for the relationship.

Particularly when negotiating long-term, multiyear contracts with contract manufacturing organizations (CMOs), it is crucial that terms be drawn with an awareness of future market plans and requirements, with opportunity for upside, but protection against downside.

Lead times for technology transfer and validation will push capacity start-up activities high on the prior-

ity list, when demand, clinical, regulatory, and manufacturing process uncertainties are greater. Because of these risks, some companies can be left with severely underutilized capacity (>50%), or significant shortages of supply capacity. Effectively managing the inherent risks in capacity investments and commitments drives some companies to develop staged or risk-based approaches to bringing up capacity, or exploring risk-sharing strategies for significant investments.

At one company, for instance, initial demand projections 30 months before launch showed a substantial growth curve in the

first five years of commercialization. However, uncertainties in the outcome of clinical data, FDA labeling requirements, and timing of approval led to an appreciation of the downside possibilities.

A capacity build-out plan was implemented that included smaller sizing and staged startup of production lines so that incremental capacity could be delayed or abandoned if projections decreased. As a result, when the forecast was reduced 40% by marketing, startup plans could be delayed accordingly. By securing manufacturing capacity incrementally the company has the option of accelerating or delaying investment.

CONCLUSION

The development and build-out of an effective commercial supply chain is a complex and multifaceted initiative. It must begin early in the product development stages with strategy and planning, and its implications last well into commercial production. If some basic tenets are followed as an integrated part of product development and launch planning, the resulting supply chain should be well suited to meet not only near-term launch requirements, but also longer-term strategic business objectives. ♦

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