

Where should early stage drug companies have contracts in their supply chain?

Somewhere during clinical development, executives at early stage drug companies will ask themselves “Where do we need contracts in our supply chain?” For a developer of biologic drug products, this question might come up in Phase I. For a developer of small molecule drug products based on existing drug substances, this question might not come up until Phase III. Catalysts for asking the question include: a vendor asking for a long term supply agreement, investor concern about commercialization planning, regulatory advice to have quality agreements, a desire for lower vendor pricing, the need to access or protect intellectual property, and the general sense that it’s “the right thing to do.” This article will provide a commercial, not legal, perspective on where early stage drug companies should enter into supply chain contracts.

What is meant by supply chain?

Figure 1 provides an overview of the commercial, post-approval, supply chain for a virtual drug company.

The ultimate goal of the commercial supply chain is the reliable, *cost effective supply of in-spec product satisfying demand, cGMP, Environmental/Health/Safety standards, and other strategic business requirements.* Most early stage drug companies and their investors hope for an exit prior to drug approval. However, funding and negotiating dynamics are such that these companies should keep the commercial post-approval supply chain in mind. They may have to take their product to market to obtain the best (or an acceptable) exit valuation. In addition, execution against a credible supply chain strategy subtly declares “we are prepared and proceeding to market; the deal value goes up from here,” providing both reassurance to late stage investors and leverage in negotiations with potential acquirers.

The major components of a supply chain include:

- **Raw Material & Equipment Suppliers.** These vendors supply starting materials, excipients, adjuvants, cell culture media, packaging components, specialized equipment, and other items used in the manufacturing process. For drug products based on existing drug substances, the drug substance may be sourced as a raw material.
- **Drug Substance CMO(s).** These Contract Manufacturing Organizations are known by a variety of acronyms, including CDMO (contract development and manufacturing organization) and CRAMS (custom research and manufacturing service). These firms manufacture the fine

chemical or biologic drug substance and are typically involved in its process development. Drug substance CMOs come in a wide variety of scales and capabilities – the supplier of small volume early clinical materials may not be the supplier of Phase III and post-approval volumes. Depending on the situation, a drug company may have multiple CMOs to mitigate risk, respond to upside demand, and control costs. Complex process technology, such as a small molecule with a number of synthesis steps and/or unique chemistry, may necessitate the use of several CMOs to make the intermediates.

- **Drug Product CMO(s).** These firms are also known by several terms, including DFMP (Dosage Form Manufacturing and Packaging), Fill/Finish, and secondary manufacturer. Drug product CMOs can be involved in both process and product development. As with drug substance CMOs, the drug product CMO supplying small volume early clinical materials

may not be the (or sole) supplier of Phase III and post-approval volumes. A drug company may need several CMOs to complete drug product manufacturing, mitigate risk, and satisfy regulatory requirements in different countries.

- **3PL.** This a 3rd party logistics company that serves as the

warehouse and shipping organization for the drug company and may also provide order-to-cash and other services. Drug product is shipped from the 3PL to customers (e.g., drug distributors).

- **Ongoing Non-CMO Service Providers.** This category of vendors is a catch-all for other service providers who are used in the supply of a drug product. This category includes cell banking services and 3rd party analytical testing and release services.

Where should early stage drug companies have contracts in their supply chain? What pitfalls should they look out for?

The specific answers to “where” and “what” will vary for each company based on its business and supply chain strategies, process technology, and other factors. However, from a commercial perspective, here are a few thoughts that executives at early stage drug companies may want to keep in mind:

- **Assume success.** That is, assume that your company will be acquired, will license its product(s) to another company for development and commercialization, or will commercialize its own product(s) post-approval. Therefore, enter into supply chain contracts that a profit-generating operating company

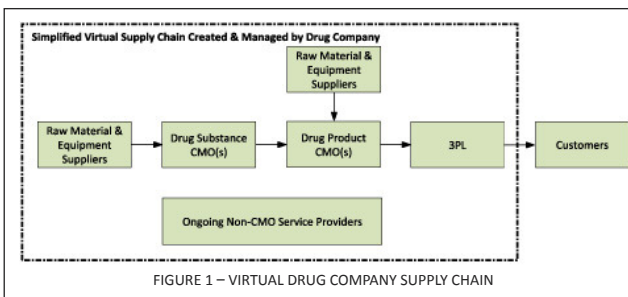
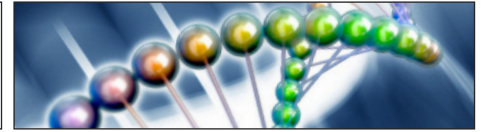


FIGURE 1 – VIRTUAL DRUG COMPANY SUPPLY CHAIN



would expect and could live with because (a) that is who the acquirer/licensor will be and (b) that is what your company might have to become.

•**You are the customer.** Remember that you are the customer with money to spend – maybe a few thousand dollars with a given vendor today, but perhaps tens of millions of dollars annually in a few years. While you may not always be right, you should obtain value for your spending or take your business elsewhere.

•**Vendor vs. Partner.** A vendor is not a partner unless that vendor is co-investing real money (not just the opportunity cost of being paid by you vs. someone else with an early stage product) and sharing in your gains and losses. While drug companies and their vendors can certainly have very mutually beneficial long term relationships that may seem like partnerships, early stage drug companies in particular should keep in mind that there is a difference between a partner who shares investment risk and a vendor who is compensated by its customer.

•**Strive for good contracts.** Supply chain contracts can range from near term transactional (“make X kg of drug substance for Phase II for delivery by Y date”) to long term far reaching (“supply X% of our post-approval demand for Y years”). Regardless of the contract’s duration or breadth, poorly written or hastily prepared contracts can haunt companies, particularly where intellectual property, exclusivity, pricing, and changes in ownership or control are concerned. Be cautious when entering into long term or broader scope contracts; make sure there is a clear benefit to doing so, build in flexibility for changing conditions, and carefully consider under what changes in fundamental circumstances would the early stage drug company either want “outs” in a contract or want to limit the vendor’s outs.

•**Stay flexible.** Venture capital investors may be comforted by an early stage drug company with supply contracts through launch plus a couple years. But big drug company acquirers may view such supply contracts as a hindrance for liability, synergy, and/or deal leverage reasons, and therefore assume success, strive for good contracts that a profit-generating operating company would like, and build in reasonable outs to preserve flexibility.

•**Consider cultural fit.** Supply chain contracts are not a substitute for good working relationships between people and the cultural fit between organizations.

Early stage drug companies should consider obtaining supply chain contracts where it is necessary to:

- Secure reliable supply of raw materials and services at an attractive and/or predictable cost on acceptable terms and conditions.

- Specify quality requirements and methods for resolving quality issues.
- Allocate liability and mitigate risk.
- Clarify roles, responsibilities, timing, and communication.
- Define ownership – who owns what intellectual property.
- Detail treatment of special situations – take or pay agreement to cover capital expenditures, meet or release pricing, acquisition of supplier or customer, etc.

A few words on what is most important

Supply chain strategy is the framework for determining where supply chain contracts are needed and what should be in them. The pre-work elements for supply chain strategy are the high level business strategy and an objective assessment of current and expected future process technology. These two elements, covering geographic markets, development timing, competitive positioning, intellectual property, desired economics, technology gaps, and other factors ultimately dictate what flexibility is needed, what needs to be accessed or protected, when, where, and at what cost by supply chain contracts. Both of these elements are needed to answer “Where do we need contracts in our supply chain?” While good supply chain contracts can certainly be concluded in the absence of the bigger business and technology picture, the risks and costs of having to “fix” or “live with” something later go up.

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Hal Craig founded Trout Creek Consulting (TCC) in 2007 on the principle that management consultants with strong problem solving and finance skills, significant operating experience, and industry knowledge will deliver superior value to clients through improved decision making and effective execution. TCC’s offerings include defining Actionable Strategies, providing Deal Advisory services, and creating Life Science Supply Chains. Mr. Craig, who earned his MBA from the University of Michigan and his BSChE from the University of California at Berkeley, entered the life science industry in 1984; his experience includes drugs (biologic and small molecule) and devices. Mr. Craig is also on the Physical Sciences Investment Advisory Committee of Ben Franklin Technology Partners of Southeastern Pennsylvania. Away from TCC, Mr. Craig volunteers as an Assistant Scoutmaster with the Boy Scouts of America.

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