**Cell Therapy Supply Chain Marches On**

November 10, 2015 / by [**Jacob Ceccarelli, PhD, Biotechnology Engineer, PCT**](http://www.pctcaladrius.com/pct-pulse/author/jacob-ceccarelli-phd-biotechnology-engineer-pct)

Like an army, cell therapy marches on its stomach, and good supply chain management can (literally) keep it fed. However, the “soldiers” of cell therapy are the most extreme of gourmets. They demand ingredients of the highest quality, that are tightly regulated, rarely found off-the-shelf, are often from a sole supplier, and are, therefore, very expensive. Near and long-term planning are essential for mitigating the supply chain risks of nourishing this ragtag militia as it grows into a legion of connoisseurs.



Procuring high-quality ingredients is the first hurdle a cell therapy developer faces, and this alone can create supply and sustainability bottlenecks. Few providers can manage the burden of producing products that will enable their customers to meet Good Manufacturing Practices (GMP) standards, something that is required for manufacturing clinical product, limiting the number of suppliers and creating a sustainability issue: a major commercial liability. Market demand can also cause shortages for smaller customers, like cell therapy developers, while hospitals and other large or critical consumers are prioritized. An example of this is the ongoing saline shortage, caused by rising overall demand. Few direct actions can be taken to mitigate this problem, but overall mindfulness of the market and building good relationships with multiple suppliers can guide your supply strategy. As the cell therapy industry grows, more suppliers will be willing to invest in the quality systems required.

There are many cell therapy product suppliers at various stages of corporate maturity offering off-the-shelf and custom materials, and members of PCT’s Center for Innovation and Engineering actively seek out suppliers that offer innovative solutions. In our view, process development is also a part of supply chain management, and steps with each type of supplier can be taken to minimize your supply and cost of goods sold (COGS) risks:

* *Traditional suppliers* of big pharma, blood banking and academia that are now dipping their toes in cell therapy are the most reliable. Although vigilance is required, these types of suppliers can be counted on to understand the regulatory requirements, and sometimes specific needs, of cell therapy. Many materials can be sourced from multiple suppliers and are mainstays of biological processing, making larger suppliers the prime choice for many materials. Custom products, such as particular tubing set configurations and culture medium in bags, although expensive in phase 1, can often be procured and integrated early into the process, minimizing the need for subsequent changes.
* *Medium-sized suppliers*, often with a significant percentage of their business in the cell therapy space, are moving to meet the demands of the industry. These are somewhat mature companies, generally those with a flagship product line that fills a niche and those well-established in the industry. They are generally knowledgeable about manufacturers’ needs and can provide a robust supply of products, although their scope is limited. They may also be more willing to take risks on new innovations than larger players. COGS can be a scalability risk with manufacturers of this size, especially if they are the sole supplier of a critical product. Ideally, supply agreements should be negotiated early; insufficient supply from these types of providers can be expensive at best, and halt production at worst.
* *Smaller companies* are generally the most flexible (with their specialty products) and may be willing to work closely with you to make their products work. However, their knowledge of your needs is much more limited; quality systems may be lacking, validation is often left to the end user, and importantly, sustainability may be a problem for certain companies. There are few catastrophes worse than building products that will not exist in a few years into your process. PCT takes an active role in partnering with nimble innovators, conscious of the fact that extensive testing is required before new technology can be adopted.

Clearly, stocking your cell therapy kitchen demands a keen understanding of where your process is and where it needs to go. Choosing high quality ingredients early on is often unpalatable – sticker shock scares the squeamish – but a mature decision maker builds an economy of scale into their process, and realizes the value of that decision as production booms.