



Contract Sourcing

A Q&A With Brik Eyre, GM Of Baxter Healthcare BioPharma Solutions

By Dan Schell

How are CMOs differentiating their offerings?

Brik Eyre: The CMO industry has become increasingly competitive. There continues to be overcapacity in the market. We are seeing an increase in globalization, customer service philosophies such as on-time delivery commitments, expansion of service offerings (i.e.

additional regulatory, development, and packaging services), and product innovation as a way for the industry to remain competitive. CMOs are evolving their service and product offerings with a specific focus on accelerating time to market to maximize the partner's commercial value. Developing manufacturing capabilities in emerging markets to reduce costs is also being seen within the CMO industry.

At the same time, CMOs must be prepared to respond to the growing biologic drug pipeline and increasing need for aseptic formulation, fill, and finish operations.

What specifically do CMOs need to do to prepare for biologic pipelines?

BE: With biologics comprising a significant portion of pharma companies' pipelines, it's a critical time for CMOs to invest in their infrastructure due to the sensitive nature of biologics. Investments in regulatory and research and development staff are equally critical. In addition, there is a need for experience in aseptic formulation, fill, and finish, as well as an ability to handle biologics in certain combination therapies.

CMOs can offer effective partnering solutions to pharma companies by way of valuable manufacturing resources in terms of specialized equipment and technical know-how for biologics that may otherwise be burdensome for pharma companies to invest in.

Why would a pharma company choose to use a U.S.-based CMO?

BE: In a global marketplace, it's not necessarily

about the location of the CMO partner, but more importantly, it's about the technical expertise and the specific goals the pharma company has for the product. Several CMOs have global networks and previous experience with global regulatory agencies, and this can prove to be a competitive edge for pharma companies looking to quickly and reliably access global markets.

Do you see any regulatory or quality advantages in partnering with CMOs?

BE: A global CMO brings experience and expertise in regulatory filings within the specific target market, helping to ensure the product reaches the market quickly and efficiently. Based on this experience, the CMO will have the "know-how" to partner with the pharma company and can help to reduce the risks associated with logistics and supply chain concerns. In addition to audits by the FDA and EMEA, global CMOs are also subject to audits by regulators of other countries, its pharma partner clients, and in some instances, its own corporation (if part of a larger organization). These additional, frequent audits can help provide peace of mind through quality assurance.

What are CMOs doing to reduce their environmental footprint?

BE: In addition to assessing a CMO's experience, technical expertise, reputation, culture, and track record, an emerging consideration in choosing a partner is the overall sustainability in terms of financial strength, as well as reduction of its environmental footprint. Pharma companies should be considering the efforts that a CMO makes to

reduce waste and conserve water, as well as how the CMO assesses its suppliers in terms of sustainability.

A CMO should be able to explain what it does to reduce its environmental footprint and to conserve critical resources. Specifically at Baxter, we were recently recognized as *Newsweek's* No. 1 company in the healthcare market for green initiatives and were named to the Dow Jones Sustainability Index for the 11th year in a row.

What are the advantages/disadvantages of a focused or targeted CMO?

BE: A "focused" CMO brings some advantages to the table including specialization in specific delivery systems or molecule types (i.e. cytotoxics), while the disadvantages could include a limited portfolio offering and limited ability to manufacture worldwide. As part of a pharma company's due diligence, it should assess its project needs and determine what type of CMO will provide the best solution to meet its goals and objectives.

Give some advice for executives considering outsourcing vs. in-house.

BE: Take the time to understand the value that can be derived from a mutually beneficial partnership. Once a decision to outsource is made, it's critical to define expectations and determine how the success of the partnership will be assessed. Building a relationship with a CMO can offer true value in terms of flexibility in manufacturing operations, specialized technology, and product differentiation. ●