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As the sophistication of products continues to grow, so do the risks associated with choosing the right partner

Jun 1, 2007

By: [Bikash Chatterjee](#)
BioPharm International

The old saying, "May you live in interesting times," takes on new meaning in our industry today. It has been nearly three years since the FDA issued the final report for its landmark initiative, *cGMPs for the 21st Century: A Risk Based Approach*. This single publication has challenged us to rethink every aspect of the drug development lifecycle. And it assumes new, greater meaning as we attempt to assess the emerging capabilities of the global marketplace.



Bikash Chatterjee

Outsourcing, of course, has been a cornerstone of our industry for decades. Historically, the industry has sought contract organizations for early-and late-stage services. In the past, preclinical programs relied on specialty service sectors to provide protocol development, execution and analysis services for toxicology, and preclinical modeling support. Mature programs looked to contract organizations specializing in clinical support and commercial packaging support. In the good old days, a supplier quality audit and forecast commitment within a contract formed the foundation of an outsourcing quality plan.

Today things are very different. The stagnating IPO market makes it increasingly difficult for emerging companies to bring their products to market. Without the cash to fund late-stage clinical trials or build commercial facilities, these firms have no choice but to license their products and outsource the manufacturing. But as the sophistication of products and the spotlight on product development continue to grow, so do the risks associated with choosing the right outsourcing partners.

Scale up and technology transfer have always been complex undertakings. In the 1980s and 1990s, when contract packaging was the lion's share of the outsourcing activity, labeling errors were the primary reasons for regulatory citations and recalls. Nowadays, we in the industry typically outsource product manufacturing as well as packaging and distribution. Think of the potential for quality issues before us. Complicating the challenge is the lure of emerging contract manufacturing organizations (CMOs) and clinical research organizations (CROs) overseas which promise a highly educated workforce with well-funded facilities and operations at highly attractive prices.

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The reality is that the tasks ahead of us are complex. In the US we have struggled to meet the compliance expectations of the FDA. Now we have the opportunity to apply a risk-based framework to our development and quality plans. The stakes of the game are higher; success no longer relies simply on using classical quality metrics to assess a suitable CMO. The CMO's participation in regulatory claims will soon escalate; to what degree, however, is up to us. We will now have to rely on them for far more than just execution of processes. These organizations will play a significant role in our technical, regulatory, and market claims. Knowing this, we must evolve our criteria when evaluating and selecting CMOs and CROs, and address all aspects of this new relationship. Cost, technical ability, experience, stability, compliance capability, and organizational flexibility all take on added significance in our decision making. How well US and European CMOs and CROs embrace this truth, along with how quickly emerging firms from the Far East adapt to this new requirement, will set the outsourcing landscape for the next decade.

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