Pharma's Changing Strategic Planning Landscape

The last few years in the pharmaceutical industry have seen unprecedented upheaval, with changes to the marketplace on all fronts. In the U.S., consolidation on a massive scale amongst the elite of the industry raises new questions about competitiveness and what it takes to keep it.

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On the regulatory side, the FDA is well on the road to its transformation from an overhead intensive approach to quality to one that focuses more on scientific rigor than on compliance. While the outcome for brand name and generic pharma is still not fully understood, there can be no doubt that the entire industry recognizes that the levels of scientific rigor and document traceability will need to be higher than ever before.

While change has always been a part of the life sciences landscape, the rapid pace and magnitude is significant, as it pertains to our quality and business paradigm. With the emergence of the BRICK (Brazil, Russia, India, China and Korea) countries comes their capability to supply low cost APIs that now extend to the global supply chain. And this underscores the need for more effective, far-reaching strategic planning.

I believe that several new considerations of the strategic planning exercise are relevant in today's marketplace. The first involves extending the global supply chain, both up and down. Initially, many of the emerging markets presented an opportunity for low cost APIs. For many therapies this represents a significant factor of the overall standard cost. However, early attempts to measure these overseas manufacturers against ICH Q7A fell far short of what European and U.S. manufacturers were doing. At this point, the question became, can we add our own additional tests to satisfy our level of risk anxiety and leverage the financial opportunity? Over the last ten years the sophistication of these API manufacturers has increased, with China alone supplying 80 percent of the world's APIs and over 40 percent of the U.S. market's APIs. Along the way there have been some very high profile missteps that have cost customers dearly. Despite the quality risks, there is little doubt that low cost API suppliers will remain a central strategy for most U.S. and European pharmaceutical companies.

In addition to API manufacturing, big Pharma is exploring the cost benefits of expanding manufacturing into these emerging markets. At this juncture, the business and regulatory considerations become inextricably intertwined. As an integral component to any Business Continuity exercise, the regulatory strategic and tactical plan will provide the key to leveraging available capacity and capability within an overseas operation. Leveraging a highly educated workforce and having access to lower cost capital makes good strategic sense. While the benefits of these new markets are undeniable, the complexities of project management escalate exponentially. Peculiarities with local building codes (when designing a facility in China, an old building code written during WWII required that we put a bomb shelter in the ground floor of the manufacturing building!), the influence of local unions and the constant vigilance required to ensure workmanship standards against design are just a few of the challenges to meet when trying to construct an overseas facility.

While the advantages of these supply chain expansions are clear, industry is looking for other opportunities with less business risk. One rapidly growing area involves escalating outsourcing for the pre-clinical discovery process. The discovery process represents two strategic opportunities in terms of competitiveness. First, outsourcing the discovery activities allows parallel processing when evaluating

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time to market (TTM) reduction. Second, the GxP (Good Practice guidelines) overhead for this activity is less critical: it requires less compliance and due diligence. Even so, utilizing these outsourced pre-formulation services needs to be done thoughtfully, so there is confidence in the data and conclusions.

As the global supply chain expands globally, the need for control and visibility throughout the process is ever more critical. The FDA highlighted this in their 2006 guidance regarding e-pedigree. Regrettably, the industry has been slow to embrace this guidance and the agency has been reluctant to enforce it. Hand in hand with this expansion come the issues of information management and security of this information, central to ensuring supply chain integrity. As more stages of the drug development lifecycle are outsourced, the need for data integrity and knowledge management becomes more important. And this risk becomes more complicated as the emerging markets grapple with a steady stream of evolving Intellectual Property (IP) law. IP protection is often the lynch pin component to a competitive strategic plan and it factors prominently in the decision making process. Fortunately, technology has provided solutions which can quickly impart security and traceability. RFID and data encryption have become more commonplace for global deployments, particularly in mature organizations where sophisticated quality and costing principles, such as Cost of Poor Quality (COPQ) are integral to measuring business performance. Stealth technology exists that can be applied to a network to make it invisible to hackers or counterfeiters attempting to hijack data.

The final element that has become more prominent in our strategic thinking is sustainability. Over the past 30 years, the concept of sustainability has evolved to reflect the perspectives and expectations of both the public and private sectors. And they differ somewhat. A public policy perspective would define sustainability as the satisfaction of basic economic, social and security needs, now and in the future, without undermining the natural resource base and environmental quality on which life depends. From a business perspective, the goal of sustainability is to increase long-term shareholder and social value, while decreasing industry's use of materials and reducing negative impacts on the environment.

But what is common to both perspectives is recognition of the need to support a growing economy while reducing the social and economic costs of economic growth. To this end, Leadership in Energy and Environmental Design (LEED) based designs are growing as a foundation for any strategic business or facility plan expansion. As social responsibility creeps into the measureable objectives of an organization's strategic implementation, the ability to balance being a good corporate citizen with shareholder value will become an essential element in any successful long-term plan. Although they may not share the same sustainability mindset, even the emerging markets recognize the value of sound energy management and effective use of natural resources to sustain business growth.

As our markets take shape, evolving an organization's strategic business plan to adapt to these new elements will be essential to continued success in a marketplace in flux. As regulatory professionals, we need to understand—not just be aware of—the impact and interplay of these elements. This will allow us to chart a regulatory path that will not only ensure compliance, but also support the broader longer-term drivers for business performance we will need to remain competitive in the years to come.

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