Extending the Visual Factory to the Global Marketplace

Its time to move the Visual Factory from the shop floor to the boardroom.

BY BIKASH CHATTERJEE, PRESIDENT AND CTO, PHARMATECH ASSOCIATES

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As a Lean Six Sigma practitioner, I have seen first hand the impact these principles can have on an operation, its culture and the ability to respond to market challenges. Many sectors of the large pharma, biotech and the medical device industry recognize the value of operational excellence for near-term business performance. Other sectors, such as the generics industry, blood products and nutraceuticals have been slow to adopt these approaches, mired in the daily challenges of operational inefficiency and lost profits that have been the hallmark of improvised business management.

Yet to distill the benefits of operational excellence down to bottom-line profit generation would overlook the true business advantage. I often hear that the tools used during Six Sigma projects are nothing special and have been used before. True, but the strength of programs lies in the cultural transformation that takes place as an organization begins to embrace the framework of objective investigation and evaluation. Whether the program is looking to reduce standard cost, increase yield or capacity, integrating a standardized framework—based on scientific understanding and innovation—will deliver measurable business benefit and tear down the silo mentality that plagues our industry.

What can we do to improve business performance? Let's focus on long-term competitive advantage and extend these principles to strategic business thinking. I am not talking about creating new dashboards, but changing the methodology for decision-making. In other words, move the Visual Factory from the factory floor to the boardroom. The Visual Factory strives to communicate the critical performance metrics for a process. Coupling measurable performance metrics (process stability, process velocity) with improvement methodologies such as Six Sigma and Lean Manufacturing, the Visual Factory becomes the agreed-upon basis for evaluation and decision-making.

How do we apply this concept to the global marketplace? As our supply chain diversifies, the challenges of controlling variation across our product's value stream escalate exponentially. There are several areas where the benefits of such an approach could be immediately realized. Today many global operations are revisiting their manufacturing and distribution strategy, to look at eliminating poorly performing business units and shifting or absorbing key functional capabilities. Extending the evaluation criteria beyond pure financial performance can keep organizations from being encumbered with the loss in performance that comes with catastrophic change.

For example, if two sites have analytical testing operations performing product release testing, the temptation is great to eliminate and combine operations in a single operation and reap the cost benefits of headcount and facility reduction. All too often, these consolidations end in failure because the expertise, skill set, native process and product knowledge are lost in the consolidation. Rather than evaluating the two labs based upon analytical equipment and headcount, another approach may be to apply a Lean Manufacturing approach to the two operations.

Developing a value stream map for both operations could reveal the technical strengths resident with each organization. Perhaps one organization also supports product development and clinical stability testing and the other does not. Rather than consolidating based upon tenure or salary, a restructuring of the two operations could be made which distributes key technical personnel across the organization, some into R&D, clinical manufacturing and QA product release where the highest performers can bring

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their expertise and experience to bolster lagging performance areas. The immediate financial end-result is the same, reduced operating expenses, but the overall impact, in terms of pure business performance capability, is significantly different.

Next, combine these tangible differences with measurable performance metrics, such as lab testing velocity or right-the-first-time stability testing. This will allow the organization to recognize and value the benefits of this approach. Let's raise the bar for evaluation of the true cost and benefit of cheaper overseas services!

Other areas which could benefit from an expanded operational excellence approach include Business Continuity Planning (BCP). BCP looks to establish alternative business solutions in the face of catastrophic business interruption. The need for an effective BCP program has never been more pressing than today, with the looming potential for business interruption from a swine flu pandemic. Most analyses estimate the first wave of a pandemic could interrupt operations in an effected region for six weeks or more. A poorly conducted BCP which does not consider all aspects of a product's value stream—including IT, raw material, equipment, facility, distribution and regulatory compliance elements—will not succeed. For vaccine manufacturers, this becomes even more complicated with the likely escalation of government involvement in any response plan. Here again is an opportunity to leverage operational excellence tools with Lean and Six Sigma to ensure the critical success factors will have been identified in advance of any activity.

We are still working on the promise of reduced time to market, reduced program risk and greater process and product predictability. As an industry that prides itself on scientific integrity, there has been a grudging acknowledgement that there may be a better way to develop and bring our products to market. There is no doubt that the pressures to increase business performance are only going to intensify in the coming years. Paper exercises and theoretical modeling will only get us so far. When business performance becomes a question of life or death, the margin of error becomes very small.

About the Author

Bikash Chatterjee is president of Pharmatech Associates. He is a certified ISO 9000 Lead Assessor, a Six Sigma Master Black Belt and has over 15 years experience in the implementation of Lean Manufacturing programs in the life sciences industry. He holds a B.A. in Biochemistry and a B.S. in Chemical Engineering from the University of California at San Diego.

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