



## **A Tefen Series: Operational Excellence in the Life Sciences**

### **Part 1: State of the Industry**

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#### **Executive Summary**

The life sciences industry is under pressure from the decline in the discovery of block-buster products, aggressive strategies from the generic manufacturers, the emergence of competitors from the East, and the global economic downturn. These factors are causing the pharmaceutical, biotech, and medical device companies to rethink the way they operate.

Growth is no longer the mantra of the Life Sciences industry, but it is survival and maintaining a competitive advantage. The ability to supply products in the most cost-effective manner through efficiency initiatives has become necessary just to survive. Over the last 5 years, this has led life sciences companies to embark on operational excellence (OpEx) programs, based on lean, six sigma and other improvement methodologies. This paper summarizes research conducted by Tefen Ltd. in 2008-2009 on these OpEx programs, and how they have reshaped the way life sciences companies develop, supply, and even sell their products.

#### **The Decline of the Blockbuster**

The 'big-pharma' model was based on the development of blockbuster drugs, which provided billions of dollars in revenue. This model traditionally meant that when small-scale niche products were found, they were discarded or sold to smaller companies where lower operating costs ensured the profit margins generated made them

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profitable to develop. However, as the number of blockbuster drugs being discovered started to diminish, and the investment needed to generate new drugs increased, the big-pharma model started to look unviable.

What happens when this model for development no longer works? Investment is now being poured into previously ignored industries and technologies. The biopharma and biotech sectors do not have a great deal of direct competition, since most of the drugs have been developed for small, rare conditions which had historically been ignored by big-pharma.<sup>1</sup> With the growth of investment in these sectors this situation is changing. The requirement to produce increasingly commercially viable products will eventually drive the opposite of this to occur. However, the consumer take-up of biotech and biopharma products due to their more targeted approach to medical conditions and subsequent success in treatment may prevent a repeat of the pharmaceutical bust from coming to these sectors for some time.

## The Rise of Generic Competition

The emergence of generic manufacturers has become an increasing challenge for big-pharma. These companies are preying on the blockbuster drugs even before they come off patent, causing severe declines in revenue for the big-pharma companies. With lower operating costs, no research investments to recoup, and small marketing budgets, generic products are able to quickly enter the market with cheaper products, gaining 88% of the market share within 2 years.<sup>2</sup>

Consumers are increasingly demanding cheaper products without being aware of the investment required to develop new drugs. The pricing structure of generics is causing large-scale revenue loss for big-pharma, which in turn reduces their ability to invest in new drug discovery. Therefore, the new trend is to partner with or acquire biotech companies with a solid pipeline, which has a relatively long patent life on their existing products, providing protection in the short-term against generic exploitation.

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1 Biotechnology in Europe: Industry Profile, Datamonitor, Aug 2008

2 The Pharmaceutical Market Outlook to 2018: Key Threats and Opportunities for Big Pharma and Its Responses to Them. Dr Sarah Riley, Business Insights, 2008

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## Competition from the East

The emergence of cheaper, rival products from companies based in eastern countries such as India, China, and Singapore is not a new challenge for big-pharma. For over a decade, leading pharmaceutical companies have been buying into established companies or building sites of their own in this region. These sites tend to be much larger than their traditional Western counter-parts due to tax-breaks and cheaper labor. These strategies enable companies to transfer their existing products from their American and European bases to reduce the production costs, and when balanced with the increased transport and distribution costs, enabled further profits to be made.

The recent growth of the Chinese and Indian markets has provided an interesting opportunity for pharmaceutical companies. Their presence in this region will enable them to supply their previously unaffordable products quickly, with low distribution costs to the fastest growing economies in the world.

However, as the economies grow, competition also grows, and soon the marketplace will be flooded. The regulations governing quality and ethics in medical products in these regions have typically been poorly maintained, and as such the market has been monopolized with cheap, ineffective, and sometimes dangerous copies. To change this trend and win the consumer over to the more expensive big-pharma products, further operating cost reductions are required. The size of the emerging markets makes them impossible to ignore, and so it is imperative for pharmaceutical companies to undertake these cost-reducing initiatives.

## The Credit-Crunch

While the current economic crisis is affecting the pharmaceutical industry, there are several factors that reduce the negative impact of the “credit-crunch.” Historically, big-pharma companies are cash rich and thus can continue to invest in product development and acquisitions. Secondly, the necessity to purchase pharmaceutical products in order to prevent illness ensures a reliable source of income, especially for products which are provided by national medical services.

However, revenue from many non-essential product lines has been hit, and most pharmaceutical companies have announced site closures and job cuts. It is clear that cost reduction is on the agenda. Pfizer has announced up to 19,000 job cuts, GlaxoSmithKline approximately 10,000 jobs, and AstraZeneca upwards of 6,000.<sup>1</sup>

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## Is Operational Excellence the Answer?

*Operational Excellence is when each and every employee can see the flow of value to the customer, and fix that flow when it breaks down.* -The Institute of Operational Excellence

The state of operational excellence is therefore that in which no activity performed in the company is wasteful, its products are made or supplied only when needed, and its employees are authorized, trained and motivated to make positive change to support its customers. This means that customers are happy, costs are minimized, and the company triumphs over its competition.

If operational excellence is the destination, pharmaceutical companies are using structured programs to make the journey. The use of techniques such as lean or six sigma allows companies to combat the root causes of waste and variability and make their way towards Operational Excellence. These techniques have evolved over the last 10-20 years, and are seen as being applicable in the pharmaceutical sector where process reliability and efficiency is becoming a source of competitive advantage.

Lean manufacturing, based on the Toyota Production System, is a set of tools and techniques for reducing waste within any process. Waste can be unnecessary activities such as waiting, delays, and storage.<sup>1</sup> Six Sigma originally developed by Motorola, is a set of techniques for measuring, identifying and reducing variability within processes. Process deviations and failures, human variations, flow and demand fluctuations are a small example of variability which can be tackled using six sigma methodologies.

Tefen conducted research on AstraZeneca, Bayer Schering, GSK Bio, Ipsen, Janssen, Merck Serono, Novartis, Nycomed, Schering Plough, and Wyeth during 2008 and 2009 through consultancy engagements and interviews with OpEx Leaders on Life Sciences OpEx programs. These companies' programs ranged from 10-year old programs to just 1 year old.

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<sup>1</sup> Toyota Production System, Taichi Ohno (1988), Productivity Press



## Conclusion:

The state of the life sciences industry is being affected by the decline of blockbuster drugs and competition from generic manufacturers and the East, and the economic crisis. So what can be done to reduce the effects of these problems? Companies like Astra Zeneca, Wyeth, Schering-Plough, and Merck have all turned to Operational Excellence to create positive change in their organizations to position themselves as industry leaders.

Part two of this series, “Operational Excellence Programs in the Industry,” will explore the benefits of a lean and six sigma approach, and the necessary management to make the program work.

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## About Tefen

Tefen is an international management consulting firm, committed to improving overall operational effectiveness for Fortune 500 companies around the world. The firm's main areas of focus include operations excellence, manufacturing, quality, customer service, research and development and supply chain management. With its "hands-on" approach philosophy, the company has achieved tremendous success in delivering quantifiable and value-driven results for its clients in a variety of industries, including healthcare, life sciences, general manufacturing, high-tech and financial services. All of Tefen's support programs are ISO 9001 certified. Tefen currently employs over 300 professionals worldwide.

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