



A Tefen Series: Operational Excellence in the Life Sciences Part 2: Operational Excellence Programs in the Industry

Executive Summary

Tefen Ltd. conducted a study in 2008-2009 on 11 life sciences companies, including AstraZeneca, Bayer Schering, GSK Bio, Ipsen, Janssen, Merck Serono, Novartis, Nycomed, Schering Plough, and Wyeth. The research focused on their Operational Excellence (OpEx) programs and is discussed in this three part series.

In part one of the study, “The State of the Industry,” Caldwell, Mathew, and O’Donnell discuss how the life sciences industry is being affected by the decline of blockbuster drugs, competition from generic manufacturers and the East, and the economic crisis. “Operational Excellence Programs in the Industry,” part two of this series will explore the benefits of a lean and six sigma approach, and the necessary management to make the program work.

Operational Excellence Must Focus on People

The current operational priority faced by many life sciences companies is to reduce the cost of goods sold. Forty percent of the companies who participated in this study stated this as the main aim of their OpEx program. Secondary objectives such as improving process reliability, releasing cash, and becoming more flexible to customer needs were also highly important. All of the participants stated the need to increase the speed of product flow.

Some companies use their OpEx programs to solve challenges specific to them (i.e. to harmonize practices and cultures following a merger).

What is apparent with these companies, which have been running OpEx programs for more than a couple of years, is that there slowly emerges a greater emphasis on people. This is evidenced by the fact that leadership effectiveness, people development, improvement culture, and performance metrics such as cost and delivery, have become the focus of attention. After all, if OpEx is really to mean “everyone can see the flow of value to the customer and fix it when it breaks”, this has huge consequences for an organization. It means people must be empowered and trained to make their own process changes, people must recognize that they are part of a larger team serving the customer, have authority to make change in others’ areas, and that leaders have to be prepared to relinquish some control, and trust their subordinates to make change.

Operational Excellence Should Not be Measured by Financials Alone

Many researchers have made the link between performance measurement and achieving strategy.¹ Without proactive and relevant metrics, investment in OpEx can go to waste. The three traditional key metrics of cost, quality, and delivery feature most highly. Capacity absorption and cost avoidance is key to companies who are experiencing growth. Working capital is popular for the companies who lack cash.

More mature OpEx programs turn their attention to the attitudes and maturity of their organizations, as they further recognize the true meaning of operational excellence. Measures that are typically used are: number of employee suggestions implemented, number of people trained, and number of teams initiated. These programs have their measures integrated into the sites’ general performance metrics. Seventy-five percent of the life sciences companies researched have already done so, while the rest are not far behind.

Operational Excellence Benefits From a Lean and Six Sigma Approach

Of the improvement methodologies, the most common used by pharmaceutical OpEx programs is Lean (every company researched used Lean Manufacturing in one way or another), followed by six sigma. Both methodologies have advantages and disadvantages. Lean can be perceived as purely a headcount-cutting technique and as a potential contributor to quality problems caused by cutting corners. Conversely, the heavily data-reliant and statistically-based approach of Six Sigma is seen by some as over-intellectual, uninspiring, with limited applicability. In addition, an over-emphasis on tools, rather than people driving the change can damage the program. Hence, it is recommended to use a hybrid lean six-sigma approach. If well designed, this will incorporate a

¹ Mills et al., 2002

structured, simple problem-solving approach, run by cross-functional teams working together to identify and eliminate waste. Eighty-five percent of life science companies are using a hybrid approach, and not one company researched uses six sigma alone.

The theory of Constraints is only deployed by a minority of companies, and only where growth is a key objective of the program. However, Goldratt's "Five Steps to Continuous Improvement" are not used in any company as an overarching methodology. Peripheral methodologies such as Design for Six Sigma and Business Process Re-engineering are sometimes employed where needed.

Operational Excellence: Moving from Program to Way of Life

An OpEx program should be like any other program- including a sponsor, a charter, a steering committee, etc. It should be driven as a top-down, directive program with a clearly defined scope, rather than a philosophy which may be up for interpretation. OpEx programs are typically given a name, a budget, and a great deal of focus initially. Most programs are called Operational Excellence, OpEx or OE. A few companies use the term Excellence or Business Excellence. There are a collection of other names, such as Continuous Improvement, Lean, or Best in Class. Early stage programs should have a defined suite of "work-streams", each with their own group of experts to help coach along the way.

As the programs matures, they transform in nature, and become a way of life. Mature companies have managed to drop the program's name and work streams, and the tools have become embedded in peoples' daily working routines. This is enabled by added effort of training, improving resource skills, and embedding the language of OpEx within the organization. In early stages of OpEx programs, there is a lot of emphasis on standardizing training material, problem solving techniques and tools. A more evolved OpEx program focuses on standardizing the company's philosophy and ensuring flexibility in the approach and use of tools. At whichever stage possible, companies should strive towards a common philosophy and language.

Operational Excellence Through Out the Organization

Operational excellence has wide applicability, and is relevant beyond the four walls of manufacturing. However, there is an inclination for companies to confine their programs to the manufacturing and supply operations because it provides the most tangible benefits in terms of cost, quality, and product flow. However, areas such as

commercialization , sourcing, quality assurance, engineering and maintenance also provide rich veins of improvement potential.

Traditionally it has been believed that six sigma and lean techniques are only valid for repetitive operations, but this is not necessarily true. Problem-solving approaches such as DMAIC, supported by good project management practices are appropriate to solve many types of problems. Moreover, team-work and proactive waste-identification approaches encouraged by the Lean methodology can be applied to any component of a value-stream which is misaligned or adds cost. Therefore, although OpEx programs may start in manufacturing, they should be broadened to other areas of the business.

Some companies have incorporated Development and Sales operations into their programs. Doing so is imperative because approximately two thirds of the overall cost is in R&D, Sales & Marketing. Furthermore, product development cycle times are long and altering product specification during its commercial life is difficult due to regulatory constraints. Therefore, great value can be derived by optimizing products and processes so that they are well aligned with customer requirements, cheap to manufacture, and effective across many therapeutic needs. Similarly, support functions (HR, Finance, IT, QA, etc.) are significant contributors to cost and lead-time.

Pilot Trials Prior to Expansion

In any improvement program where there are risks involved and the company can afford the time and resources, it is practical to conduct pilot trials before replicating the improvements everywhere. This enables companies to learn from new practices that work well in its environment and those that should be modified or discarded. Even in the cases where the problem solving process has been creative and thorough, and trials have been well managed and monitored, there are two main potential errors that companies make at this stage:

Rollout of improvements without regard for lessons learned during the trials: Once a sub-standard improvement has been rolled out across an operation, it is very difficult and costly to modify it. Companies often implement an initiative simultaneously across all areas, or they simply stagger the implementation across sites without adjusting based on trials. This gives the appearance of a pilot-rollout approach, but is simply a resource-constrained expansion.

Forgetting to Roll Out the Process: There were instances in many companies (particularly in Quality Control) where initial projects had been successful, but the intent to roll the processes out to other areas had been forgotten along the way. Consequently, the effort and expense of trials and modifications was not exploited.

Sponsors Need to be Visible and Supportive

As discussed earlier, OpEx needs its own budget and resources. Initially, it should be set up as a stand-alone function and in the cases where the program is run as a corporate initiative, the OpEx function generally reports to the SVP of Operations. Sometimes OpEx reports to a function, such as Quality or Finance. This structure is not recommended, as the program can be de-prioritized or over-focused towards the function's day-to-day objectives to the detriment of value-stream performance. Where this arrangement is in place initially, it tends to get reorganized once the program is more mature. Typically, some activities get transferred to the Global Operations Head, whilst others become devolved to site management ownership.

In order for OpEx programs to wield the required authority, the sponsor should be at the SVP level. S/he should hold the budget for the program and show great interest in the bottom line benefits that the program provides. It is critical that s/he provides visible, vocal support and resources, and maintain resources throughout the program, thus demonstrating commitment to its success. In two-thirds of the researched companies, the sponsor was deeply involved, helping to define the methodology used and the direction taken.

The program also needs an influential and energetic OpEx Leader to drive the change, preferably reporting directly to the sponsor. The OpEx Leader should be responsible for program governance and knowledge management.

Operational Excellence Benefits from Effective External Support

The company's maturity and objectives often determine the way external or corporate support should be used. In general, investment in consultancy delivers most value at the direction-setting, setup and initial training, and coaching of the program. Most of the coordination, governance activity, auditing, and knowledge management should be performed at the corporate level, and implementation should be assigned to the local teams as soon as possible.

The philosophy underpinning operational excellence is that employees be empowered and authorized to make positive change from within. Hence, over time, coaching and training must be passed from the consulting team to the company. While training is typically at its heaviest during the infancy of an OpEx program, coaching is valuable during the first few years of implementation until on-site resources are sufficiently capable of carrying out the coaching themselves. Subsequent to this, auditing is useful to ensure the progress is satisfactory and

benefits are being achieved. Corporate teams are best placed to ensure that the OpEx program and projects are aligned to company strategy.

Careful Management of Operational Excellence Programs

Many companies find that the benefits from OpEx programs do not initially live up to the expectations. It might be assumed that individual work-streams were unable to deliver their anticipated benefits. However, this has not been found to be a major cause. More common causes are found to be:

- Work streams start to lose stride. This is typically symptomatic of a dwindling sponsorship, re-diverted resource, and a haphazard attitude towards risk management. Although many work streams do eventually deliver the projected benefits, the cumulative effect of these delays appears as a shortfall in benefit realization.
- Often local deliverables are achieved, but there is no formal feedback through the budgeting process, so the financial benefits do not flow through to the bottom line.
- Occasionally projects are selected that have clear operational deliverables, but that do not affect end-customer or financial performance. Examples include widening non-bottlenecks and shortening lead-times of processes that are not in the critical path.

Successful OpEx programs deploy a range of project management and governance techniques to guarantee benefit flow at the desired level and rate. The program and its projects must be well thought out, and project charters used to specify scope, deliverables, timescales and resources. Steering processes at corporate and site level should be followed to ensure external changes are considered, progress is monitored and action is taken. Mechanisms to track milestones, operational benefits, and financial benefits should be employed. Risk Management is one area which tends not to be as structured as it should be, and this identified as a significant reason for delays in benefit realization.

Use of formal change management principles, as advocated by Kotter (8 steps), Lewin (unfreeze-change-refreeze) and others, is generally low in many OpEx programs. Moreover, simple techniques to drive cultural change are often not well understood or deployed. The topic is seen as important, and terms such as communication, culture', awareness' and change' are often mentioned during steering meetings. However, change-theory is not valued enough to reach the training curriculum, and many senior managers regard it as common sense,

rather than a legitimate management science. Therefore, it is often the case that the OpEx message does not find its way down to the shop floor, and the capability of Supervisors to champion projects is not maximized.

The use of benchmarking as a mechanism to instill a sense of urgency and potential benefits is not as widespread as it is in some other sectors, notably automotive, distribution and retail. This could be because many challenges relating to quality and compliance are thought to be sector specific.

Communal Knowledge and Operational Excellence

Companies recognize that the way they manage the knowledge surrounding their OpEx programs is sub-optimal. Knowledge capture is often not proactive, and knowledge sharing can be poorly driven and coordinated. This results in multiple approaches across sites and the risk of confusion when teams are brought together.

Most companies ensure some material is available, via the intranet or similar. The sort of accessible material includes diagrams of the governance processes, formal supporting documentation, and training material (including leadership training, project management training, awareness training, and courses for Green and Black Belts). The latter is often provided by Consultants. Occasionally, project documents and case studies are available, though usually this is not the case – a fact highlighted as a concern by most companies.

However, it is the experiential data that is lacking – the know-how of what worked well and what worked poorly. Seventy-Five percent of companies feel that most of the knowledge concerning operational excellence is too tacit to be formally laid down. One company researched, whose program was a year old, had not instituted knowledge sharing processes at all. The knowledge tended to reside in a small core of people, and this represented a lost opportunity for people lower down in the organization to learn from past mistakes.

Half of the companies interviewed have a statement which describes their OpEx vision. The younger programs have not formalized their vision, but it is typically on the agenda. Companies that are more than two years into their programs tend to use a 6-month or annual OpEx assessment to highlight areas which need more focus. These tend to concentrate on the enablers to OpEx (whether value-stream mapping has been conducted, KPIs are in place, number of Black Belts that have been trained, etc), and not so much on performance levels, practices and processes that need improvement.

Conclusion

In order for an operational excellence program to succeed, it needs to be fully supported and managed. Essentially the OpEx program needs to become a “way of life” for your organization. In the final part of this series “Learning From the Industry,” Caldwell, Mathew, and O’Donnell will explore the best practices and lessons learned from the 11 participating companies.

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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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