

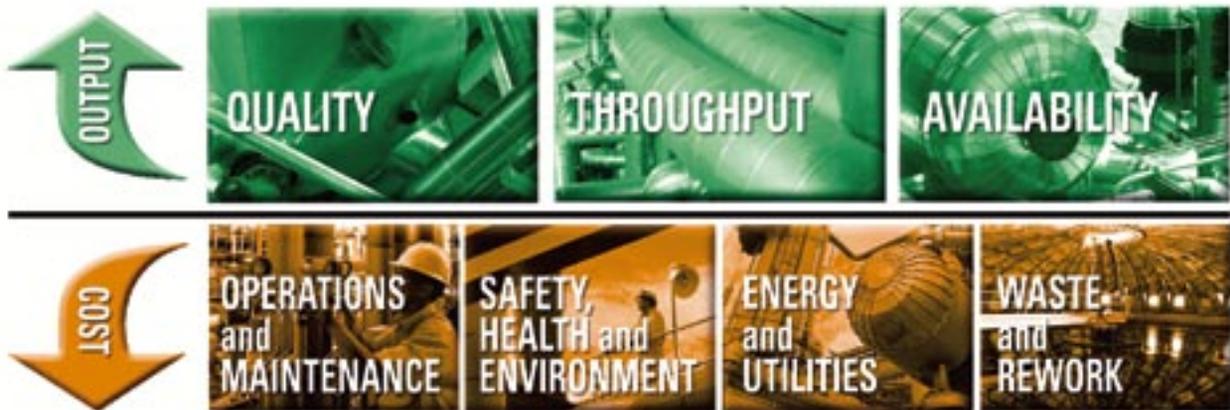
Operational Excellence In Pharma

In the pharmaceutical industry, achieving operational excellence is no longer an option. By *Sathi Kannan*, Senior Manager, Life Sciences and Advanced Solutions, Emerson Process Management Asia Pacific



The business environment of the life sciences industry is becoming increasingly demanding, where only those companies committed to excellence will thrive; those that don't may well find their survival in danger. The challenges are clear to all: decreasing levels of reimbursement, lawsuits, fewer blockbuster discoveries, unexpected competitors, and the list goes on. The solution for most companies today can be summed up as the pursuit of excellence – superiority in operations and

made 'under the radar', real progress towards the ultimate goal must involve multiple levels of management. This is especially true when the necessary changes will affect multiple departments. Giving more managers a stake in – and the expectation of taking credit for – a successful outcome can have a remarkable way of making resources available and causing obstacles to melt away.



execution of business processes – and has come to be called Operational Excellence.

Operational Excellence, aka OpX, strives to improve quality, increase yields, speed throughput, and reduce waste. It involves most of the current business tools: Six Sigma, Lean, Footprint Rationalisation and Premier Resource Management. OpX covers all areas of a business, and requires the integration of operations management methodologies in ways that optimise people, assets, and processes. Like links in a chain, the weakest portion of a business – R&D, production, quality, sales and service, etc – determines the strength of the whole. No business can achieve excellence if any one of these areas is less than excellent, and a severe breakdown in any part, or the failure to integrate all the parts properly, will harm business performance and jeopardise shareholder value. This article discusses what is involved in operational excellence and examines the steps to achieve it.

Getting Started

Perhaps the most important consideration in instituting any change in company methods or operations is to gain the support of management. While small changes can be

This is not to say that the same methodologies, tools, skills, and assistance will be suitable for all parts of your organisation. In just one part, for example, one could use the full set of Six Sigma tools, go for Lean Manufacturing, or combine them to create Lean Six Sigma. Perhaps a customised approach would be more appropriate.

Setting Expectations

Other questions that must be answered include how to handle any required certification, what particular management tools and processes are already being used, what new ones might be required, and how those



Operational excellence demands looking at the right tools & processes.



The steps towards achieving operational excellence

new tools and processes will be integrated into the operation of the organisation. And don't forget personnel preparation and training; trying to drop new systems into place without having the people ready in terms of acceptance, skill sets and expectations has caused many horror stories. It is also important to know how much data will be required for the new system to work properly. Having either too much data (data paralysis) or not enough (data-starvation) can tie things in knots.

It is often a good idea to bring in a consultant who has gone through and guided similar transformation for others. But it is important to take a careful look at whether the candidate has experience in similar businesses? Does the person have a library of general guidelines that can be tailored to fit your organisation? To use the last example in the previous paragraph, a guideline that helps to ensure that the amount of data is collected and analysed matches the complexity of the problem can go a long way towards building team confidence and providing measurable results.

Right Tools

The next step is deciding which of the available business improvement tools available – Six Sigma, Lean Manufacturing, Business Performance Management, etc – are most appropriate for successfully instituting Operation Excellence in each part of the business. Let's take production as an example. Much of the production in the life sciences business is done in batches, and batch processing combines elements of process control – level, flow, temperature, PH, pressure, density, etc – and discrete manufacturing – start/stop, open/close, transfer, clean, and so on. Product packaging, for example, is almost always more of a discrete manufacturing operation than a continuous processing one.

Getting Leaner

In such a mixed environment the most successful (Smarter Six Sigma Solutions). A good consultant may also make use of Value Stream Mapping, Collaborative Diagrams, Design of Experiments, Business Process Mapping, Quality Systems, Fishbone Diagrams, and others. Lean Six Sigma was created by combining Six Sigma DMAIC (Define, Measure,

Analyse, Implement, and Control) methods with those of Lean Manufacturing; it may include Kaizen, FMEA (Failure Mode and Effects Analysis), DOE (Design of Experiments), and QFD (Quality Function Deployment).

However, it is important to keep in mind that Lean Six Sigma tools and methods are not sacred and inviolate. Everything changes with time, and the methods your organisation adopts must be flexible enough for your own people to make appropriate alterations as times and circumstances change. Inflexible systems eventually lead to operational sclerosis.

DMAIC

DMAIC is an essential part of Six Sigma. Operational excellence involves all parts of the enterprise, but its final goal is to increase the return on invested capital (ROIC). We will look at how to handle each step: define, measure, analyse, implement and control in order to achieve this objective.

Definition: definition or assessment phase involves identifying opportunities to produce quantifiable results. These might include, for example, a specified increase in profitability, a goal for ROIC, and a particular increase in right first time (RFT) percentage.

Since much of production in the life science industry is batch processing, a program to shorten batch cycle time can generate improvements (and increase ROIC) all the way down the line, from production to sales and service to warehousing and distribution. But since changes to reaction rates are not usually feasible, the improvement must often come from other areas, for example shortening the time needed to investigate and resolve processing discrepancies prior to releasing the finished product for shipment.

Once the improvement areas have been identified, it is time to establish the order in which they will be addressed,



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OpX implementations usually combine Six Sigma and Lean Manufacturing to form Lean Six Sigma or S4



Shortening batch cycle time generate improvements and increases ROI.

and, as mentioned, to quantify the expected benefits. This may require considerable effort, and involve inputs from different parts of the enterprise.

Measurement: Few, if any, projects ever get approved without first being able to quantitatively illustrate the current state and what would be a reasonable amount of expected improvement. Input will come from all areas affected and involved.

Analysis: begins with an examination of current practices; one good method for doing this may include development of Cause & Effect (Fishbone) diagrams to illustrate the contributing events. These events can then be converted to numbers; Value Stream Mapping (VSM) diagrams are often useful here, as they can allow comparison of an ideal sequence of events with what exists. Areas of potential improvement often become apparent at this point.

Improvement: involves benchmarking and value stream mapping to prioritise opportunities. A word of caution here: When estimating potential improvements it is worthwhile to compare similar activities and indices – right-the-first-time (RFT) to quality reviews, for example – not just to those of other companies in the same industry but to world-class companies in all industries; while a 2004 survey showed that a RFT to quality review of about 96 percent (3.3σ) may be world-class in the pharmaceutical industry, for example, that same survey showed that world-class manufacturing and processing facilities across multiple industries were achieving a 99.4 percent (4.0σ) RFT to quality review. Achieving best-in-class results within one's own industry may be commendable, but it leaves unfulfilled the goal of being truly world-class.

Control phase: involves monitoring results to ensure expected improvements are being achieved.

Eye On The Prize

Simply making improvements in a few areas is not enough to achieve Operational Excellence. OpX requires a level of corporate performance that will garner praise from the investment analysts who advise the actual owners of the company. It requires using the right tools, methods, and advice and combining them with dedication to achieving true world-class status.

It requires constant work, attention to detail, and the honesty to examine one's own shortcomings and correct them, and to never settle for what once worked, or works in some places, but constantly striving for the elusive goal of being the best of the best. Many factors contribute to world-class performance, but the best opportunity for achieving operational excellence is where the money is spent and made: production.

OpX Advantage

Emerson Process Management's OpX Advantage Program provides clients cost effective access to recognised Life Science industry expertise. The programme begins with an initial assessment which typically takes two to three days and is conducted by a joint client/Emerson team focused on defining areas of opportunity for throughput improvement, cost reduction, and increased availability. When the initial assessment is completed, plant management is presented the findings and a written report.

Included in the report are:

- Details of the findings with associated potential improvements that can result in high-level, definable benefits;
- Proposed next steps, which may include a more detailed and focused study, are also included in the report;
- Broadly quantified benefits that have been linked to available business level information; and
- An outline of how Emerson Process Management can assist the client to capture the identified opportunities.

Success Drivers

Initial assessment success is driven by three key items – appropriate time carved out for key plant personnel involvement; access to relevant operational information; and a client representative who can facilitate obtaining answers and/or schedule interviews and who also reviews and comments on report drafts. Without commitment to these key elements, the quality of the assessment can be significantly diminished. Often the initial assessment reveals associated and/or enabler projects. Assessing and developing these projects is completed during a detailed study, the duration of which is dependent on findings in the initial assessment. 

ENQUIRY NO. 4500

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