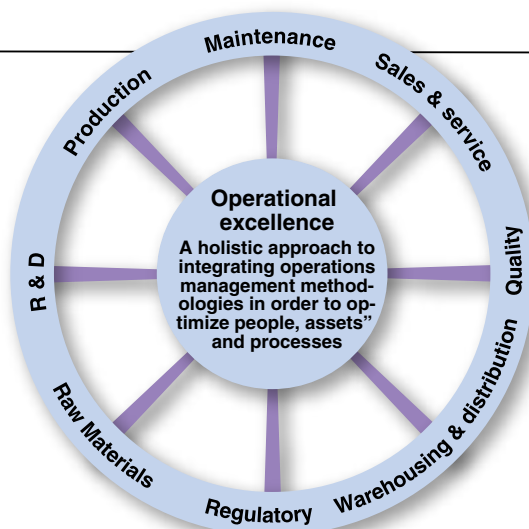


# Operational Excellence Begins Here



**FIGURE 1.** Each part of the “OpX wagon wheel” should operate in harmony with all the other parts to ensure smooth running

**Achieve operational excellence in batch processing through a commitment to improved operational efficiency**

**Michalle Adkins**  
Emerson Process Management

The pressures and challenges placed on the chemical process industries (CPI) have been heralded so often that even a person on the street can articulate most of them; and the list continues to grow — cost containment, lawsuits, fewer blockbuster discoveries, unexpected competitors, and many more. The cold hard reality is that the CPI have entered into a tough, cruel business world where only those companies committed to excellence — to becoming the best-of-the-best — will enjoy success.

Jack Welch, former CEO of GE, describes *excellence* like this: “To me, excellence means being better than the best. Its achievement requires an introspective assessment of everything we do, say, or make, and an honest inquiry: ‘is it better than the best?’ If it is not, we will ask ourselves, ‘what will it take?’ And then, we will rally the resources required to get there” [1].

What Welch and others are describing and what many companies have begun to pursue is *operational excellence*.

According to the online encyclopedia Wikipedia, “Operational excellence is the goal of conducting business in a manner that improves quality, obtains higher yields, faster throughput, and less waste. Sometimes known as OpX, operational excellence is the state or condition of superiority in operations and execution of business processes. Many different business tools are used

in the pursuit of operational excellence. These tools include Six Sigma, Lean, Footprint Rationalization and Premier Resource Management.”

Obtaining a state of operational excellence requires applying a holistic approach that results in integrating operations management methodologies in ways that optimize people, assets, and processes.

Imagine OpX within your organization similar to the way you view the wagon wheel in Figure 1. If any single part of the wheel — rim, hub, spoke, felloes — is incapable of performing in harmony with all the other parts, the ability of the wheel to continue rolling smoothly and reliably forward is greatly jeopardized. Translated into business jargon, if any single area of your business — R&D, production, quality, sales and service, and so on — is not performing in concert with the rest of the organization, the ability of the company to satisfy the shareholders is greatly jeopardized.

All of this begs the question, “Where does it make sense for a company to begin in order to achieve OpX?”

## Where to begin

Stephen R. Covey [2] suggests that “beginning with the end in mind” is always an important part of any program or process, and securing management support can be crucial to achieving total success. This is not to belittle what can be accomplished using available tools without management’s support. However, with management’s

backing greater opportunities exist that can produce astounding results across the entire organization. Additionally, when management is part of the process, successes are celebrated, roadblocks disappear, funding becomes available, cooperation and consistency abound, trials and tribulations are less devastating, and the journey simply becomes more fun for everyone.

Organizations that are already on the OpX journey report that different business functions — maintenance, production, R&D, and so on — generally require different methodologies, tools, skills, and assistance to achieve a sustainable level of OpX success.

For example, the following questions come to mind: should you apply the entire Six Sigma toolset, incorporate lean manufacturing, mix parts and pieces of each to form Lean Six Sigma, or utilize some other customized approach? If certification is required, how will the organization manage each certification? If new tools and processes are being used to manage the business on a daily basis, how and to what extent will training on these new tools and processes be rolled out? How do you avoid data paralysis (gathering more and more data) and data-anemia (not gathering enough or the right data)?

Often, especially during preliminary introduction of OpX into various parts of an organization, the wisdom and experience of consultants with domain expertise can save time and money. Besides having hefty creden-

## SUMMARY OF THE EXAMPLE

**Define:** reduce release time by 10%

**Measure:** Time and date stamps on batch records

**Analyze:** Cause and effect diagrams illustrating contributing events

**Improve:** Benchmarking and value stream mapping prioritizing opportunities

**Control:** Monitor results to ensure expected improvements are being achieved

**TABLE 1. CALCULATED SAVINGS  
FOR SINGLE PRODUCT INTERMEDIATE STATE**

Category of savings	Calculated savings
Increase throughput	\$425,000
Improve planning process	\$4,250
Eliminate paper batch record processing	\$102,000
Reduce manpower for batch record execution	\$250,000
Reduce manpower for batch record approval	\$238,000
Reduce number of deviations	\$150,000
Reduce/eliminate paper log books	\$8,500
<b>Total savings</b>	<b>\$1,177,250</b>

tials that are relevant to the business, the consultant's portfolio should include a library of general guidelines that can be tailored to fit your organization. For example, by implementing a guideline that helps to ensure that the quantity of data collected and analyzed is appropriate for the complexity of the problem, the team quickly builds confidence and efficiently delivers measurable results.

No doubt you are aware of the many business-improvement tools available, such as Six Sigma, Lean Manufacturing, Business-Performance Management, but how do you determine what tools are most appropriate for successfully injecting OpX into the various parts of your business, say production?

### A practical methodology

One significant portion of the batch processing industries is the life-sciences industry. When you think about it, batch processing is an orchestrated mix of process control (level, flow, temperature, and so on) and discrete manufacturing (start/stop, open/close, transfer, clean, and so on). As a result of the U.S. Food and Drug Administration's (FDA) Process Analytical Technology initiative, this industry now has additional demands for ongoing operational improvements that represent significant new opportunities that can be applied to batch processing in general. Examples from this industry will be used to illustrate implementation of OpX.

The more successful OpX meth-

odologies being employed for batch production combine Six Sigma and Lean Manufacturing. They call this Lean Six Sigma or S<sup>4</sup> (for Smarter Six Sigma Solutions [3]).

Additional tools that experienced Lean Six Sigma consultants may apply include: Value Stream Mapping, Collaborative Diagrams, Design of Experiments, Business Process Mapping, Quality Systems, Fishbone Diagrams, and others.

Lean Six Sigma is actually an adaptation of the traditional Six Sigma DMAIC (Define, Measure, Analyze, Implement, Control) methodology (see, for example, *CE* November 2003, pp. 62–67) combined with the improvement methods popularized by Lean Manufacturing and can include Kaizen, FMEA (Failure Mode and Effects Analysis), DOE (Design of Experiments), and QFD (Quality Function Deployment).

Certainly the expertise and experience of the consultants you select to help ensure you correctly commence your OpX journey is important; however, since twenty-first century businesses are highly dynamic, the tools the consultant brings and eventually leaves with your organization need to easily accommodate change. Be sure the consultant's Lean Six Sigma methodology provides sufficient flexibility for the consultant to tailor a program that will accommodate your current business environment. The methodology should also accommodate being re-tailored by your employees in order

to address future business environments. Anything short of this degree of flexibility will eventually hamper your OpX progress.

### Learn by example

As previously stated, operational excellence is a holistic approach to integrating operations management methodologies in order to optimize people, assets, and processes.

Concentrated to a single focused statement, OpX is about increasing the return on invested capital (ROIC).

In the define (assessment) phase, ROIC opportunities are identified as measurable, quantifiable results, such as:

- Increase profitability by 5%
- Exceed a 10% return on the invested capital
- Increase RFT (right first time) from 95% to 99.99%

Within the life-science industry in particular, shortening the overall batch-cycle time, including the time required to investigate and resolve processing discrepancies before the finished product is released for shipment, can have a significant impact on ROIC within production, sales and service, and warehousing and distribution.

In order to illustrate the Lean Six Sigma methodology, this article will use an example which is actually a composite of multiple case histories.

**Define (assessment):** When commencing a production facility assessment, the goal is to answer (define) two questions:

1. Of all the improvement opportunities you identify, which one should you work on first?
2. What tangible results will this opportunity improve?

Once you begin, there are likely to be many additional improvement opportunities identified, the challenge is sorting through all these opportunities in order to arrive at the one or two you must work on first.

In our example, the goal was to reduce the time required to release a finished product to shipment by 10%. Among the discussions that helped define the goal are the following:

- There is a tremendous amount of paperwork required in order to release a product

**TABLE 2. CALCULATED SAVINGS FOR MULTI-PRODUCT PAPERLESS FUTURE STATE**

Category of savings	Electronic work instructions & in-process material tracking	Data integration	Cycle time improvements	Total by category
<b>Quality</b>				
Improved batch record review and release	\$518,500	\$430,000	\$0	\$948,500
<b>Throughput</b>				
Reduce batch cycle time	\$0	\$0	\$2,040,000	\$2,040,000
Reduce batch release cycle time	\$0	\$0	\$714,000	\$714,000
<b>Availability</b>				
Extend calibration cycles	\$1,105,000	\$0	\$0	\$1,105,000
<b>Operations &amp; maintenance</b>				
Minimize operational duplication	\$332,000	\$485,000	\$0	\$817,000
Reduce maintenance overtime	\$468,000	\$0	\$0	\$468,000
Improve control, monitoring, and reporting	\$93,500	\$46,800	\$0	\$140,300
<b>Utilities</b>				
Reduce electricity usage	\$0	\$0	\$361,300	\$361,300
<b>Waste and rework</b>				
Eliminate atypical batches	\$204,000	\$0	\$0	\$204,000
<b>CAPEX Savings</b>				
Reduce commissioning & startup	\$0	\$0	\$1,190,000	\$1,190,000
<b>Total savings:</b>	<b>\$2,721,000</b>	<b>\$961,800</b>	<b>\$4,305,300</b>	<b>\$7,988,100</b>

- Tracking all the paper is cumbersome
- Inventory of WIP (work in progress) or finished goods is increased
- Islands of automation produce islands of data
- Inconsistency of applications abound
- Manual brute-force efforts are often used to get product released

While some of these bullets obviously fit our defined goal, others may not be so intuitively obvious. For example, “increasing inventory” is likely to be the “cushion” necessary to meet customer requirements in an environment that is unable to predict how long it will take to release intermediate product and then release finished product for shipment.

When each of the discussion topics were explored in greater detail, every one emerged as a significant contributor to the time required to release a finished product for shipment.

For this composite example, the client/consultant teams developed collaborative diagrams indicating the sources of batch-end data, the data flow paths (including each time a human physically handled various pieces of data or paper) and the frequency of data back tracking that resulted from incomplete or missing

data, to name a few. The resultant picture showed a variety of tortuous paths to resolving batch discrepancies, getting appropriate signoffs, and being able to finally release the finished product for shipment.

But how did these project teams determine what constituted a reasonable reduction for each project?

**Measure (study):** 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.

Clients explained the problems differently and frequently used different terminology, but each agreed the goal was to reduce the time required to release a finished product to shipment. (For this article we are using an average of multiple projects thus the 10% value.)

Using the time-date stamps logged on the mass of paperwork for 100 or so batch-records the client/consultant teams determined that the average time required to release a finished product for shipment was about 60 to 80 days. The teams then developed cause-and-effect (Fishbone) diagrams to illustrate the contributing events which included:

- Missing and ambiguous entries

- Incorrect entries and entries in the wrong place
- Clarifications required, such as illegible handwriting and crossed out entries
- Calculation and rounding errors
- Deviations outside defined control limits
- Miscellaneous questions

The next step was to convert events into numbers. For this step, the teams developed Value Stream Mapping (VSM) diagrams to show how long it would take to release a product for shipment if all the required information was available and accurate the first time. When placed along side VSM diagrams illustrating various delaying event scenarios, the potential for improvement became obvious. But was it as good as it could be?

Benchmarking is a widely accepted means of learning how the activities of one company compare to those of other companies performing similar ones. Benchmarking within an industry provides comparisons among “like” companies, but even the best within an industry might not be the best when evaluated across industries.

A 2004 survey [4] revealed that most pharmaceutical companies achieve about 85 to 95% (2.5 to 3.1σ)

## START AN OpX IMPROVEMENT PROGRAM

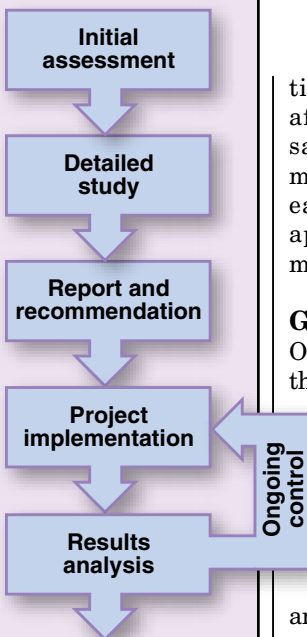
**D**evelop or work with a partner to implement an OpX improvement program for your life-sciences or other manufacturing. If working with a partner, insist on recognized industry expertise and a proven track record of accomplishment.

An OpX Improvement Program (Figure 2) should begin with an initial assessment, which typically takes two to three days. Partners in this process can assist with defining areas of opportunity for throughput improvement, cost reduction, and increased availability. When the initial assessment is completed, the findings should be presented to plant management and subsequently incorporated into a written report. The report should include:

- 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
- An outline of how the team can assist to capture the identified opportunities

Initial assessment success is driven by three key items: appropriate time carved out for key plant personnel's involvement; access to relevant operational information; and a client representative who can facilitate obtaining answers and/or schedule interviews and who also reviews and comment 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 a detailed study is normally dependent on the findings in the initial assessment. □



times reduced or denied, but even after some give-and-take, the total savings of the future state remained compelling enough that in each case executive management approved various investments in multi-year projects.

### Get started

Operational Excellence (OpX) is more than setting a goal of conducting business in a manner that improves operational efficiency. It's even more than improving quality, obtaining higher yields, faster throughput, and less waste. It is about achieving a state of corporate performance that Wall Street analysts acknowledge, admire, and reward. OpX is about being the best of the best.

Achieving a state of operational excellence requires using the right tools, methods, and advice combined with unwavering commitment, patience, constant encouragement, trust, celebration of success, objective reviews of misses, and the flexibility to accept that just because something worked (or did not work) in one location is not a guarantee that it will produce similar results in all similar locations.

So, are shareholders, Wall Street analysts, and financial institutions showering accolades and praise upon your company? If not, show no fear and begin the operational excellence commitment right in the heart of your organization, right where a lot of the money is spent and made — production. ■

*Edited by Gerald Ondrey*

### Author



**Michalle Adkins** is an OpX Consultant at Emerson Process Management (103 Enterprise Dr., Royersford, Pa. 19468. Phone: 610-569-4005; Fax: 610-569-4001; Email: michalle.adkins@emersonprocess.com) She has over 15 years of industry and consulting experience in the areas of operational excellence consulting, project management, production planning, vaccine manufacturing, automation, computer validation and engineering. In her role at Emerson Process Management, she has consulted with major pharmaceutical companies on projects that have included MES solution justification, OpX opportunities and system life planning. Prior to joining Emerson, she was with Merck & Co., Inc. for 13 years. Adkins has a B.S. Ch.E. and an M.E. in industrial engineering.

right-the-first-time (RFT) to quality review with the best companies achieving RFT to quality review were at about 96% (3.3σ).

On average, the case history facilities were experiencing about 19,500 defects per one million opportunities or 3.6σ. In other words, these clients are as good as the best, at least when compared to their peer companies. However, the survey also provided results indicating that world-class manufacturing and processing facilities across multiple industries were achieving a 99.4% (4.0σ) RFT to quality review, which equates to only 6,000 defects per million opportunities — far better than the composite case histories. Thus, a 10% improvement target was a conservative improvement goal.

The point is, Wall Street analysts might throw your company a couple of kudos for being among the best of your peers or within your industry segment, but achieving operational excellence is not just about beating your competition, it

is about being among the best of the best across all industries.

### Wrapping up

In the example, the client/consultant teams went on to develop improvement roadmaps illustrating two scenarios. The first scenario illustrated what the teams recommended as a temporary state, with improvements in procedures and practices that would provide near immediate financial benefits while building a foundation for a future semi- and/or fully-automated solution. The final scenario revealed a paperless future-state with document management software ensuring that information critical to releasing the product to shipment was accurate and complete as it was being developed.

Besides cost calculations, justifiable savings calculations were also developed for these scenarios. The results are summarized in Tables 1 and 2.

As often happens with such projects, savings “claims” are some-

### References

1. Jack Welch, Key Annual Speech to Shareholders, 1981 ([http://callcentres.com.au/GE5\\_Jack\\_Welch.htm](http://callcentres.com.au/GE5_Jack_Welch.htm)).
2. Covey, Stephen R., “Principle-Centered Leadership” and “The 7 Habits of Highly Effective People,” Simon and Schuster, Inc., N.Y. 1992.
3. Breyfogle III, Forrest W., “Implementing Six Sigma,” Wiley Interscience, N.Y., 2003.
4. Benson, Roger, McCabe, Jim, “From Good Manufacturing Practice to Good Manufacturing Performance,” *Pharmaceutical Engineering*, July/August 2004.