



Why Six Sigma Equals Failure for Life Sciences

Using Six Sigma to reduce errors is vital, but it still leaves you vulnerable to catastrophe. To create the most defect-free process possible, you need to unleash the power of workforce management.

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The costs associated with making a mistake in the life sciences industry can be staggering. Remember when one of the world's pharmaceutical giants recalled 100,000 bottles of its popular medicine, costing the firm more than \$50 million? Or when another company withdrew its pain medication from circulation and watched its stock price collapse, wiping out more than a quarter of the firm's market value in a single day?

Product recalls, returns, and expirations are estimated to cost the pharmaceutical industry \$2 billion a year¹.

In most commercial enterprises, eliminating errors from the R&D and production process is a goal. But in life sciences – when you consider the human health and financial risks at stake – eradicating errors is an *imperative*.

How Can You Help Keep Your Company Off The Front Page Tomorrow?

To avoid unwanted headlines, today's life sciences companies are actively pursuing Six Sigma as a methodology for reducing errors, optimizing quality, and ensuring that their products are as safe – and as profitable – as possible. Six Sigma seeks to stabilize controls and minimize defects by removing variability from business processes. And the key to achieving this result is the use of applied statistics. However, it is not just the understanding of the numbers, but the application of analysis that is essential. With the power to transform raw data into actionable information, managers can make decisions that affect real change — change that can minimize mistakes, ensure a safe product, boost productivity, and eventually increase profits.

What Is Six Sigma and What Does It Mean?

It is commonly thought that General Electric created Six Sigma. In fact, Motorola devised the Six Sigma methodology back in 1981. Sigma is the Greek word for standard deviation, which represents a particular variation from a mean. Six Sigma seeks to minimize this variation in manufacturing and business processes by identifying and removing instances of defect (errors). Using Six Sigma, variation is reduced *but it is not eliminated*, as you can see below:

2 sigma = 68 percent

3 sigma = 93 percent

4 sigma = 99.4 percent

5 sigma = 99.97 percent

6 sigma = 99.99966 percent

6σ

Notice that at 6 sigma, there are still 3.4 errors per million processes. For life sciences, this margin for error can mean the difference between a successful product launch and a multi-million dollar recall.

¹ Healthcare Distribution Management Association

Six Sigma Is Good – But It's Not Good Enough

Six Sigma is an effective strategy for reducing mistakes but it cannot eliminate them entirely. If and when an organization reaches the sixth sigma, which is no small feat, it is still making 3.4 errors per million processes. Thus, if a drug company manufactured the aspirin we take for a headache under this standard, it wouldn't merely be poor practice, it could be downright dangerous for the consumer. Similarly, if an insulin manufacturer were to get the formula right 999,996.6 times out of a million, would we call that error rate adequate to the need?

In short, when consumer health and safety hang in the balance, *life sciences companies cannot tolerate even a single error.*

So how can you augment your Six Sigma strategy to attack even the smallest margin of error?

The key is to address the biggest cause of variability at its source – *your life sciences workforce.* More and more life sciences companies today are leveraging new **workforce management** strategies to optimize the quality and performance of their most important capital – their Human Capital. Workforce management offers proven methodologies and operational best practices to improve workforce productivity, reduce risk, and control labor costs. Using innovative technology-based workforce management strategies, these firms are reducing variability in the performance of their workforce with unprecedented success.

Reducing Variability At Its Source – The Men and Women Who Work For You

It may come as no great surprise that in life sciences, the largest contributor to variation — and error — is people. Your workforce thus represents the greatest and most immediate opportunity for you to get closer to your goal of zero errors per million.

To push past the sixth sigma, it becomes essential to put in place a workforce management strategy that can help people perform at their peak — a methodology that permits managers to:

- Optimize employee scheduling for maximum predictability and quality
- Supervise employees with real-time management tools that isolate variability in performance so course corrections can be made *immediately* – before errors affect quality
- Identify problem areas and trends so you can improve overall workforce performance
- Minimize absences and other factors that create variability in the process

Driving out variability means closely managing R&D, production, and distribution processes to minimize defects in the product cycle. Workforce management can help you do this in a number of ways.

Workforce Management: The New Strategy For Minimizing Defects Per Million

The concept of workforce management – optimizing the performance of the workforce to maximize productivity, minimize errors, and reduce labor costs – is best deployed across both the R&D and manufacturing arms of a life sciences company. People in R&D are often regarded as

polar opposites of manufacturing employees. As highly paid (mostly salaried), highly educated professionals, R&D employees are typically seen as not requiring labor management. However, considering that these employees control the most expensive and fragile part of the development process, using workforce management to improve your R&D processes is just as critical as analyzing the shop floor activities of your manufacturing workers.

In the end, people still account for the largest amount of variability, no matter their roles. Take time-to-market for a new drug, for example. If you are not first, you might as well be last. But human errors in R&D can cause years of delay, making your innovation obsolete by the time it arrives to market – if it arrives to market at all. Millions of processes occur during the R&D phase. So 3.4 errors per million is completely unacceptable, having the potential to derail an entire product launch.

There are 4 areas where workforce management best practices can help you optimize your Human Capital across both R&D and manufacturing:

1. Scheduling
2. Absence management
3. Analytics
4. Labor and project costing

The Scheduling Challenge: Optimizing Shifts to Avoid Errors

Fatigue and/or distraction have been to blame for some of the world's largest disasters. Chernobyl, Three Mile Island, and the Exxon Valdez debacle all occurred during the night shift.² Operators directly responsible reported fatigue as a significant factor in the events leading up to their errors.

Using a workforce management strategy, you can take the guesswork out of scheduling and avoid dangerous errors associated with fatigue, poor-fit workers (workers in the wrong shift at the wrong time), or sudden absences that create holes in the workflow. By closely matching labor to demand and responding in real time to scheduling changes, you can avoid the extra costs associated with either under-scheduling (lost productivity) or over-scheduling (people standing around on your dime).

Why are more and more pharmaceutical companies using 12-hour shifts? There's a good reason.

Accidents and errors often occur during either start-up or shutdown periods. Employees who are getting acclimated during the beginning of a shift may not have the proper focus. At the end of a shift, their concentration may be distracted by thoughts of outside activities. By employing two 12-hour shifts (vs. three 8-hour shifts), you can reduce your shift changes by 33%, potentially reducing incidents of error. Keep in mind, several studies have shown no difference in fatigue or

² William A. Charland Jr., "Night-Shift Narcosis" *The Rotarian*, January 1992

alertness between 8 and 12 shifts *when schedules are designed optimally*.³ This is where the right workforce management scheduling tools can be vital to creating error-free workflows.

For example, many companies already employ 12-hour shifts but aren't doing it effectively because they assume that day and night shift employees want the same rotation. The reality is that many groups on night shift need a different system. And health and safety issues can be rampant during those hours, regardless of the shift length. When night-shift employees get days off, they typically revert to a "day-shift mentality," sleeping at night and being active during the day. With the wrong rotation schedule, they can end up with excessive rotations between day-shift and night-shift mentalities, which will lead to exhaustion. That circumstance can add to the fatigue with which they are already burdened. The result? More errors, not to mention serious health and safety concerns. Workforce management can help obviate these issues by creating optimal schedules that keep employees performing at their best.

Absence Management: Identifying and Mitigating the Impacts of Absenteeism

When your employees don't show up for work, they can't get their jobs done. They can't help your company hit its R&D benchmarks and production goals. Even worse, unplanned absences can create holes in the workflow that can generate errors and mistakes with potentially catastrophic consequences:

- Added workloads – fewer people doing more
- Work disruptions and shift changes – and it's all happening in real time
- Mandatory overtime and its associated fatigue factor
- Increased stress on the employees who have to make up the difference
- Morale issues that can affect quality of work

Workforce management can give you real-time visibility into time-off trends, planned leaves, and unplanned absences so you can take active steps to reduce overall absenteeism and the impact it has on your people. What's more, unpredicted absences like the dreaded "sick call" can be quickly resolved with replacement strategies, helping you to curtail the spillover effects of employee absence on daily productivity and quality. The goal is to minimize the harmful impacts of absenteeism on the workforce and keep your employees' error rate per million as low as possible.

Controlling absenteeism is also about controlling costs.

Unplanned absences cost an average of 6 percent of payroll per year⁴. This number represents direct costs — to pay absent employees — as well as indirect costs like lost productivity and overtime wages. It's no wonder life sciences companies are proactively combating this issue.

³ Tucker, Barton, and Faulkard, "Comparison of 8 and 12 Hour Shifts: Impacts on Health, Wellbeing, and Alertness During the Shift" *Occupational and Environmental Magazine*, February, 2010

⁴ Mercer, Inc., October 2008

Analytics: Gaining Real-Time Visibility Into How Your Workforce is Performing

The key to increasing productivity and reducing errors in the workforce is to have *real-time visibility* into what's happening in your R&D labs and on the shop floor –the thousands of tasks and sub-tasks that are conducted by both people and equipment. The goal, ultimately, is to:

- Understand project and task status – *who is doing what* – in real time (vs. after the fact)
- Identify unproductive time and transform it into productive time
- Align people with work and ensure that the highest priority projects are always staffed with the right number of people
- Pinpoint where R&D or production errors are occurring or about to occur – and take immediate corrective action before those errors propagate
- Identify problematic trends so you can resolve them – such as the unacceptable performance of your most error-prone employees

This level of visibility is most easily acquired in an information-rich workforce management environment that uses analytics software. Workforce management solutions can capture large amounts of performance data and turn it into *actionable, real-time management information* that managers can act upon.

Old-world techniques like paper, pencil, and stacks of spreadsheets cannot easily translate into actionable information. Fortunately, rather than having to manually sift through mounds of data to find out what is happening – after the fact, when it is too late – labor analytics software is now available that can give you this visibility *in real time*.

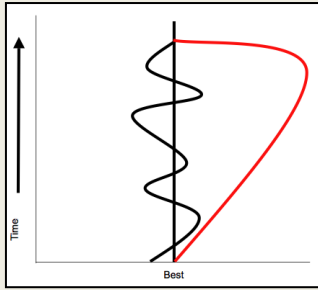
Now that this technology is available, more and more life sciences companies are adopting it to address critical questions that, until today, had been largely impenetrable:

- What is happening right now and how can I maximize productivity and output?
- Where do our errors originate and why?
- What are our most harmful trends and problem areas?
- Which employees are the least effective and how can we avoid similar poor-fit hires in the future?
- Conversely, which employees are the most effective and how can we propagate their success through the workforce?
- Which of our supervisors manage the most effective teams?

Six Sigma is all about identifying weaknesses and removing them. Analytics can be easily deployed to accomplish the same goal. For example, you can use analytics data to train your most error-prone performers with information gleaned from the most successful management strategies – the strategies proven to be mistake-free. If your lowest performers cannot be trained, then it becomes essential to get them out of the process. You cannot afford to wait for them to commit more errors.

Catching Deviations Early So You Can Correct Them

All employees deviate from “best practices” and create variability in their performance



that can lead to errors – no one is perfect. The key is to catch and correct these deviations as early as possible. Here, you can see the benefits of using workforce management to do course corrections on a daily vs. weekly basis. Course correction is when an employee isn’t doing something right or well and they need to be “managed”. The black line illustrates course corrections done on a daily basis using workforce management. The red line demonstrates what happens when deviations aren’t caught until a whole week goes by. The difference in the area of deviation between the weekly and daily course corrections represents the lost costs and lost productivity when errors aren’t caught early.

More Accurate Labor Costing: Making Every Dollar Count

Do you know your labor costs? Of course you do – you can simply look at your overall payroll. But the real challenge is being able to identify how those labor dollars are spent on a project or task level. If you can’t understand how paid time is spent – who is doing what and when – then you have poor visibility into your true project costs and the causes behind variances that can lead to errors. Ultimately, you must guess which corrective steps to take.

A workforce management environment can tell you how many labor hours have been invested by which employees on a specific project, process, or task. Both direct and indirect hours can be captured, enabling you to understand estimated ROI based on current actual costs, as well as where shortages and excesses of talent exist within a newly expanded company. You can use this information to eliminate significant amounts of time abuse, such as unnecessary overtime or indirect “lost” time (e.g., wasted time created by idle or non-productive employees) that can lead to errors, morale issues, and worse. This lost time cannot be controlled if it cannot be seen.

With workforce management, you and your executive team can gain insight into:

- How your paid workhours are being allocated (reconciling paid labor to output at a project or task level)
- How those dollars can work harder for your organization (increasing productivity while controlling your costs)

The opportunities to improve productivity while reducing errors are dramatic. In one survey, 77 percent of organizations using workforce management realized a 10 percent plus boost in productivity and more than one third gained a 25 percent plus increase in labor output⁵.

Today's Workforce Management Systems and Software

Without a workforce management strategy in place, managing common labor events – such as unexpected employee absences, overtime equalization, vacation requests, skills requirements, union rules, and labor laws — can be an administrative nightmare. Instead of functioning as strategic assets out on the floor, managers are often stuck in their offices with pen, paper, and spreadsheets trying to sort out the mess. Quality suffers. Errors are common. The workforce under-performs. Internal policies might be broken and occasionally labor laws broken as well.

When deployed properly, today's software-based workforce management systems can offer an integrated, cohesive solution to these challenges. As second-generation technology, today's workforce management software is a perceptible improvement from the nascent products of 10 years ago. The use of advanced workforce management — including automated scheduling, absence management, and analytics software tools — has become a proven strategy for removing errors from the process. It can take the human factor out of play and push your organization closer to a zero-error environment.

Conclusion

Six Sigma is a highly useful quality strategy for the life sciences industry, but it should not be your only approach for minimizing errors. Combining workforce management strategies with Six Sigma to go *beyond* the Six Sigma goal can create a more complete quality strategy and help your company:

- Create the most error-free process possible
- Accelerate time to market
- Improve consumer safety
- Increase output-per-employee
- Lower risk
- Achieve higher profitability at the end of the day

Don't stop at the sixth sigma when the ultimate goal is to eliminate *every possible error you can*.

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⁵ Reed Business Research Survey