

Less Overfill Can Mean More Profit

Applying Lean and Six Sigma Can Save You Money

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“For many manufacturing companies in the business of filling packages, adopting best-in-class methods to reduce overfill can create a competitive advantage by reducing production costs and regulatory risk.”

– J. Michael Spratt, USCCG Printing and Packaging Practice Leader

When filling packages, the first requirement is to meet governmental regulations for compliance with net content declarations. However, these standards do not specify limits for overfilling. That’s your problem! Overfill has the same net effect as giving away money. In high volume operations, it can quickly add up to tens or hundreds of thousands of dollars on an annual basis.

On the other hand, under-filling is not an option, because of customer satisfaction demands and strict regulatory requirements. If companies under-fill, the fines and the damage to their reputations can be even be more costly. Many com-

panies today feel that overfilling is the only way to avoid regulatory fines and maintain customer loyalty. So, their goal is to get as close as possible to the target fill weight without going under it.

This seems perfectly sensible, but many companies have difficulties meeting this goal. Is it because they do not fully understand their process capabilities? Or, have they not adopted correct tools and techniques, e.g., Lean, Six Sigma, or technology, to help reduce variation and control processes? Perhaps it is simply a matter of execution. The answer lies in part or all of the above.

Reducing Variation Using Lean and Six Sigma

Minimizing and controlling fill weight variation is key to redirecting a considerable amount of money to the bottom line. Some financial gains can be made without directly attacking process variation, but by not addressing it, total benefits will not be fully realized. Those operations that have been successful in minimizing overfill have attacked variation *and* added quality measures to midstream manufacturing processes.

Many organizations have learned that Lean and Six Sigma methods, tools, and techniques work well together to achieve quick process improvements and greater product consistencies. Although Lean equals zero waste and Six Sigma equals zero variation, it's important to recognize that there is some overlap, because Lean addresses variation, as well.

Reducing variation affects the entire value stream (a uniquely Lean view) because it will provide more consistent yields, which means that yields can be predicted based on input. Therefore, you can design your process to flow more continuously, with less just-in-case inventory and improved lead times. Very often this is an under-appreciated benefit of reducing variation.

If we look at improvement through both Lean and Six Sigma lenses, we have the necessary tools, methods, and strategies to not only uncover the root causes of process variation, but also to pay attention to the obvious causes. Manufacturers must start to recognize that the two cannot be separated when it comes to developing an overall improvement effort. USC Consulting Group (USCCG) has helped clients in a variety of industries reduce millions of dollars in overfill using both Lean and Six Sigma tools, methods, and techniques as the following two examples will demonstrate.

Reducing Overfill at a Candy Manufacturer

Our client's confectionary products include marshmallows and a variety of different types of jellybeans. One plant generates approximately four million marshmallow products annually, including holiday products for Easter, Halloween, Thanksgiving, Christmas, and Valentine's Day. In addition, they produce over six million cases of other molded products, in this case, jellybeans, across twelve packing lines.

The molded products are packaged in a number of sizes ranging from a half-ounce holiday Halloween pack to a ten-pound bag. Using high-speed equipment, those packages fill at the rate of 400 to 500 units per minute. Our value stream map clearly showed high retention points, high scrap and rework levels, and low machine utilization stemming from numerous production interruptions due to poor process control, equipment issues, and mechanical breakdowns.

All of the equipment is highly automated and, with one packaging line running at 400 units a minute and another at 180 units a minute, there are a lot of fast moving parts. Supervisors knew that improving machine efficiencies would help them achieve the company's strategic objectives of reducing supply chain costs, increasing throughput, and reducing fill weight variation.

Applying Lean and Six Sigma

We determined by performing process capabilities analysis that putting statistical controls in place alone was not going to deliver the entire benefit of reducing overfill. Accordingly, our consulting team also applied Lean and Six Sigma methods, tools, and techniques, along with technology, to reduce fill weight variation and rejects, thereby increasing throughput.

We established and developed meaningful data collection and analysis capabilities for the production lines supported by a technology application USCCG custom-configured for our client. The application accumulates and interprets such raw data as downtime, line and labor efficiency, production yields, scrap figures, and average fill weights, which it then translates into actionable, real-time reports. Trends and patterns for packaging-run issues, machine breakdowns and over-weight conditions, among others, are made available so that timely adjustments can be made in the most cost effective way.

Since many of our client's processes are continuous, process interruptions create significant start-up issues, scrap, rework, and fill weight variation. We addressed the equipment and machine failure issues by developing and creating a more robust maintenance program. We chose a less rigorous program than that of Total Productive Maintenance (TPM) as a first step to avoid undue strain on client resources at that particular time.

We revamped the inspection program for major and minor mechanical components and applied preventive maintenance according to vendor recommendations and available maintenance data.

Operators were also trained in how to inspect minor mechanical parts of the machinery and address observed defects by lubing, tightening loose parts, and replacing minor worn components that were easily accessible.

We employed 5S at all lines to deal with workplace conditions that lead to various wastes like delays due to defects and machine failures, all of which contribute to fill weight variation. Lastly, we also deployed visual controls to monitor process performance and identify and remedy root causes of problems.

Process Capability and Statistical Process Control

We analyzed actual fill weights and compared these values to standard fill weights. We then compared actual and standard fill weights to label claims. In all cases we found that the actual and standard weights were higher than label claim by as much as 7%.

When observing the process, we realized that the operators were reacting in response to fill weight measurement feedback and interfering in the processes when they should have left them alone. This was a contributing factor to the high process variation relating to fill weight variation. The need for statistical process control (SPC) charting by line and product was clearly evident. We trained all operators in the basic principles of control charting and taught them how and when to respond to out-of-control conditions. Control limits were established using historical data and the Western Electric Rules¹ to detect out-of-control conditions.

Figure 1A on page 4, shows the overall process capabilities while Figure 1B shows the corresponding Xbar & R charts for 60.1 gm jellybean packages before improvements were made. The data distribution is normal; thus, a normal model is used to obtain our statistics. The lower specification limit (LSL) of 54.7 is the maximum allowable variation (MAV) for this label weight according to the National Institute of Standards and Technology. This means that no one package can be below the MAV of 54.7 gm. The label weight is indicated by the green target line, which is the vertical dotted line in 1A.

1. The Western Electric Rules are general rules for detecting "out-of-control" or non-random conditions for data plotted on a run chart (plot of data as a function of time). The Western Electric Rules were designed under the guidance of a committee appointed by the engineering staff of the manufacturing division of the Western Electric Company. The rules appeared in the first edition of the Western Electric Handbook in 1956. This book has evolved into the AT&T Statistical Quality Control Handbook.

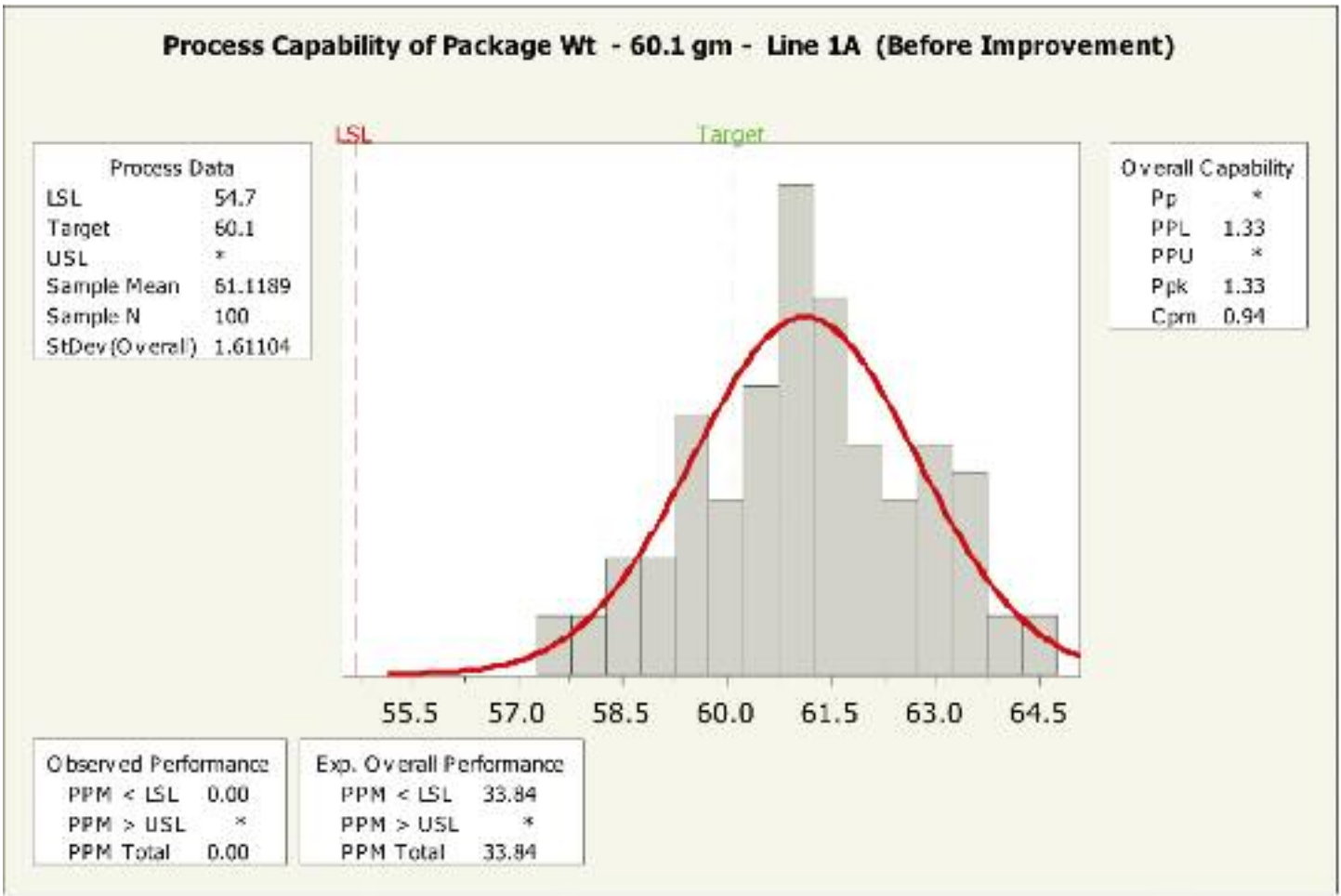


Figure 1A

Figure 1A shows overall process capability before improvement of jellybean package fill processes; the Target (Label Claim) = 60.1 gm, Average = 61.12 gm, and standard deviation (SD) = 1.61 gm.

Before Applying Lean and Six Sigma Tools and Techniques

When looking at Figure 1A, the left tail of the curve is very close to the MAV and does not permit shifting the curve to the left (closer to the target) without risking packages below the MAV. In the current process state, the model tells us that approximately 34 units will be produced below the MAV for every million generated, indicated by parts per million (PPM).

It should be noted that all process lines have check balances with a kick-off mechanism in the event packages are generated below the MAV. Hence, no units are packaged below the label weight; however, those products are repackaged in secondary process steps, which increases operating costs. The overall capability value (Ppk) is 1.33, which was calculated with respect to the MAV, and translates to a 4 Sigma level process. Although a 4 Sigma level process is average within the industry, it is not adequate to allow us to reduce overfill. The sigma level is a sta-

2. The Xbar-R chart is a type of control chart that can be used with variable data. Like most other variable control charts, it is actually two charts. One chart is for subgroup averages (Xbar). The other chart is for subgroup ranges (R). These charts are a very powerful tool for monitoring variation in a process and detecting changes in either the average or the amount of variation in the process. The charts provide an indication of when a process should be left alone and when a shift in the process has occurred as a result of assignable cause.

tistic used to describe the performance of a process to the specification limits. The higher the sigma level, the fewer defects or products are expected outside the specification limits. A 4 Sigma process is expected to generate just over 6000 defects for every million units produced with process drifts.

Figure 1B below shows the corresponding SPC Xbar & R chart². The data points in red are out-of-control conditions, which indicate special causes and process instability. The R chart shows the average range within subgroups to be 4 gm. This means that, when measuring several packages within one subgroup, the average maximum value minus the minimum value is about 4 gm.

To be able to reduce overfill, we needed to reduce the variation, or “squeeze the curve,” so that the left tail is farther away from the MAV. This, in turn, allowed us to shift the curve to the left toward the target, thus reducing overfill with little risk of generating more packages below the MAV. We also wanted to achieve process stability.

After Applying Lean/Six Sigma Tools and Techniques

After applying our Lean techniques to significantly reduce production interruptions and mechanical downtimes, as well as coaching and mentoring operators on how to properly use

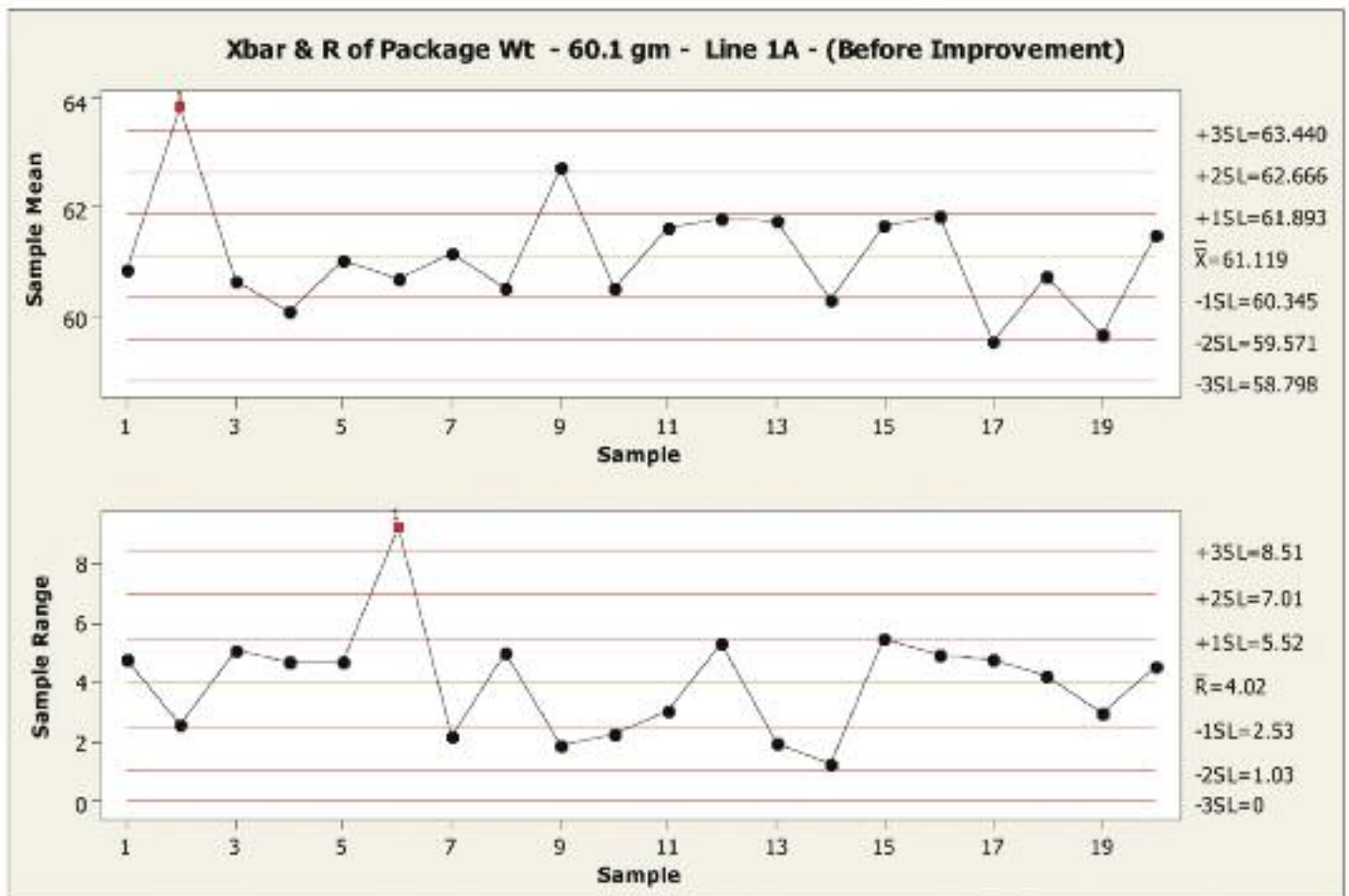


Figure 1B

Figure 1B shows the corresponding X bar & R SPC chart before improvements. The red squares indicate out-of-control conditions.

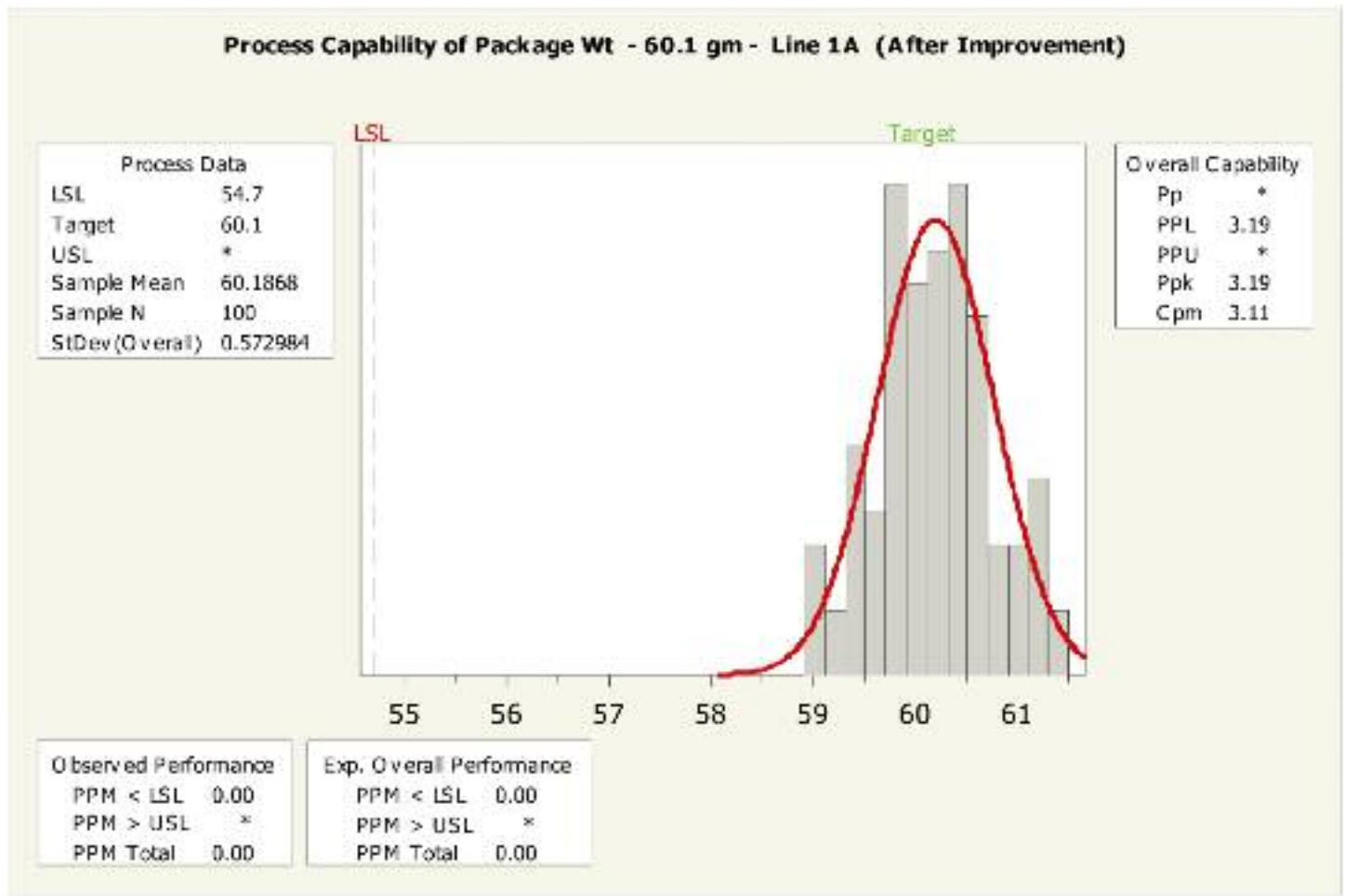


Figure 2A

Figure 2A depicts overall process capability after improvement of jellybean packages, where Target (Label Claim) = 60.1 gm, Average = 60.19 gm, and SD = 0.57 gm.

SPC charting to shift the process, we were able to reduce the variation and shift the curve to the left - closer to the target. The resulting overall process capability is shown in Figure 2A. The achieved mean is 60.2 gm, reducing giveaway entirely for this product (a weight reduction of 1.7%). The standard deviation has been reduced by 65%, resulting in a process greater than 6 Sigma. At a 6 Sigma level, less than 3.5 defects will be generated for every million units produced. Moreover, the model suggests there will be no packages manufactured below the MAV, eliminating repackaging costs and/or scrap. Figure 2B is the resulting X bar & R chart, which exhibits process stability or the absence

of special causes. The reduction in variation is also evident by the control limits. The Range chart also shows process stability and a 66% reduction in the subgroup range average (4.02 gm to 1.328 gm).

As processes were improving, we continued to redefine control limits and introduced additional test rules, based on the data and inputs from the quality department and production teams, which helped attain better fill rate accuracy. In total, we trained some 120 associates over three shifts in SPC so that machine adjustments and modifications could be made throughout each shift.

Financial Results

The proof is in the numbers. In molded products (jellybeans) alone, overfill was reduced by 50 percent and productivity rose between eight and 12 percent. On the marshmallow side, productivity improved nearly 10 percent and marshmallow overfill was reduced by 40 percent. All of these improvements translate to significant financial gain for our client, who said, “We were looking for a return on investment at around \$3 million on an annualized basis, and we got that and then some. And when I say annualized savings, it’s not that we got the savings one time and we’re going to fall back. We recovered our initial investment in the first year. More than that, we created a

culture where we can continue to grow that number. I don’t think there’s any potential end to the upside.”

Working with our client’s senior management staff, we managed to increase the level of thinking driven by Lean and Six Sigma principles and rules. Thinking drives behaviors, behaviors drive actions, and actions drive results. How sweet it is!

Reducing Overfill in Pharmaceuticals

This case history demonstrates how a tiny shift in weight allocation in prescription tablets can result in substantial savings for a pharmaceutical company and still meet federal requirements and patient needs.

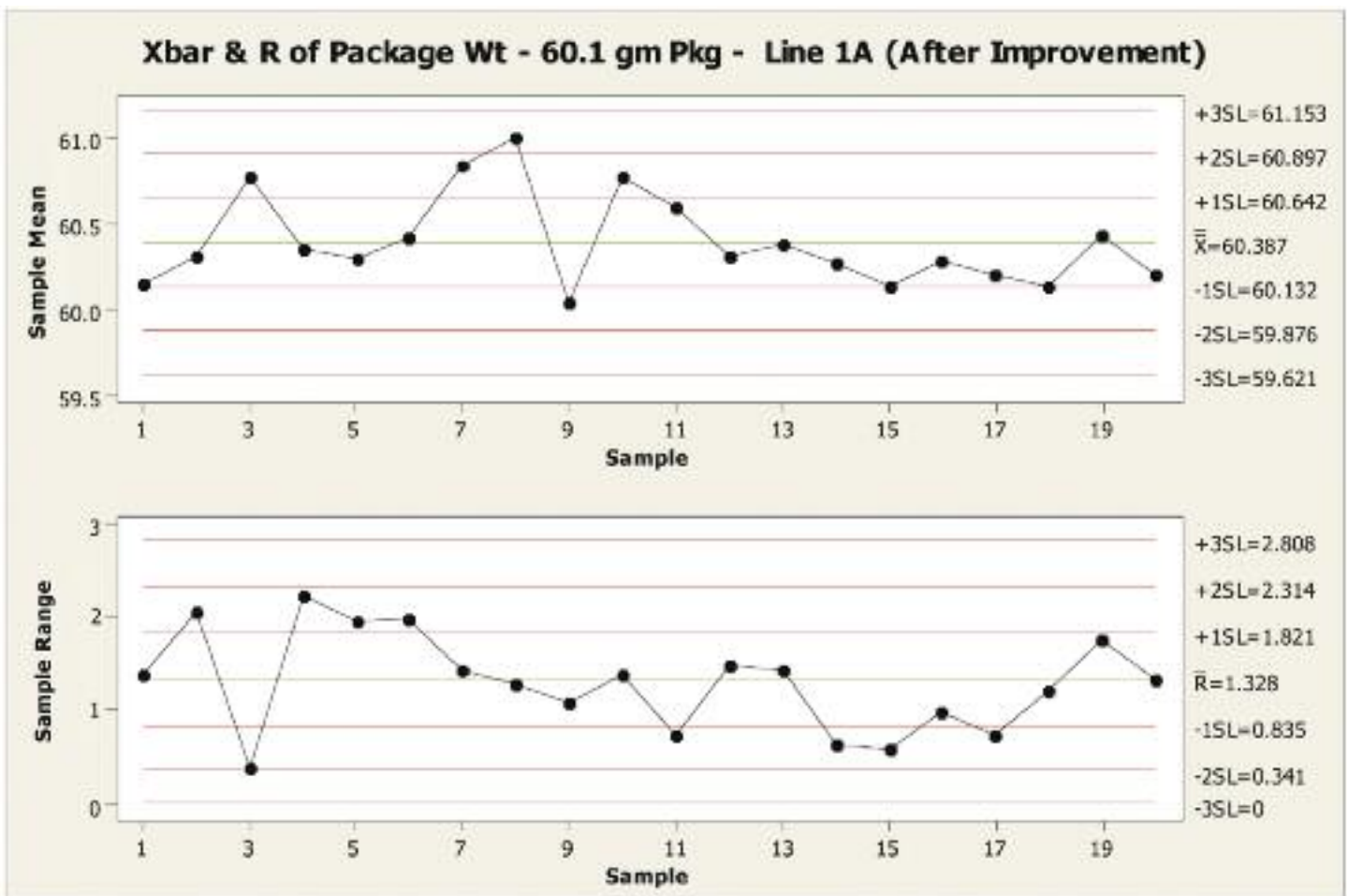


Figure 2B

Figure 2B illustrates the corresponding X bar & R SPC chart after improvement, showing the presence of common-cause variation only (process stability). Reduced variation depicted smaller differences between the control limits and a reduction in the average target weight and range value.

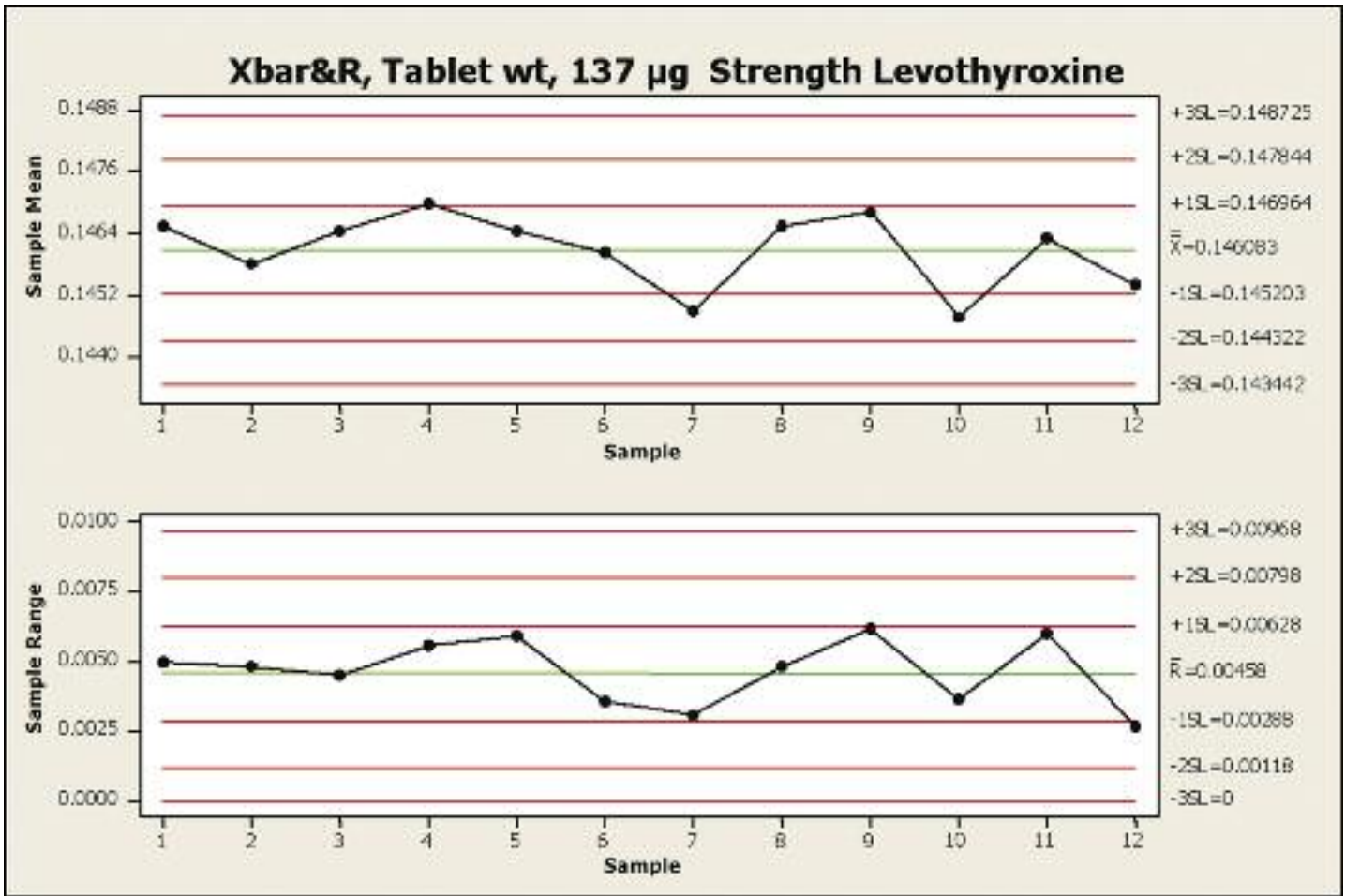


Figure 3. Xbar & R for tablet weight, 137 microgram strength levothyroxine tablets.

The federal government expects the industry to adhere to all specifications for fill weight variation for capsules, tablets, and sterile solids. Not adhering to these requirements may lead to the costly recall of an entire lot, including fines and a damaged reputation. Drug manufacturers tend to trail companies in many other industries in measuring and controlling product quality because many executives hesitate to change the status quo, fearing higher costs. We helped our client overcome these fears utilizing our proven techniques in controlling overfill. Our client has two plants consisting of blending, manufacturing, and packaging operations. One of the plants produces ramipril (generic name) gel capsules, tablets, creams, and ointments, all of which are prescriptive. Ramipril belongs in a class of drugs called angiotensin-converting enzyme (ACE) inhibitors, which are used for treating high blood pressure

and heart failure and for preventing kidney failure resulting from high blood pressure and diabetes. The other plant makes one product only – levothyroxine (generic name), a replacement for a hormone normally produced by the thyroid gland to regulate the body’s energy and metabolism. Levothyroxine is given when the thyroid does not produce enough of this hormone on its own. The drug treats hypothyroidism (low thyroid hormone) and is also used to treat or prevent goiter (enlarged thyroid gland), which can be caused by hormonal imbalances, radiation treatment, surgery, or cancer. This particular plant manufactures the levothyroxine product in eleven different tablet dosages.

After analyzing our client’s processes at both facilities, there was clear evidence that all fill processes were in statistical control (process stability). Figure 3

shows the X bar & R chart of weights for 137µg strength levothyroxine tablets. Special causes and low variability were absent for all strengths and processes, as is shown for the 137µg product.

We decided to focus our efforts primarily on statistically analyzing processes in the current state and making decisions as to whether and by how much we could shift the current process to reduce overfill. We used Lean tools and techniques only minimally because we felt the effort did not justify the gains in variation reduction. In other words, we attempted to reduce overfill with the current process variations.

The overall capability of all processes was better than a 5 Sigma level (less than 4 defects generated for every million units produced). Normal distribution models were used to fit the data. The 137µg strength is shown in Figures 4A, 4B, 4C, and 4D. There are many requirements that must be met when reducing tablet weight, but we monitored three main requirements during our analysis: tablet weight, % uniformity, and % assay.

Studies showed that all other requirements would be met when shifting these three main requirements within the lower and upper specifications.

Figure 4A: Overall process capability of 137µg tablet weights, Average = 0.1458 gm, SD = .0012 gm; LSL/USL are lower and upper specification limits for tablet process weights. Figure 4B: Overall process capability of 137µg tablet % assay and uniformity, Average % Assay = 101.8; standard deviation (SD) = 2.38%; LSL/USL are lower and upper specification limits for tablet % uniformity. Figure 4C: Overall process capability of 137µg tablets after shifting the curve to lower weights by 0.002 g. Average weight = 0.1438 gm, LSL/USL are lower and upper specification limits for tablet process weights. Figure 4D: Overall process capability of 137µg tablet % assay and uniformity after shifting the curve toward lower % assay by 2.4%. Average assay = 100.4 %; LSL/USL are lower and upper specification limits for tablet % uniformity.

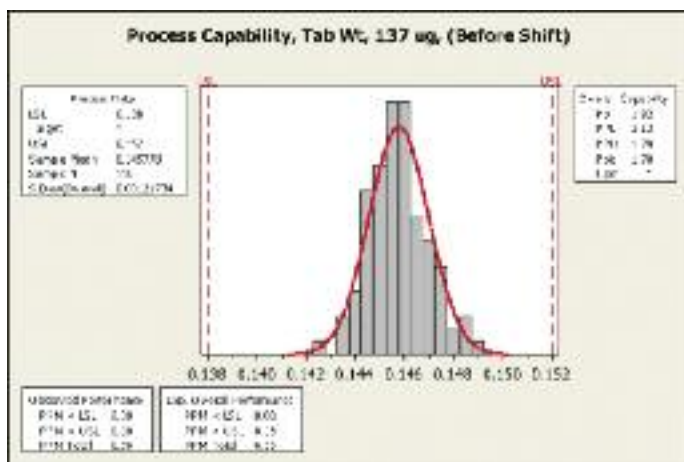


Figure 4A

Figure 4A shows the overall process capability for tablet weight (137µg strength) with an average of 0.1458 gm. The average tablet weight requirement is between 0.1420 gm and 0.1490 gm. The single tablet process specification is between 0.1380 gm and 0.1520 gm. All tablets were well within this specification.

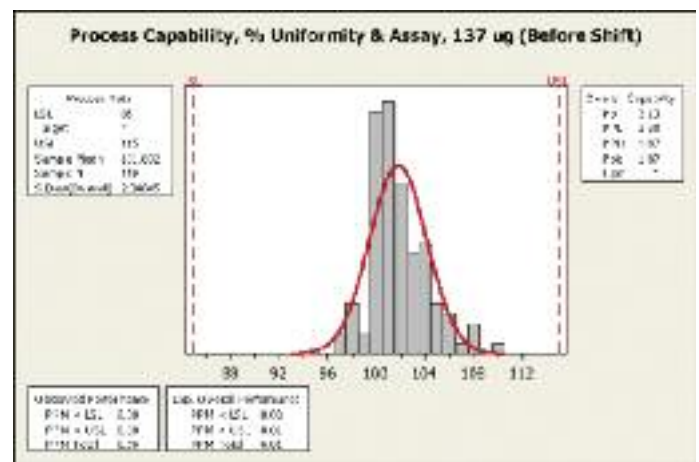


Figure 4B

Figure 4B provides the overall capability of both % uniformity and % assay. The average % assay requirement is between 98% and 110% and the overall process capability shows an average of 101.8% - well within the requirement. The % uniformity requirement is between 85% to 115% shown by the specification limits. The tails of the normal distribution curve are well within these requirements, with essentially zero probability of being outside the limits.

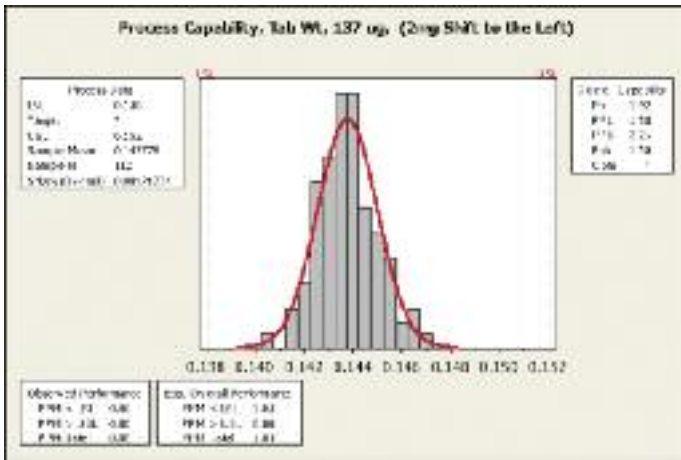


Figure 4C

Figure 4C shows the overall capability for the average tablet weight after reducing the single tablet weight by 0.002 gm. The average tablet weight is now 0.1438 gm and still well within the process specification of 0.1420 gm and 0.1490 gm. Moreover, all single tablet weights are within their specification of 0.1380 gm to 0.1520 gm.

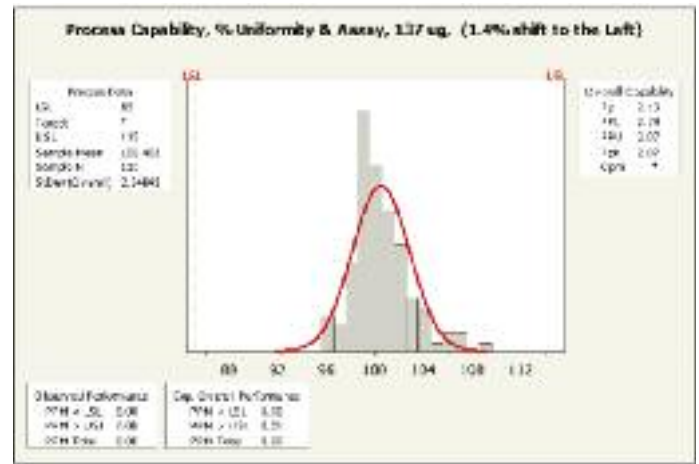


Figure 4D

Figure 4D shows the resulting % assay at 100.4%. The % uniformity is also well within the specification limits.

Financial Results

Between both facilities and product lines, the total tablet weight reductions translated to a \$3.3 million savings in active material usage with absolutely no risk to our client or patients.

Closing Comments

USC Consulting Group's proven methods and techniques in Lean and Six Sigma have helped clients reduce overfill by millions of dollars. We customize our approach according to the challenges presented by each client's processes. The analysis performed with our confectionary client indicated that both Lean and Six Sigma techniques were required to help reduce variation to reduce overfill. On the other hand,

the stable and low variation of our pharmaceutical client's processes primarily required Six Sigma tools and techniques to achieve a similar outcome.

Many organizations continue to give money away to customers or have not taken the "guess work" out when making decisions to reduce overfill. As a result, organizations do not capitalize on the total benefit or, even worse, increase the risk of lot recalls. Accurate analysis of process data and its interpretation, as well as effective execution of applicable Lean and Six Sigma tools, is critical to ensure that process changes are implemented correctly. Using Lean and Six Sigma can help your company reduce variation, improve productivity, and reduce overfills.

About the Author



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Frank J. Esposito, Ph.D., leads USC Consulting Group's Six Sigma Practice. As a Lean/Six Sigma Master Black Belt, he is responsible for organizing and leading Six Sigma engagements for the process improvement firm's diverse group of clients. Dr. Esposito has held senior positions focusing on productivity

improvement in a variety of organizations. He has trained many Black Belts and Green Belts across numerous industries, where he has implemented Six Sigma initiatives in combination with Lean.

Dr. Esposito earned his doctorate degree in materials science and physical chemistry from the University of Western Ontario, London, Ontario. He earned a masters degree in the same field from McMaster University, Hamilton, Ontario, and his bachelor of science degree in chemistry from the University of Windsor, Windsor, Ontario.

About USC Consulting Group

USCCG is an independent operations management consulting firm with nearly 40 years' experience in business performance improvement. It combines extensive subject matter expertise with enabling technology to drive and sustain superior results. The firm offers an array of services that include Six Sigma, Lean transformation, supply chain optimization, process improvement, project management, value

stream mapping, training and facilitation, blended learning solutions, modeling and simulation, and asset performance management. It includes many Fortune 1000 companies among its clientele. USCCG is a Microsoft Managed Partner headquartered in Tampa, FL, with offices in Chicago and Toronto. For more information, visit www.usccg.com.



First we make it work. Then we make it last.®

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