

Accounting for the cost of quality: a case of squandered opportunities

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ABSTRACT

BFM Global Medical Company expanded its footprint in the N95 mask industry during the COVID-19 pandemic using grant funds from the Defense Production Initiative (DPI). BFM was under pressure to deliver large quantities of its product to the global market as quickly as possible at a time when the local labor market was ill-equipped to provide the needed specialized labor. Because of the quality compliance aspects of the job, these positions were more technical and demanding compared to similar positions at BFM. However, the pay scale across the plant was the same. Further, temporary workers were paid a significantly lower wage rate. Ultimately, the use of temporary workers increased overtime, turnover, absenteeism, recruiting costs, training costs, production errors, scrapped product, downtime, and shipping costs. This case study encourages students to think about making decisions that focus on generating the greatest return on investment by maximizing value and minimizing adverse outcomes.

Keywords: labor efficiency standards, quality compliance, labor wage standards, cost accounting, COVID-19, indirect costs

Author's Note: This case study is based on the observation of several pandemic-related medical devices being rapidly spun up to meet pandemic demands. No proprietary or confidential information can be inferred from this case study.

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INTRODUCTION

Early in the days of the global COVID-19 pandemic, BFM Global Medical Company (BFM), a subsidiary of Acme Distribution Inc. (a wholesaler who acquired BFM to vertically integrate manufacturing), bid on contracts for N95 mask production under the Defense Production Initiative (DPI). Before the pandemic, BFM had produced the base (filter) material and then shipped it offshore for conversion into masks. Under the terms of the Berry Amendment, US Defense purchased fiber products are required to be produced in the United States (Spearman, 2020). This scenario required rapid construction of new production and testing equipment.

Raw material, labor, and equipment shortages were all exacerbated by time pressures to deliver large quantities of product to the global market as quickly as possible. BFM received a government grant to purchase additional equipment and was also prioritized for raw materials deliveries, helping to mitigate this issue. However, the local labor market was ill-equipped to provide the needed specialized labor to perform the quality control function. Further, there were multiple disconnects between top management and those making the day-to-day production decisions.

CASE DETAILS

Quality Compliance

N95 masks are regulated by the U.S. Food and Drug Administration (FDA) as a Class 2 medical device (U.S. Food and Drug Administration, 1999). Because the results of failure can be severe, quality compliance and a zero-defect target must be achieved. Parameters such as headband strength, seal quality, and filtration efficiency are highly controlled. Packaging and product lot numbers must match for traceability. Documentation for each mask must be traceable back to raw materials inventory controls and equipment settings. The FDA requires that manufacturers maintain a Device History Record (DHR) to provide objective evidence of the suitability for the marketplace of a product and the traceability of all materials used in the production of the product, including the certificates of conformance for all raw materials, test data, and label reconciliation and traceability for any given lot of finished product (U.S. Food and Drug Administration, 1999). This document allows for full traceability for recall or removal from the marketplace if required.

Labor

Heavy reliance on skilled labor was the result of a series of decisions made by upper management. In general, the background of these managers was wholesaling, not manufacturing, and this was reflected in the executive's incentive compensation plan. Management was rewarded for minimizing product cost. Also factoring in was the difference between the rural location of the plant, which many of the executives had never visited, and the urban location of the headquarters which housed upper management in a different state.

First, the decision was made by upper management to use the existing production design for the masks, even though it had been superseded by more efficient technology. This decision created an even greater higher reliance on skilled labor as indicated in Table 1 (see Appendix)

and more demands on individual employees. BFM is located in a rural area with limited availability of skilled labor. Further complicating the scenario was the injection of funds from the federal government to subsidize unemployment benefits. At the same time, a fulfillment center that offered competitive wages for unskilled labor opened in the area of the plant.

Second, the decision was made to use the labor usage standards provided by the overseas facility. This data was provided to corporate leadership and used as directives to the local manufacturing plant. The following assumptions were made by upper management:

- 1) The labor data provided by the overseas manufacturer were correct, exact, and relevant.
- 2) The domestic facility would be able to produce somewhat more efficiently than the offshore facility.
- 3) The cost savings from not transporting the raw materials for conversion at the offshore facility and returning the finished goods to the US would offset the higher wage rates paid to US workers.

The decision to adopt the labor usage standards from the offshore facility, based on these assumptions – which turned out to be false -- created significant pressure to meet potentially unrealistic costing and production demands.

ASSUMPTIONS

Early in the setup of the new equipment, a team was sent to study the operations of the offshore operation, including packers, team leads, process technicians, maintenance personnel, and engineering. When the team's quality engineer ran time studies of the quality operations, it was determined that one Quality Assurance (QA) Inspector was required for each production line for each shift team. As there were multiple production teams, this would require multiple QA Inspectors to fill these roles. However, the facility's cost accounting that had been shared with corporate leadership indicated that less than 0.5 QA team members were used per line. In other words, each QA Inspector was assigned to two or more production lines. The lower labor costs and less-than-exact documentation practices allowed the excess labor to be hidden in other operations within the offshore facility. Not all persons in the offshore facility supporting these job roles were fully trained to fill these positions, but they were able to do the repetitive high-volume, lower-skill operations. Due to FDA requirements, different job responsibilities, and labor costs, this was not viable at BFM's production facility. Despite these findings, the decision was made by BFM upper management to continue to allocate QA labor at less than 0.5 QA Inspector per production line.

The decision to use the offshore company's labor usage standards ultimately increased labor costs as a result of overtime, employee turnover and the resulting learning curve, competition in the labor market, and disparate pay scales between permanent and temporary employees.

To comply with the QA labor allocation approved by management, QA personnel would need to operate at over 160 percent efficiency for the prescribed 12-hour shift to complete the required tasks or two production lines. This resulted in extremely high levels of overtime which was paid at rates of 1.5 to 3.0 times the normal labor costs (dependent on if the time was straight overtime, Sunday, Holiday, or off-shift differentials as this is a 24/7 operation).

The high turnover resulted from several factors, including competitive pay for unskilled labor at the neighboring fulfillment center and generous unemployment benefits which enabled

workers with no childcare or health concerns to stay home. Further, the QA team positions work a swing shift. Normally, these employees work 2 days on then 3 days off, then 3 days on, and 2 days off before changing from day to night shift or night to day shift. The job grade for the QA positions throughout the facility was the same with the same pay scale. This position in other areas of the plant came with far less responsibility, stress, and overtime while paying the same pay schedule. This situation created a high risk of bidding on internal positions in the plant, resulting in a loss of the value gained experience in the learning curve. With the manning at these levels and the overutilization of labor, there was no cushion to cover vacation or other paid time off for medical or family leave, and individuals leaving the department or the company.

High turnover also resulted in additional costs due to the learning curve of the QA personnel, further lowering efficacies. Temporary workers were often used on the packing and inspection process of the line. Temporary workers are typically a high turnover labor pool in the best of times. Various factors in play during the pandemic made this problem even worse: ill workers and their families, as well as those with known exposures to COVID-19, lack of childcare, and government assistance for the unemployed all continued to contribute to absenteeism, walk-offs, and voluntary terminations.

During this same time, amped-up activity at major Dotcom distribution warehouses in the area increased demands for temporary and skilled workers and incited wage wars to get them. This resulted in BFM being forced to hire lower-skill workers. This and the lack of workforce continuity placed further demands on the QA personnel. To further complicate the personnel dynamics of the department, temporary workers received a lower pay scale for like work. While this is normal in manufacturing, the pay differential played into dysfunctional behavior, including a disregard for performing tasks effectively and efficiently.

Impact on Quality Costs

Due to the overutilization of the QA personnel, the product was often run “at-risk” and placed on quality hold until testing and FDA-required paperwork could catch up. This delay could be hours or days. If the material did have the appropriate documentation or pass all the quality tests, entire lots were either on long-term hold for records correction or heightened inspection, further increasing labor costs. Large amounts of warehouse storage were occupied by work in process as a result of this delay. Many times, entire production lots were scrapped, resulting in lost sales opportunities as well as wasted labor, material, and energy. Additional costs were added as the defective completed medical devices had to be destroyed in accordance with FDA guidelines. This procedure requires even more documentation in addition to the cost of the process itself: the product must be processed through a third party for destruction (usually incineration) and, in turn, a certificate of destruction had to be issued for documentation (U.S. Food and Drug Administration, 1999).

Lots that were not able to enter the marketplace created shortfalls in deliveries. The company was forced to pay expedited shipping costs and incurred late delivery penalties which added to the operational costs. This further eroded the profitability of the operation. In the end, new contracts were not awarded and the new lines of equipment were placed into mothballed status at a time when there was still high global demand for the product.

CONCLUSION

While other factors came into play, it was ultimately the decision to use labor standards based on demonstrably false assumptions that started the downward spiral that ended a lucrative business line for BFM. By underestimating labor requirements for quality assurance in the hope of cutting costs on the front end by roughly \$40,000 US per year per production line, the company ultimately squandered a multimillion-dollar sales opportunity and dumped tons of scrapped product.

ANALYSIS

This case invites students to consider the implications of seemingly minor decisions on the profitability of a manufacturing enterprise. An opportunity that executives considered to be a “cash cow” was squandered, largely as a result of the decision to minimize labor costs and standards. Given the market demands for the product in question, this should have been an operation that was not only meeting global demand but metaphorically printing money while running production. The efforts to save relatively small cost but high-value items (the added QA personnel) by minimizing labor costs resulted in not only paying many times that labor cost in OT, penalties, and expedited shipping fees in real dollars, it contributed to the loss of future opportunities to produce profits. Additionally, the department suffered more than 100% turnover in the QA team. Valuable knowledge and experience were lost. The following are some of the key takeaways from the case:

- (1) Do not filter input data to match an existing bias. Investigate and confirm or negate the validity of the input. In this case, top management had rationalized that the masks could be made using the same cost structure as the offshore facility because American superiority would ensure that the time demands and labor requirements were easily met. The decision to use the labor standards of the offshore facility ignored important geographical and cultural decisions. Despite sending down a team to verify that the standards were reasonable and the team discovering poor record-keeping, a different division of labor, and other factors which clearly showed the standards to be unreasonable, upper management chose to retain them.
- (2) Develop cost models that account accurately for manufacturing costs and labor. In this case, when BGN bid for the government contract, they used the selling price that had been established for product produced at the offshore facility. The assumption ignored that the facility had far cheaper labor and there were significant differences in defined job responsibilities between the US and the offshore production sites.
- (3) Understand the mantra of “Tell me how I am measured, and I will tell you how a perform”. In this case, the metrics established for success or failure of the management team, the costing, and sales teams were counterproductive to the end goal of a profitable and sustainable product life cycle of a high-demand product. Management was tasked with maintaining the prescribed headcounts and costs. Sales was tasked with selling the product in a marketplace with increased competition from multiple startups that were not fully certified or FDA compliant. This was a supply-side economics situation for a high-demand product and the sales price should have been set accordingly.
- (4) Understand that “Slow is smooth and smooth is fast”. Avoid covering a demonstrated problem by not accepting there is an issue with the original plan and executing a proper

course correction because of the constraints of the above. Admit when there is an issue and fix it properly.

- (5) Make sure information flow goes in both directions from the parent company down and the child company up. In this case, a company with a very successful history in distribution made an effort to vertically integrate a manufacturing operation to reduce costs. But as a manufacturing operation is impacted by different business factors than a distribution operation, management's lack of a complete understanding of the production model created costly mistakes.
- (6) Trust but verify. When data comes in such as production and labor costs from offshore entities, it must be evaluated carefully. Due to regulatory, geographic, and cultural factors, managerial and cost accounting and documentation practices vary globally.
- (7) Harmonize Job Pay Scales when possible. While the use of temporary and contract workers is commonplace in the manufacturing world, this, combined with the high demands of the jobs, contributed to squabbles, turnover, and in some cases less attention to detail. Even if no benefits were provided to the temporary and contract workers pay equity for the same jobs would have reduced these issues. The negative impact is that temporary worker agencies receive a percentage markup on the wages for overhead. The question is should this increase in overhead be accepted as a tradeoff of the flexibility of using temporary labor.
- (8) Pay the market wage. Ultimately, the market wage is the wage that must be paid to entice individuals to be good employees. The fulfillment warehouses constrained BFM's labor pool with offerings of permanent jobs requiring similar or higher wages. These jobs were more menial and less stressful. At the same time, the enhanced unemployment benefits provided by the Federal Government created a situation where one could make nearly as much as a full week for not working. While this benefit helped many who had caretaking roles during the pandemic, it created further constraints on the labor pool and turnover in both the temporary and the permanent workforces. Turnover amongst the lower-skilled packers and visual inspectors created further demands on QA personnel and opened the gates for possible quality escapes, eroding the company's reputation as well as increasing costs and scrap.

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APPENDIX

Table 1: Quality Assurance Team Members

Position	Responsibilities	Skills Required	Job Class
<i>QA Inspector*</i>	Responsible for the Device History Record; monitors production for deviations from procedures; executes in-process quality testing	Strong reading comprehension, written communications, computer literacy, and math skills; basic understanding of statistics; ability to understand and interpret work instructions and procedures, calibrate test equipment, execute testing, and document to FDA standards	Permanent
<i>Team Lead</i>	Facilitates production operations and works with production team, material handlers, technical and facility support, and engineering; ensures meeting of production schedules; supervises changeovers and collection of production testing		Permanent or Temporary
<i>Process Technician</i>	Executes raw material changes on production line and in-process adjustments within specified limits; subs for packer/inspector for breaks		Permanent
<i>Internal Material Handler</i>	Stages raw materials at the line; ensures that the traceability is maintained and data provided to QA personnel; labels finished case unit product and ensures accuracy of the labels; moves cased material to QA hold area for release to distribution warehouse		Permanent or Temporary
<i>Area/ Department Lead</i>	Coordinates with temp agencies for staffing; meets the requirements of any job roll in the department with exception of QA and technician		Permanent or Contractor
<i>External Material Handler</i>	Transports material to the warehouse and raw materials to the production area		Permanent or Temporary

<i>Packer/ Inspector</i>	Picks product from the machine for visual inspection; packs and labels dispensers; ensures traceability numbers of lots are correct and recorded.		Permanent or Temporary
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*FDA Guidance requires that the QA Inspector is independent in reporting structure from production management and serves to ensure the quality of the product (U.S. Food and Drug Administration, 1999).

