Medtronic Manufacturing Increase Capacity

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Abstract

Medtronic is a Fortune 500 company that dedicates in designing and manufacturing of medical devices. The company created an insulin pump that serves the function of an artificial pancreas. To develop a duplicate of the manufacturing line, the project team asked for a $1.5M budget approval. This project was completed and created more than 200 new jobs directly and indirectly. The completion of this project means that a life-changing product can always be available for the patients that need it.

Introduction

Medtronic is a Fortune 500 corporation that specializes in the design and manufacturing of medical devices. In their product portfolio, a large variety of medical equipment for different parts of the human body can be found such as: heart, brain, muscles, pancreas and more.

Medtronic developed a Next Generation insulin pump that serves the function of an artificial pancreas and lets the patient live a normal live without the need of injecting insulting through needles daily. This pump is computerized and is completely automatic. It monitors the sugar in the patient blood and decides if insulin is needed or not.

From year to year, diabetes is increasing rapidly in the USA and Puerto Rico. This increase is making the manufacturing line be at 100% capacity. The company was missing revenue due to the restricted levels of manufacturing capacity. Each year, the sales projections are doubling, but the manufacturing was at a 100% capacity. Each quarter, more product is needed to supply the demand. From 150,000 units per year, now 293,000 units are needed. This means a 93% increase in the manufacturing capacity; The objective of this project was to manage the development of a duplicate line for the insulin pump. The creation of a duplicate line would double the manufacturing capacity and would improve business revenue, market share and patient needs. Figure 1 demonstrates the capacity increase outflow.

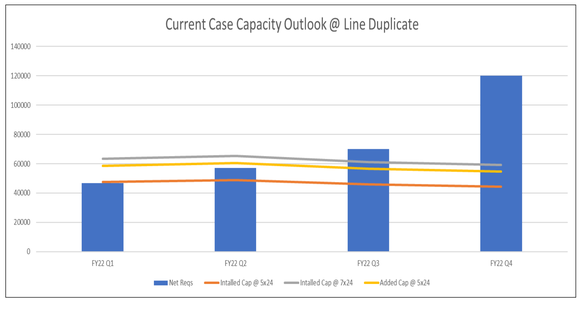

Figure 1
Projected Outcome

Plan And Execution

To accomplish this project, the team had many challenges from beginning to end. Medtronic is a large corporation with headquarters for diabetes in California. This information is included to give the perspective that to request a budget approval can be extremely difficult in some cases. The team asked for $1.5 Million in budget approval. The way to convince the management for this approval included a presentation with the current and projected manufacturing quantity. The projections determined that the Return on Investment has an expected time of six months. The budget request included a timeline for the engineering resources, leaders, and validation procedure.

Various challenges were considered in the process of the request. In previous occasions, the lead-time of the equipment coming from the supplier were very precise due to the criticality of this large projects, but due to the COVID-19 pandemic, the supplier manufacturing, validation on site and shipping were taking longer. The project team took that into consideration and established in an expedited timeline.

Hiring engineering resources, technicians and equipment operators is always a challenge because these new employees need regulated training and constant follow up due to the regulations of the FDA and the quality of the product. First, the project team hired an experienced project manager to execute every day and request from management. This project manager worked hand to hand with the internal team and kept in scope that the purpose for all this project is to be able to supply the great demand for the products.

The project timeline included working on weekends and required the help from other departments. The importance of the completion date in a project is highly important due to the market share that the company will gain or lose by that date.

In the development of the project, the team took all considerations of challenges to make the correct timeline and the management of the company is counting on that date to keep moving forward. This fast-paced timeline was the main reason that the budget got approved.

Results and Discussion

The project kept moving forward the entire period. The team was able to travel to the supplier plant to execute a FAT test. This test was made to make sure the supplier made all the specification and request from the team. This test passed with a score of a 100%.

After this test, the equipment was sent to Puerto Rico. The expected lead-time was six weeks and did not got late. By the time the equipment arrived, the layout and utilities were setup for the quick accommodation of these.

The engineers started the Installation Qualification (IQ) tests. This test is to make sure the specification on details both in software and hardware are in the equipment. This entire test was made for each equipment and presented no deviation and was finished in the correct scope. The IQ was then approved by the manufacturing and quality engineers.

A Test Method Validation (TMV) was made for each equipment. This test measures the minimum passed units needed for acceptance. The TMV needed a 95% reliability to be accepted in company standards. After this validation was completed, the results were accepted by the quality engineer.

The next test was needed for all the equipment that stored data. This test is not only a pass or fail, it has a result on specific numbers, but it also requires a process characterization test (PCR). This PCR test needs a confirmation run of a specific number of units. The 100% of units need to pass between the range of results for acceptance. No issue was found in this test. It was approved by the corresponded teams.

The final step of this processes was closing the CSVR. This report has every single specification needed for the acceptance of the equipment due to FDA requisites. This project had zero issues and zero deviation. The results were found 100% acceptable with a 90% yield and was on track for submission.

Conclusions

This project being for a duplicate line made the path easier because a number of documents already existed that were used for equivalency. All the equipment and processes were submitted to FDA and completely approved. Now, Medtronic has a second manufacturing line for the diabetes pump, and it can supply more product and increase the revenue by a 100%.

During this project, various areas of opportunities were found to make some equipment and processes more efficient to minimize the cycle time in each unit. This way, new equipment is not needed every time. Just by adjusting the efficiency the number could increase.

Future work

In future work, a third line is being considered in the same time scope. This project created more than 200 new jobs directly and indirectly. The completion of this project means that a life-changing product can always be available for the patients that need it.

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