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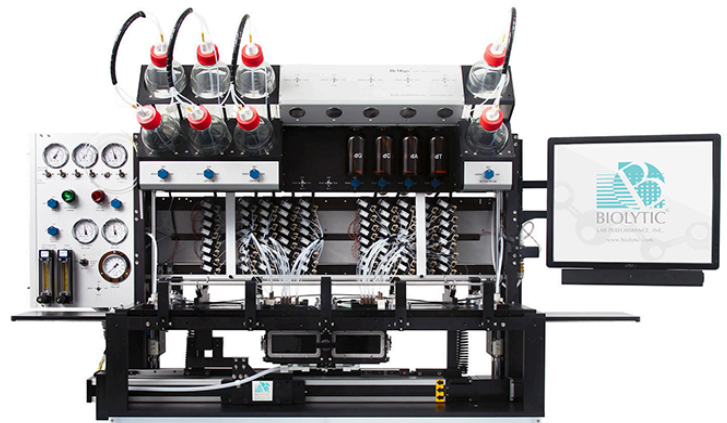
Background



Located about 20 minutes out of Santa Clara University in Fremont, lies the company Biolytic. Despite the company being located in a regular business park, the business itself is anything but regular. Biolytic stands out among other companies as it develops some of the most cutting-edge biotechnology that exists today. Biolytic manufactures machines that can create multiple batches of large strands of DNA and RNA, as well as the accessories used to run the products and instruments they sell as a whole. Tom Demmit (pictured left), Biolytic's founder, is a biomedical engineer who has been in the biotechnology field since 1975. His extensive experience in the industry allowed him to develop a visionary and clear mission for Biolytic from day one of its founding.

As mentioned previously, Biolytic sells many different instruments for their field, however, their most popular and flagship product is the Dr. Oligo Synthesizer. The Dr. Oligo Synthesizer was first created in 1997 and was designed to artificially create strands of DNA and RNA for several purposes such as R&D, genetic engineering, and more.

On a broader scale, Dr. Oligo allows for DNA and RNA creation via solid surfaces such as aerogel, unlike conventional methods like on Petri dishes. This process, called oligonucleotide synthesis, is remarkably more efficient as it can reliably create dozens of identical or even near-identical DNA strands with minor differences for whatever purpose the user needs.



Over the decades, Biolytic has innovated time and time again in making its synthesizer better than it was in the year before, and in doing so, has developed loyal customers along the way. Biolytic serves both domestic and international customers ranging from government institutions, and academic institutions to pharmaceutical companies from its single location in Fremont. Most commonly, Biolytic uses its products and services for serving diagnostic and therapeutic applications. James Demmit, Senior Director of Operations of Biolytics and the man we interviewed for this report, stated, "I can't name exactly who we provide for, but if you're thinking of them, we probably do." Furthermore, Dr. Oligo and the services provided by Biolytic can aid in drug development, vaccines, and test kits, and are used for general testing in determining where a virus may have come from. Future applications of the methods used by Biolytic are endless but a few of the more prominent uses of the technology include even more

advanced nucleic acid-based therapies like DNA/RNA vaccines, technologies using CRISPR CAS-9, protein engineering, or even research into DNA-based data storage. All of these topics can start to blend together for someone with a limited background in biology, however, James guided us throughout the tour and used the following example for the future of their field. In the case of pharmaceutical applications, when a patient takes a medication via a pill, the pill is digested and the components of the drug are spread throughout the bloodstream and delivered to the body by almost a scattershot method. This can be effective, however, the process is not as efficient and effective as it could be. The future of these applications that Biolytic plays a key role in involves a different approach. Instead of being dispersed via the bloodstream, a medical practitioner or even a machine can attach the required drug to an artificial DNA strand created by Dr. Oligo where the medicine and strand can specifically target the location of the treatment, acting as a search function like on Microsoft Word.

Inventory Management

After learning a comprehensive background about Biolytic regarding its history, application, and goals for the future with James Demmitt, we continued our interview by asking about how Biolytic maintains fluid operations. The challenge of running a company is monumental, especially so for a business that has been around for nearly three decades while simultaneously being positioned on the frontlines of innovation and relevance. Clearly Biolytic must have been doing something right. Essentially, Biolytic's strategy boils down to a few components, those being: keeping a strong eye on sales forecasting, demand and capacity planning, maintaining a lean manufacturing practice, offering as much customer and product service as possible, and maintaining a fulfilling environment for those involved in the company.

Our first questions were about Biolytics' inventory planning techniques. Mr. Demmitt elaborated on their process of actively monitoring Biolytic's inventory. Rather than relying strictly on forecasting models, those in charge of operations prefer to make more present decisions, based on a variety of information on hand in order to gauge how many machines they could effectively build. Gathering information from the previously sold products, some assistance in general forecasting, and sales-based reports on past performance and earnings were some of the methods Mr. Demmitt mentioned.

Biolytic's Dr. Oligo is quite complex and comes with many moving parts, resulting in several variations in demand and differences among each material used in manufacturing the Dr. Oligo machines. Moreover, each component on the machines has a separate reorder point, very similar to the process we became familiar with in Game 2 during our course. Biolytic prefers sourcing its raw components from nearby suppliers, in doing so they can skip middlemen while growing stronger relationships with local businesses.

The methods that Biolytic practices the most stems from their values of "lean manufacturing. Lean manufacturing is a production process based on the ideology of maximizing productivity while minimizing waste within a manufacturing operation. The Lean in lean manufacturing sees waste as anything that does not add value that customers are willing to pay for. Lean manufacturing has numerous benefits such as reduced lead times, operating costs, and improved product quality. We've learned numerous iterations of lean manufacturing throughout our course,

with almost every chapter covering efficiency and reducing time for processes while maintaining quality. Biolytic realizes the value of lean manufacturing and finds that it's better to order “just in time” where they could use the excess money to invest in other areas. Avoiding things like excess inventory, overproduction, and overproduction is critical. Even the subject of unutilized talent was covered while speaking to Mr. Demmitt as they wish to train those in manufacturing in every possible step of creation in the Dr. Oligo.

8 wastes of lean manufacturing



 **Limble**

While lean manufacturing can be an optimal strategy, in Biolytic’s case, it can come with a few hiccups. Some members of Biolytic have mentioned that the company can suffer at times because of its lean methodology. More specifically, Biolytic is familiar with the problem of lacking a proper amount of supplies to run their production efficiently at times. Our group has been able to analyze a portion of the Biolytic’s supply chain data and recognized that ordering just in time has had some drawbacks in the past.

Overall, Biolytic does a great job ordering their components from their preferred suppliers, however because of their lean process, they are left with little wiggle room for supply chain interruptions. Oftentimes, they are left with extended lead times with little to no safety stock for some components. Not just Biolytic, but every business in the world was affected by the pandemic, and while nobody could have expected such an event to take place in early 2019, it does hold as a great lesson in preparation for large scale events, and how a business could survive the potholes that it entails.

Safety stock is an extra quantity of a product that is stored in a company's warehouse or property to prevent a situation that clogs up the manufacturing or production process, ultimately halting the business. Our group has determined that increasing Biolytic’s safety stock from none to some that would consider world wide supply chain issues , adjusting the ROP and being mindful of the optimal stocking quantity would cushion the blow of unexpected events and greatly improve their ability to consistently deliver products. Given the fact that Biolytic specializes in a field with scarce competition, they hold leverage when it comes to the organizations they supply. It can be understandable why Biolytic might not see the greater lead times as a priority in their business model, however, adding additional safety stock would only improve their efficiency.

Quality Check

Moving forward from lean manufacturing and the recommendation of increased safety stock, James further emphasized Biolytic's strong value in customer support and quality. Biolytic has a three-part quality check system to ensure that their products are running properly and effectively before shipping them out to the customers. There is minimal exception for the margin of error with their product compared to other manufactured products because of the detail and precision that must take place for the machines to produce reliable and safe outputs.

James explained that their first step in quality assurance is to inspect the condition of each component of the machine during the manufacturing process. Each piece of equipment, component, and chemical must be thoroughly checked before the assembly process begins. Each of the departments at Biolytic has quality checks, this is extremely important to limit the chance of failure with any specific part.

Secondly, after each component is individually checked, the assembly process begins. Once everything is assembled properly, an additional check of the machine as a whole is performed. All components are double checked to ensure that nothing was damaged during the process of fitting and of course there is a quality check on the build overall. Mr. Demmitt mentioned that this part of the process takes the longest. This second step can take upwards of 3 days for each machine, where if one piece is experiencing complications, they must loop back to step one for the piece causing issues.

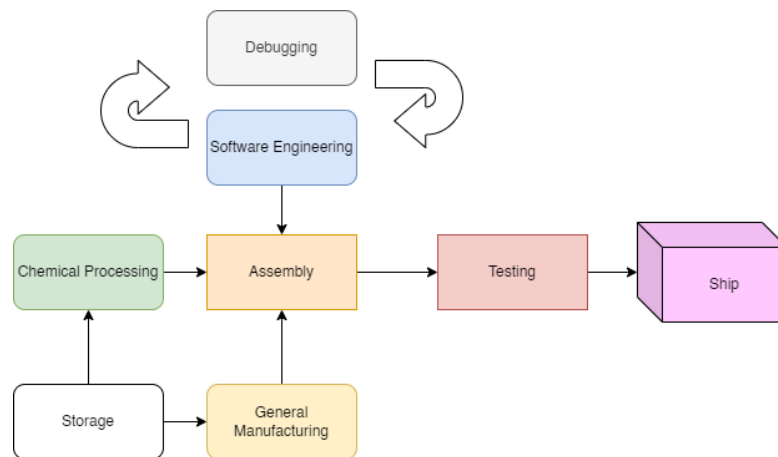
After step two is complete, with all components running properly, and the machine as a whole is in good condition, Biolytic performs tests on sections of the machine as a customer would. The three step process used by Biolytic underlines their care of quality checking.

Assembly, Facility Layout, and Supply Chain

At Biolytic, there are two different flow processes to mention. The general supply chain process and the manufacturing process for the components and assembly they do in-house. First with the supply chain. Again, Biolytic prefers to source all of its raw materials from local suppliers, supporting the local area and minimizing transportation time and costs. The vast majority of the time they have a steady supply of materials from their suppliers which allow them to meet most urgent requests with reasonable timing. However, during the COVID-19 pandemic, as mentioned previously, Biolytic had to extend lead times because of supplier processing. During this, it was taking months for the supply chain to stabilize. Once materials are received at Biolytic Labs, on comes the assembly process at Biolytic where they create, service, and fulfill orders from their customers. . At this point the supply chain continues with Biolytic's customers using machines like Dr. Oligo to carry forward and develop further products, eventually reaching the average consumer.

Diving further into Biolytic's manufacturing process, they have a variety of sections to their facility that all have separate responsibilities for the process. Mr. Demmitt emphasized that they do not practice a typical assembly line. Instead, Biolytic has 13 people in the manufacturing sector with each technician having their own bench and tools to assemble different parts. After

receiving any order that cannot be made in house from local suppliers, the products are appropriately stored within specific zones at the Biolytic facility. During the tour, James mentioned that larger inventory is stored in the main warehouse while smaller materials go into separate rooms.



From there, areas such as the manufacturing department can begin the assembly or servicing of machines. The assembly process considers parts technicians craft themselves. Chemical components are placed in separate rooms which were made specifically for the chemical engineering process. Finally, the software sector develops the programs to run the machines while also debugging issues present in the current version of the software. After everything has been put together the machines are tested and stored safely until they are ready to be shipped.

In the case of a bottleneck, Mr. Demmitt explained that they heavily encourage employees to notify management of situations that could impact the means of production and manufacturing. They want to instill the value of receiving suggestions from the employees to keep things running efficiently, like in the case of a bottleneck issue. In efforts to avoid this issue, Biolytic focuses its efforts on cross-training. Biolytic technicians are trained to manufacture a variety of parts and a workshop is made easily accessible, allowing them to practice on parts that they are not familiar with. James explained that this cross-training method challenges their employees, and allows them to develop more skills and efficiency overall. Adding onto that, the company finds that cross training and assembling in the manufacturing sector improves the quality of the company and allows greater feedback to their processes. Biolytic technicians are also required to take a biochemistry training course within the company. James explained that in order for technicians to ask questions and provide feedback, they must understand the parts they are manufacturing and how or what they are used for.

In the end of the interview James reiterated their value in continuous improvement. They often ask questions instead of assuming and go through several individuals to make decisions such as determining a reordering point, etc.

Recommendations for Improvement

After speaking with James, we noticed that one of their main issues was keeping a constant lead time for their instruments. The operations team at Biolytic tend to prioritize their own intuitions rather than utilizing their forecasting system to order new stock inventory. As a result, new inventory shipment varies throughout the month and it seems difficult for them to determine when to purchase more stock. As stated on their website, it is made clear that they are currently having issues with some of their suppliers due to Covid-19. This is causing their already 'lengthy' lead time to increase, which may be bad for future business.

In one instance, they ran out of wires due to the lack of safety stock and Biolytic technicians were unable to work on parts that require those supplies. This seems to be a continuous problem as they're still currently facing this issue. As stated from a Biolytic technician, they will be unable to finish an instrument before the customer's requested deadline due to insufficient supplies. Technicians were forced to go around the warehouse in search of older, used wires to complete those parts. As a result, we believe the quality of the wires will vary as some are older than others. It is afraid that this may cause the quality of the instrument as a whole to decline much quicker compared to those with newer parts. We believe that it is important to have the quality of all future Dr. Oligos to stay constant as it could be a bad look for the business if not otherwise.

Another issue we noticed was their flexibility on deadlines. Technicians seem to work at their own leisure due to not being given an exact deadline for any instruments, excluding those that have been requested to be expedited. Having strict deadlines would enforce good working habits throughout the technicians. If they were to get a sudden increase in demand, for instance, technicians would be prepared to complete the instruments in a timely manner.

In conclusion, we would recommend that they strictly rely on their forecasted sales system rather than simple intuitions to avoid having an increase of lead time. Along with this recommendation, we suggest that they set a firm reordering point for all of their supplies instead of just several. We would also recommend that they have stricter deadlines for when an instrument is due as having flexible deadlines creates too much leniency.

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December 9, 2022
James Demmit
Senior Director of Operations at Biolytic
5680 Stewart Ave, Fremont, CA 94538

Dear Mr. Demmit,

We are extremely grateful for your help and would like to thank you for the tour opportunity of Biolytic and the interview we were able to have with you.

Being able to see the behind the scenes process of manufacturing a DNA/RNA synthesizer allowed us to gain more insight within the ins and outs of the different production processes. During the interview, we were able to learn what type of decision making goes into determining specifics such as setting a reordering point for materials or figuring out a floor plan for the building. In addition, we were able to learn more about the synthesis process through the educational flyers provided to us in the conference room. All of the information we were able to receive was compiled into an informative presentation along with a detailed report. Along with the report, we would like to share some recommendations that you may find helpful in regards to Biolytic's current issue with ordering inventory shipments.

We are excited to share a copy of our report with you as we hope our recommendations may help you in some sort of way.

As students of Santa Clara University, we are looking forward to continuing to see the growth of Biolytic and the help your company is providing towards pharmaceuticals and academic research.

Best regards,
Brendan Henderson
Griffin Higa
Lilian Ngo
Nathaniel Spruiell