

Manufacturing Expansion of COVID-19 Foam Testing Swabs

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Abstract – The outbreak of COVID-19 in early 2020 caused the demand for foam-tipped swabs, required for COVID-19 testing, to skyrocket. There were only two major manufacturers of foam-tipped swabs worldwide. The only US producer of COVID-19 foam-tipped testing swabs was Puritan of Guilford, Maine with a capacity of < 10M swabs per month. Puritan’s existing capacity was nowhere near the 10’s of millions needed. The U.S. Government utilized the provisions enacted under the Defense Production Act to award a \$73M agreement to Puritan on 23 April 2020 to expand capacity to produce an additional 20M foam-tipped swabs per month. Puritan was faced with daunting supply-chain and workforce challenges to increase their production capability within the 90 day deadline during a pandemic. In spite of the challenges, Puritan met the objectives set by the agreement and delivered the additional capacity on time.

INTRODUCTION

In early 2020, the World Health Organization declared a pandemic due to the worldwide outbreak of COVID-19 caused by the novel SARS-CoV-2 virus. Shortly thereafter, the President of the United States declared a national emergency associated with this pandemic. The availability of foam-tipped swabs in the quantities required for COVID-19 testing by healthcare professionals was significantly inadequate. To expedite and expand the domestic production of foam-tipped swabs required by medical professionals, Puritan Medical Products LLC (Puritan) was awarded a \$73M Technology Investment Agreement (TIA) with the United States Department of Defense, acting through the U.S. Air Force Research Lab (AFRL), to establish a new facility capable of manufacturing an additional 20 million foam swabs per month; more than doubling their capacity at the time. The funding was made available by the CARES Act, passed by Congress in response to the pandemic, and awarded to Puritan through the Defense Production Act Title III Program.

Puritan is a one-hundred-year-old, third-generation, family-owned business headquartered in Guilford, Maine. Puritan is known worldwide as a trusted manufacturer of diagnostic applicators tipped with spun rayon, polyester and calcium alginate, foam, and flock. These swab types have a wide range of uses such as genetic testing, environmental testing, and forensics. Puritan is the only domestic producer of foam, flock and spun polyester sterile swabs. Their foam swabs are essential to COVID-19 testing, including Abbott’s at home COVID-19 Antigen Rapid Self-Test Kit. Figure 1 shows a Puritan foam swab used for nasal specimen collection. The swab consists of a plastic handle approximately six inches long with the foam-based collection material affixed at one end.



Fig. 1. Puritan foam-tipped swab and wrapper.

The process used for manufacturing foam swabs is rather straight forward but requires strict adherence to quality standards while producing very large quantities. The manufacture of foam-tipped swabs consists of 2 steps; namely foam swab “tipping” and foam swab “wrapping”. Tipping involves use of a precision die to cut and adhere the foam to a plastic handle in a single step. The tipped swab is then fed into a set of sealing heads that enclose the swab into an individual wrapper. The wrapped swabs are then packaged in bulk and sent to a 3rd party sterilization facility. Despite the simplicity, the tipping and wrapping processes require highly specialized equipment which are exclusively designed and fabricated in-house by Puritan.

PROGRAM EXECUTION

Puritan was first contacted by U.S. Government health care leader’s only weeks before an agreement to expand foam swab production was put into place. Puritan was given little time to develop a detailed program plan prior to the April 23,

2020 agreement award. The Government wanted the additional foam swab production capacity up and running by July 1, 2020. The fact that Puritan and all of their subcontractors agreed to meet this aggressive deadline in the first place is nothing short of remarkable. Taking on this task pressed Puritan's supply chain at every level. Despite numerous challenges of obtaining products across the world, everything came together in a timely manner. Subcontractors and their employees displayed an unfettered commitment to meet delivery schedules. The facilities contractor literally worked 24 hours a day, 7 days a week to turn over the manufacturing floor space to Puritan on July 1, 2020.

Key Milestones Achieved

1. Construction began – April 23, 2020
2. Completed manufacturing floor space – July 1, 2020
3. Began equipment installation – July 1, 2020
4. Production started – July 6, 2020
5. Achieved 20M swabs/month production rate – August 31, 2020
6. Hired 230 full time employees – November 1, 2020
7. Facility construction complete – November 30, 2020

FACILITY MODIFICATIONS

Puritan's existing facility in Guilford, Maine was already operating at full capacity and could not be further expanded. Time constraints forced the Puritan team to utilize an existing building that could be modified to support the necessary production equipment. A 143,000 square foot facility located in nearby Pittsfield, Maine [Fig. 2-3] was identified to satisfy Puritan's needs. The former smoke detector factory contained spaces for manufacturing, offices, and a warehouse on its seven-acre property. Pittsfield is located on the I-95 corridor and is only 45 minutes from Puritan's Guilford facility. It is within commuting distance from several of Maine's larger population centers - Augusta, Waterville, and Bangor.

Puritan converted 95,000 square feet of this facility into a Class 7 cleanroom space supportive of swab manufacturing. The manufacturing area was constructed as a positively pressurized white room consistent with ISO 8 standards for air change rates, filtration, and monitoring. All ventilation, cooling, and heating was supplied via new rooftop air handling units, complete with particulate and ultraviolet (UV) filtration. The Puritan manufacturing process utilizes clean, dry compressed air to ensure redundancy and resiliency in the production operations. Remaining space was allocated for a gowning area, a quality control laboratory, training facilities, warehouse space for raw and finished product, offices, loading docks, laundry, and an employee break area.

The building required significant demolition, remediation and reconstruction as well as design work to create a facility suitable for manufacturing foam swabs. Despite these extensive modifications, the building possessed the necessary square footage to enable the minimum production goal of 20 million swabs per month, as well as additional space for future expansion. Prior to any demolition taking place, the building

was 3D laser scanned to generate precise drawings to support architectural design activities.



Fig. 2. Pittsfield facility prior to demolition



Fig. 3. Manufacturing floor space before modifications

Puritan contracted with Cianbro, a local construction firm, to undertake the engineering, procurement, demolition, installation, construction, permitting, and related services necessary to prepare the facility for installation of all new production equipment. Normally, a facility requiring this scope of improvements would have taken 12 months to complete. The Government agreement required the facility to support equipment installation beginning July 1, 2020. The compressed build schedule required that typically sequential tasks be performed in parallel while design decisions occurred during the demolition and buildout phases.

The entire roof of the manufacturing area was completely replaced; with additional supports installed to handle the weight of the new air-handling units. The air-handlers and support frames were installed on the new roof while removal of all old ductwork, sprinklers, electrical and compressed air systems occurred. New ductwork, fire suppression, electrical and compressed air lines were installed above a suspended ceiling [Fig. 4]. Required utilities and exhaust systems were designed and located to meet the specific requirements of the production equipment as well as ensuring operator ergonomics were taken into account. The entire manufacturing floor space was completed on-time and officially turned over to Puritan on July 1, 2020 to begin equipment installation and subsequent production. Government support and intervention with the global supply chain was instrumental in ensuring timely delivery of long lead items; including installation of new electrical switching gear.

Following this milestone, Cianbro's attention turned to completion of the warehouse, shipping, and receiving areas. This was a major undertaking due to the need to remove an old brick boiler house and smokestack that was housed inside of the high bay portion of the building. This portion of the building was demolished without interfering with production, which began soon after the manufacturing space was completed. During the course of these modifications, Puritan committed their own resources to convert 8,000 square feet of warehouse space into additional manufacturing floor space to house more tipping and wrapping production equipment to meet an ever growing demand for swabs. In theory, production capacity could easily exceed 80M swabs/month.



Fig. 4. Installation of HVAC equipment

EQUIPMENT FABRICATION

Historically, Puritan has designed and fabricated their own custom tipping and wrapping equipment. However, due to the urgent need to drastically increase foam swab production while maintaining current manufacturing capacity in Guilford, Puritan contracted with 3rd party vendors for all required machinery, tooling, and installation.

Antron Engineering and Machine in Bellingham, Massachusetts was selected to build 10 tipping machines in compliance with drawings provided by Puritan. These tipping machines have a projected output of approximately 28M swabs per month using a multi-shift operation. Antron provides precision machining in a wide range of materials and has extensive experience working from 3rd party designs. Antron was required to deliver all 10 machines no later than June 5, 2020.

Maine-based Bath Iron Works (BIW) was contracted to build 30 swab wrapping machines. BIW is a full-service shipyard specializing in the design, construction, and support of complex surface ships for the U.S. Navy, and has the expertise and resources necessary for rapid fabrication of industrial equipment. Puritan sent the wrapping machine designs to BIW who committed the necessary resources to manufacture the machines by the deadline set by the Puritan. The wrapping machines were to be built entirely at BIW and were required to satisfy all acceptance criteria prior to shipping. BIW agreed to deliver 22 machines in 7 weeks and the remaining 8 machines 3 weeks afterwards. Despite great progress towards

achievement of this goal, the machinists union at BIW, for reasons unrelated to this project, went on strike only days before deliveries were to commence. Puritan immediately sent machinists to BIW to complete equipment fabrication. Managers and supervisors at BIW also stepped up to complete equipment fabrication and delivery to Puritan on time.

Puritan also acquired 6 automated wrapping lines from Multivac and IDI, both based in Kansas City, Missouri. Each automated wrapping line has a production capacity equal to multiple individual wrapping machines combined. The automated wrapping lines also require a fraction of the technicians necessary to run an equivalent number of individual wrapping machines. Use of first of their kind automated wrapping lines will increase foam swab production without dramatically increasing labor costs.

SWAB PRODUCTION

Despite the majority of tipping and wrapping equipment being onsite when the manufacturing floor space was completed on July 1, 2020, Puritan's process cleanliness requirements prevented them from installing equipment right away. Once the HVAC system was certified to meet air flow requirements, Puritan immediately began installation and validation of tipping and wrapping equipment. During the course of the next several days enough equipment was operational to begin production and training on July 6, 2020. Lack of operators required to support a 2-shift operation dictated the rate of equipment installation and production scale-up. As such a minimum set of tipping and wrapping equipment was initially installed. Hiring and training of new personnel was prohibitively slow due to the ongoing COVID-19 pandemic. Achieving Government production goals required Puritan to hire a minimum of 250 full time employees. New employees were brought in on a weekly basis over the next several months. Total output from Pittsfield during July 2020 totaled only 9M swabs, but this increased to nearly 20M by August 2020; and to 40M by October 2020 [Fig. 5-7]. Hiring peaked at 440 new employees in early 2021 as foam swab production exceeded 60M per month.



Fig. 5. Production floor operations



Fig. 6. Ariel view of completed Pittsfield production facility



Fig. 7. Exterior view of Pittsfield production facility

Conclusions

Puritan teamed with Cianbro, Bath Iron Works, and Antron Engineering to increase U.S. production capability for foam-tipped sterile testing swabs required for COVID-19 testing. In less than 90 days from agreement award, Puritan began production of foam-based swabs from their new Pittsfield, Maine manufacturing facility. Production output exceeded 40M swabs per month within 6-months of agreement award; well beyond the project objective. The Puritan team performed a remarkable feat under historically difficult conditions to exceed all Government expectations.

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References

1. <https://www.puritanmedproducts.com>.