

PVA Pivots to Manufacture Emergency Ventilators



Precision Valve & Automation (PVA) has been making conformal coating systems, fluid dispensing solutions and precision valve technology for nearly three decades. With a 135,000-square-foot facility in Cohoes, PVA's products are used in the solar, semiconductor, defense, aerospace, automotive and medical device industries. The company was founded in 1992 by Anthony Hynes and it quickly emerged as a leader in fluid dispensing solutions through the debut of its automated dispensing robot system, the PVA1000. The company employs 218 people throughout its global operations including Cohoes, NY, North America, Europe and Asia.

“CEG Business Growth Solutions was instrumental in helping PVA get from conceptual product / prototype to FDA approval for manufacturing at lightning speed”

- Antonio Giordano, CFO of PVA

The Situation

In March 2020, the coronavirus pandemic prompted New York officials to order a 100 percent reduction of in-person workforces at nonessential businesses. Although PVA's solutions were already being used in the production of COVID-19 test kits, portable respirators, and mechanical ventilators, the company faced the possibility of having to furlough its workforce. However, Hynes decided to leverage his company's 28 years of experience with electronic components and robotics to pivot and make a medical device that was in high demand.

Hynes and his team quickly developed an operational prototype emergency ventilator based on a concept that had been studied at MIT and seen in the United Kingdom Department of Health & Science. The PREVENT™, is a temporary ventilator that saves medical personnel, first responders and others from having to expose themselves to COVID-19 patients while manually pumping a BVM. The PREVENT™ pumps and delivers air flow in a much more predictable manner than human BVM users. PVA estimates it can manufacture at least 250 of the emergency ventilators daily for less than \$6,000 each. By late March, PVA had presented the PREVENT™ to the New York State Governor's Office, Rep. Paul Tonko's Office, and the Office of the United States Vice-President.



The Solution

To position its operations for the manufacturing of this technology, PVA engaged the Center for Economic Growth (CEG) for assistance with achieving ISO 9001:2015 certification. This certification is an important step for meeting the Food and Drug Administration's good manufacturing practices (GMP) for medical



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devices, established under part 820 (FDA 21 CFR Part 820). The FDA's Quality System Regulation Part 820 corresponds with ISO 13485, for which PVA will also seek certification. As PVA pursued its ISO 9001:2015 certification, the company prepared and submitted an Emergency Use Authorization (EUA) request to the FDA. This notice demonstrated PVA's intent to market the PREVENT™, and show that it is legal, safe, and viable option in the fight against COVID-19. The PREVENT™ received approval under the FDA's Emergency Use Authorization (EUA) on the evening of the 17th of April.

"The grant funding from National Grid is a big help in off-setting our costs in developing this product and implementing the necessary quality system requirements throughout the process."

CEG Business Growth Solutions (BGS) recruited its strategic partner, Larry Treen of Relay Integrated Logistics & Solutions, to help PVA ensure the process adheres to FDA standards and guidelines. CEG, through the work of Treen, supported PVA by working with and coaching the PVA team in writing its Quality System program and establishing its ISO Quality Management System. Critical to this system were processes for matters such as records from federal regulations; complaints / recall procedures; overall environmental cleanliness and product cleanliness requirements; understanding American Society for Testing and Materials (ASTM) classes for masks; testing, labeling, packaging, marketing, and customer complaint procedures; and maintenance of batch records.

"We look forward to achieving ISO 9001:2015 certification over the summer of 2020, and we are ready to provide this life-saving equipment to those in need worldwide."

- Antonio Giordano, CFO of PVA



PVA employee assembles PREVENT™ device

To support this work, CEG helped PVA apply for and receive a \$35,100 National Grid Manufacturing Productivity Program (MPP Grant). In response to COVID-19, National Grid had fast-tracked this program to help manufacturers pivot or seize new growth opportunities. The MPP is administered in connection with New York's Manufacturing Extension Partnership (MEP) Centers, such as CEG. MPP funding of up to \$40,000 or 60 percent of costs can go toward redesigning workflows, certifications, addressing supply chain issues, and implementing sustainability programs for these changes.

To learn how CEG BGS could help your company, contact CEG BGS Senior Vice President, Michael Lobsinger at michaell@ceg.org or call 518-465-8975 x238.

