

VHA ADVANCED MANUFACTURING

VISION

Veterans Health Administration (VHA) has an ambitious goal: for every Department of Veterans Affairs (VA) Medical Center to be able to access advanced manufacturing capacity, providing every eligible Veteran access to the same personalized care.

BACKGROUND

VHA has utilized 3D printing in the clinical environment for over 10 years and has been a pioneer in establishing point-of-care advanced manufacturing labs bringing medical device fabrication to the hospital campus.

OFFICE OF ADVANCED MANUFACTURING

In 2020, three 3D Printing Network sites in Charleston, Richmond, and Seattle became VHA Advanced Manufacturing Hubs (now OAM Hubs), VA Medical Centers (VAMCs) with FDA-registered advanced manufacturing facilities. Three additional sites in Cleveland, Milwaukee, and Pittsburgh are ramping up to become OAM Hubs in the next few years. Inaugural OAM hubs were chosen for their experience in medical 3DP applications, site subject matter expertise, VAMC leadership support, and ability to design, test, and iterate on 3DP prototypes. OAM established a quality management system (QMS) to ensure patient safety and compliance with regulatory standards. OAM hubs have the in-house knowledge, infrastructure, and processes needed to develop, manufacture, and deliver medical devices that meet clinical needs and the expectations of healthcare practitioners and the Veterans we serve. These sites offer a range of products and services to support other facilities interested in delivering customized 3D Printed solutions to Veterans.

ANTICIPATED BENEFITS OF A MATURE VHA AM CAPABILITY

- Empowered staff operationalizing High Reliability Organization (HRO) Principles: Front line staff and patient safety teams can collaborate with AM labs to design solutions addressing root causes
- Advocacy for "N of 1" needs: AM enables this core value by providing access to personalized devices developed with advanced manufacturing technologies, like 3DP, that cannot be bought "off the shelf"
- Increased patient satisfaction: Veterans can receive devices on the same day as their appointment, while anatomical models can improve patient education and consent conversations
- Cost avoidance: Patient-matched medical devices have the potential to improve outcomes. This has been validated by VHA's own experiences, e.g., Giostent, Thermal Fuse Cover, and anatomical models)

DELIVERING INNOVATIVE ADDITIVE SOLUTIONS:



GIOSTENT

- A patient experiencing hearing loss worked with his audiologist and the advanced manufacturing team at Ralph H. Johnson VA Medical Center in Charleston to design a personalized 3D printed solution that improved the Veteran's hearing while avoiding surgery.
- VA received FDA compassionate use approval for the groundbreaking in-house developed GioStent medical device in February 2021
- Product development is underway to produce a Class 1, 510(k) exempt device to meet a wider patient need



THERMAL FUSE COVER

- The 3D printed thermal fuse cover answered a need raised by the National Center for Patient Safety for a home oxygen delivery system safety device
- OAM hubs took a design developed in collaboration between University of Pittsburgh and the VA Pittsburgh Health Care System through a phased product development process. The product is now listed as a medical device with the FDA
- OAM has manufactured 1700 thermal fuse covers and steps are underway to introduce covers to the VHA and U.S. Department of Defense markets

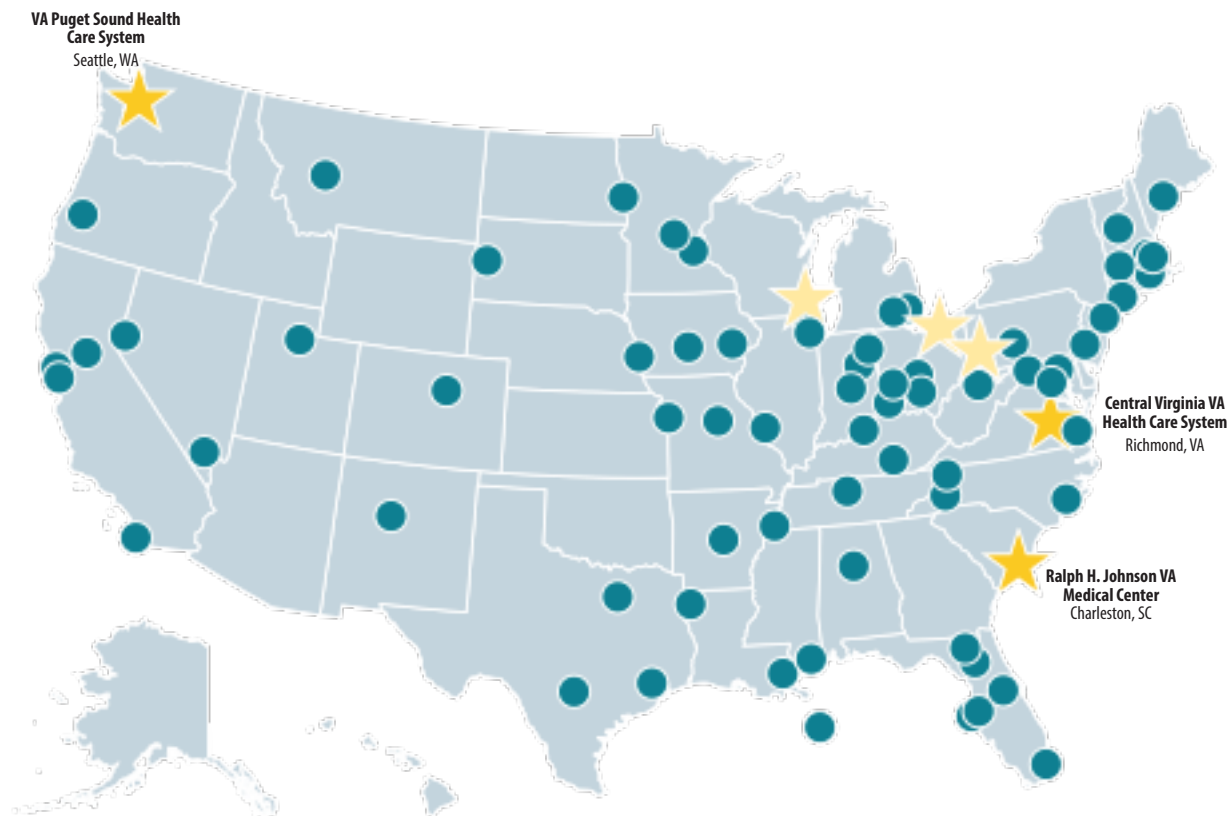
COVID-19 RESPONSE



VHA partnered with the FDA, National Institute of Health (NIH), and America Makes to clinically design, test, and evaluate the safety and efficacy of 3DP solutions, facilitating the creation of an estimated 38M face shield parts, 12M nasal swabs, 2.5M ear savers, 241,000 mask parts, and 116,000 ventilator parts were additively manufactured in the U.S. between February 15 – July 15, 2020.



VHA 3DP NETWORK SITES



- Audie L. Murphy Memorial Veterans' Hospital
- Bay Pines VA Healthcare System
- Birmingham VA Medical Center
- Bruce W. Carter VA Medical Center
- Captain James A. Lovell Federal Health Care Center
- Central Iowa VA Health Care System
- Chalmers P. Wylie Ambulatory Care Center
- Charles George VA Medical Center
- Chillicothe VA Medical Center
- Cincinnati VA Medical Center
- Clement J. Zablocki VA Medical Center
- Corporal Michael J. Crescenz VA Medical Center
- Dayton VA Medical Center
- Edward Hines Junior Hospital
- Fargo VA Healthcare System
- Fort Harrison VA Medical Center
- Franklin R. Sousley Campus
- George E. Wahlen VA Medical Center
- Gulf Coast Veterans Healthcare System
- Hampton VA Medical Center
- Harry S. Truman Memorial Veterans' Hospital
- Central Virginia VA Health Care System
- Iowa City VA Health Care System
- Jacksonville VA Clinic
- Jamaica Plain VA Medical Center
- James A. Haley Veterans' Hospital
- James E. VanZandt VA Medical Center
- John D. Dingell VA Medical Center
- John L. McClellan Memorial Veterans Hospital
- Kansas City VA Medical Center
- Lake City VA Medical Center
- Lexington VA Health Care System
- Louis A. Johnson VA Medical Center
- Louisville VA Medical Center
- Malcom Randall Department of VA Medical Center
- Manhattan VA Medical Center
- Marion IN VA Medical Center
- Martinsburg VA Medical Center
- Memphis VA Medical Center
- Michael E. DeBakey VA Medical Center
- Minneapolis VA Health Care System
- Mountain Home VA Healthcare System
- Orlando VA Medical Center
- Overton Brooks VA Medical Center
- Providence VA Medical Center
- Ralph H. Johnson VA Medical Center
- Raymond G. Murphy VA Medical Center
- Richard L. Roudebush VA Medical Center
- Roseburg VA Medical Center
- San Francisco VA Medical Center
- San Juan VA Medical Center and MOPC
- Southeast Louisiana Health Care System
- St. Cloud VA Health Care System
- Tennessee Valley Healthcare System
- Togus VA Medical Center
- VA Ann Arbor Healthcare System
- VA Bedford Healthcare System
- VA Black Hills Health Care System
- VA Boston Healthcare System
- VA Central Western Massachusetts Healthcare System
- VA Eastern Colorado Health Care System
- VA Maryland Health Care System
- VA Nebraska-Western Iowa Health Care System
- VA North Texas Health Care System
- VA Northeast Ohio Healthcare System
- VA Northern California Health Care System
- VA Northern Indiana Health Care System
- VA Palo Alto Health Care System
- VA Pittsburgh Healthcare System
- VA Puget Sound Health Care System
- VA San Diego Healthcare System
- VA San Francisco Health Care System
- VA Sierra Nevada Health Care System
- VA Southern Nevada Healthcare System
- VA St. Louis Health Care System
- Veterans Health Care System of the Ozarks
- Washington DC VA Medical Center
- West Haven VA Medical Center
- White River Junction VA Medical Center

