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AN ASSESSMENT OF BIOMANUFACTURING IN FORWARD DEPLOYED LOCATIONS

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ABSTRACT

Biomanufacturing uses microorganisms to produce chemicals or materials of interest, much like a brewery uses fermentation by yeast to produce the alcohol in beer. Biomanufacturing relies upon synthetic biology to reprogram yeast or other microorganisms to produce something of greater value, such as fuel, food, or pharmaceuticals. Industrial biomanufacturing has made significant advances and the products it can deliver include reactive coatings and textiles, sensors, optical materials that can bend light, and new therapeutics such as antimicrobials and vaccines. The convergence of synthetic biology, robotics, and artificial intelligence is opening the way to produce materials never before possible in the commercial market. These same technologies create the opportunity for the miniaturization of this technology to fit into ever more compact spaces, bringing forward deployment of these mini-factories closer and closer to the point of need.

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1. INTRODUCTION

Maintaining secure and reliable supply lines to deliver necessary materials to allied forces is crucial, especially when operating far from friendly territory. The United States and its allies face a competition for dwindling resources opposite adversaries that seek global economic dominance. Delivering food, water, ammunition, and medical supplies to national security operations in austere and isolated locations will be a deciding factor in future conflict. Through biomanufacturing we can produce these vital materials at or near the front, providing responsiveness and avoiding contested logistical trains.

The Department of Defense (DoD) sponsored the U.S. Army Capabilities Development Command Chemical Biological Center (DEVCOM CBC) to determine whether biomanufacturing hardware and related technologies can support production of vital materials in a portable unit. Over one hundred scientists from the Army, Navy, and Air Force teamed with the Defense Advanced Research Projects Agency (DARPA), Department of Health and Human Services' (DHHS) Advanced Research Project Agency for Health (ARPA-H), and the National Aeronautics and Space Agency (NASA) for the 18-month assessment effort exploring the solution landscape. This summary provides a baseline understanding for biomanufacturing technology readiness and the hurdles that must be overcome to make far-forward deployment a reality.

2. FORWARD-DEPLOYED BIOMANUFACTURING CAN MEET DIVERSE REQUIREMENTS

Deployment to contested regions requires a secure supply of materials for prolonged operations (Figure 1). Biomanufacturing facilities run at cooler temperatures and lower pressures, their operation generates fewer telltale signatures. Smaller biomanufacturing production sites are easily repositioned making them less vulnerable to targeting by adversaries. Smaller size also makes them easy to repurpose and distribute geographically. Forward production of critical chemicals and materials provides security and sustainability at or near the front that can determine the success of a mission.

2.1. Fuel

Industrial bioproduction of fuels is an established industry with multi-purpose potential for delivering drop-in fuel supplements, sustainable aviation fuels, and specialty fuels that cater to next generation missile systems and secure fuel to power air assets. Biomanufacturing can produce fuel locally or on another planet using reclaimed resources, such as water and CO2 from on-site waste generation. Onsite fuel access is critical to sustaining an operation.

2.2. Food

Industrial biomanufacturing of food is commercially established in the production of artificial protein powders and cooking oils. DARPA and the U.S. Army DEVCOM Soldier Center have led the way in the development of miniature and mobile food production for the military. The Army has built on this research to develop deployable food biomanufacturing systems that can be used to meet all the nutritional requirements of a platoon and be scaled up to feed a small town. This makes the technology useful for humanitarian and disaster relief when traditional power and manufacturing systems are down. The U.S. Army DEVCOM Soldier Center is preparing systems for field testing in 2026. These systems can also be used by the International Space Station in future long-term missions to the Moon and potentially Mars.

2.3. Pharmaceuticals

In times of natural disasters, pandemics, or global unrest, it is critical that medicine and pharmaceuticals still be manufactured and delivered to those in need. The ability to produce therapeutics at point of need, such as remote hospitals or a future lunar base, could support their operations and remove the need to stockpile of medications that have expiration dates. It's also known that long term space travel oxidizes vital micronutrients in food and erodes medical therapeutics over time, preventing long term storage beyond one year. Small, deployed bioreactors could solve these problems by providing personalized and on-demand vaccines, antibodies, and other needed therapeutics. Closer to home, small tailored

Figure 1: Conceptual graphic displaying the potential environments in which biomanufacturing can be contribute to forward operations (Arctic, Arid Desert, Island/Coastal, or Space).

biomanufacturing systems already make personalized medicine possible by delivering therapeutics tailored to an individual. This is an area being explored by DHHS's ARPA-H programs to increase access to cutting edge medicine.

2.4. Fabrication

Advanced manufacturing at forward deployed locations is an established practice by the DoD for some repair and maintenance functions, but it has been limited by accessibility to unique feedstocks. Biomanufacturing can solve this problem by converting warfighter waste into feedstocks that can be integrated into traditional manufacturing processes. Warfighters use a lot of single-use materials that create waste like wrapping and packing materials. DoW's DARPA and the DOE's National Laboratory of the Rockies (NLR) use biomanufacturing to break down these waste streams to produce feedstocks and energy through biomanufacturing. This provides onsite production that turns outputs into new inputs.

3. KNOWLEDGE AND TECHNOLOGY GAPS

3.1. The Need for Complementary Manufacturing Technologies

While the ability to create anything, anywhere, at any time may sound fanciful, it has already proven to be the way of the future, and other nations - including our adversaries - are investing heavily in it.

Worldwide, the biomanufacturing market is projected to reach $39 to 48 billion in 2031 with an estimated compound annual growth rate of 7.5-10% [1].

The early thrust of biomanufacturing investment has been directed at the production of fuels, foods, lubricants, adhesives, and textiles. The DoD's Distributed Bioindustrial Manufacturing Program has been investing in the construction of factories that will focus on the military applications of these products. The DoD has prioritized biotechnology as an emerging technology area of national security priority because our leaders know that the nation that leads in biomanufacturing will achieve both economic and military dominance.

The next era of American manufacturing will be marked by emerging technologies working in tandem with traditional operations to leverage the legacy of domestic manufacturing and secure our technological advantage. Biomanufactured materials including additives, lubricants, and new materials can be integrated to improve traditional manufacturing processes and products. Moreover, multiple integrated technologies are necessary to unlock the full potential of biomanufacturing. Robotics, automation, and AI/ML are critical supporting technologies and concurrent

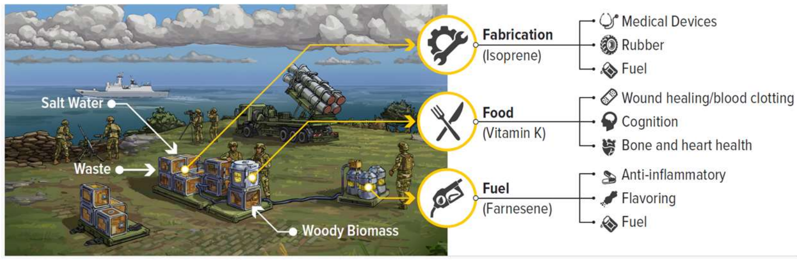

Figure 2: Conceptual graphic displaying the flexibility that biotechnology provides for operations further forward.

investment in these will enhance both bio- and traditional manufacturing to enable a robust convergent capability.

In addition to traditional factory production, advanced manufacturing, catalysis, and continuous flow chemical synthesis each deliver something that biomanufacturing alone cannot accomplish. Bringing together traditional and biomanufacturing into a single system will deliver better capability and is a better value in comparison to fielding production systems that rely on just one or the other.

3.2. Automation Reduces Cost

To get the most out of biomanufacturing technology, we will need to maximize automation of portable biomanufacturing. No users, from soldiers to astronauts, have time to extensively manage and operate manufacturing systems deployed with them. Automation of key biomanufacturing steps from fermentation through downstream processing is a current U.S. research goal, as it is one of the largest hurdles to be overcome in fielding forward deployed biomanufacturing. However, few fully automated biomanufacturing systems have been developed thus far. The challenge requires development of responsive and reactive in-line sensors and monitoring software to manage and orchestrate multiple biological and chemical operations.

3.3. Autonomy and Artificial Intelligence

Biomanufacturing is based on the growth of living organisms that have been genetically engineered to act as microscopic factories. If everything operates as designed, biomanufacturing systems are efficient and reliable. However, every living system has inherent variability that must be monitored and managed. Fully automated biomanufacturing production will require the monitoring of multiple chemical and physical operations that occur simultaneously, which will generate numerous sensors feeds with data. It will take advanced AI to provide systemwide oversight and interpretation of sensor and data feeds for data-driven decisions. Early versions of these oversight systems already exist in pharmaceutical manufacturing industry, but the technology needed for forward-deployed systems will require another leap in AI development.

3.4. Energy

Biomanufacturing systems are energy users as well as energy producers. How the system is powered will depend on where it is located and how it is deployed. Instead of cumbersome batteries and expensive generators, initial prototyping efforts will rely upon power derived from local power grids or by linking to nuclear powered naval support craft. The full report will provide greater detail.

3.5. Modularity Allows for Customization and Reconfiguration

Some automated biomanufacturing systems have been developed through U.S. federal funding, most notably by the DoD's DARPA. Most prototyped biomanufacturing systems have been designed to make a single item and cannot be reconfigured to make anything else. The assessment team recommends embracing modularity and reusability in system design to allow one machine to make a variety of materials.

Industrial modularization has already become state of the art in pharmaceutical production, driven by industry demand for plug-and-play systems and training standardization. Building a manufacturing process that incorporates distinct modules allows customization so that a single biomanufacturing system can make multiple products. Developing modules based upon an open architecture design standard would simplify development pathways and open the door for participation from industry and academia to contribute to the development of interchangeable biomanufacturing modules. An ecosystem of modules could be developed for new operations over time and new technologies could be added as they become available. The assessment team recommends developing a demonstrator set of modules that include fermentation, bio- and electrocatalysis, and solids separation methods in the prototyping phase planned for 2026.

4. CONCLUSIONS

The U.S. joint force provisions soldiers and humanitarian aid workers at the farthest regions of the planet. Other federal agencies, such as NASA, will send humans even farther in the coming years. Our ability to manufacture vital materials to meet these needs will require miniaturized, modular, and automated biomanufacturing systems that can untether these missions from the lifelines of global commerce and domestic production. Whether isolated by distance or blockade, these systems will sustain life and keep operations going wherever those operations are located.

5. REFERENCES

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