BMES
BIOMEDICAL ENGINEERING SOCIETY

Securing the pipeline: **How biomedical engineering drives American leadership**

TABLE OF CONTENTS

Introduction

While other American industries have lost manufacturing leadership to overseas competitors, one sector continues to dominate globally: biomedical engineering. This $250 billion innovation pipeline connecting university research labs to patient bedsides has made America the undisputed world leader in health technology.

U.S. biomedical businesses dominate the world because the United States leads in biomedical research and development. A robust ecosystem funds and commercializes innovative new products, making America the preeminent producer of these technologies. Unlike semiconductors, solar panels or consumer electronics, biomedical engineering has overcome the barriers to scaling up that have cost other domestic industries their competitive edge.

This innovation pipeline has created more than 2 million different medical devices across 7,000 categories, from products everyone uses like bandages and digital thermometers to powerful imaging systems and surgical robots. Each device represents a success story of American ingenuity transforming scientific discovery into real-world solutions.

PIPELINE IN ACTION: FROM LAB TO LIFE

When a burglar shot David Murphy one night, a bullet severed his sciatic nerve. Unable to control his leg and foot, he fell to the ground and crawled under a car until the police arrived. In the past, Murphy would have faced months of intense pain until his severed nerve died. He would never have walked again without a cane or returned to his job as a forklift operator.

Instead, Murphy received a then-experimental treatment: a nerve harvested from a cadaver and treated to remove every bit of organic matter — so that the body's immune system would not attack it. Under a microscope, surgeons sewed bundles of sciatic nerves into the allograft. Murphy's nerves began growing, about one millimeter per day. Within weeks, he was off pain meds. He eventually returned to his job. He began walking. Now he is running.

This breakthrough represents the pipeline in action — from university research to breakthrough treatment to transformed life.

What is biomedical engineering?

Biomedical engineering involves applying engineering principles and biological knowledge to solving problems in medicine, health care, biology and other related fields. Biomedical engineers design, manufacture and deliver everything from prosthetics, implants and measurement and imaging systems to biomedical devices, software and AI-enabled health systems. Increasingly, biomedical engineering involves developing biology-based biomedical systems that mimic or interact directly with natural cells, tissues and organs.

THE ENGINEERING ADVANTAGE

Engineering thinking separates biomedical engineering from other types of scientific and medical research. Scientists typically focus on discovery, trying to understand how and why things happen. Engineers typically apply that knowledge to solve specific health care challenges. They design solutions based on firm theoretical underpinnings and then run controlled experiments to test and optimize those designs — lots of them.

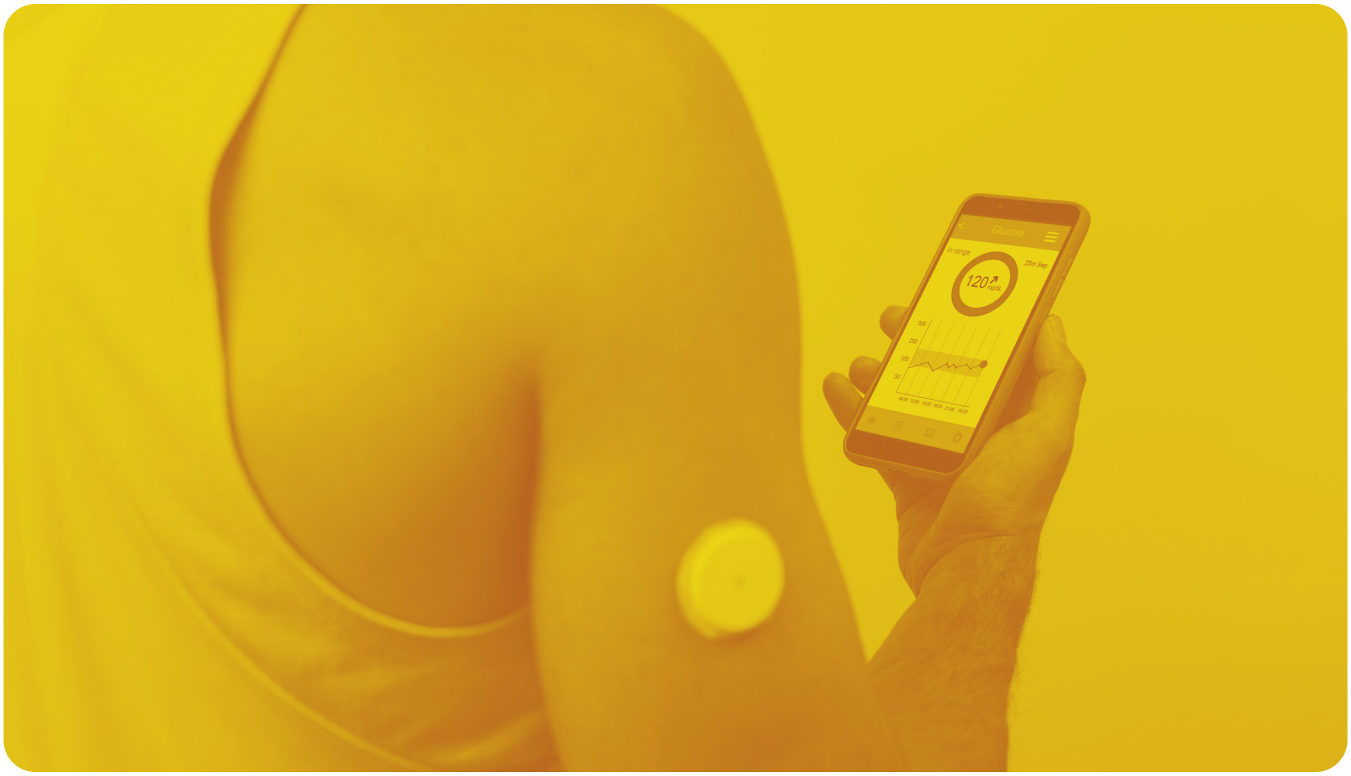
Biomedical engineers might grow three-dimensional tissues and then stretch, compress and pressurize them to study how they grow. Or they might use a strong theoretical foundation coupled with experiments to optimize hearing aid microphone placement to improve users' ability to focus on a single voice without being overwhelmed by background noise.

These innovations span an extraordinary range, from the bandages in your medicine cabinet to the recent breakthrough examples listed below:

- Developing surface textures that friction-lock hip, knee and shoulder implants into place. The textures encourage bone to grow into the implant, creating a permanent bond that outlasts implants that are glued into place.
- Using advanced electronics and predictive AI to monitor patients with chronic diseases remotely to reduce the likelihood of medical emergencies.
- Inventing resorbable fixation screws that reattach tendons to bone. The screws dissolve to form bone, accelerating healing and reducing infection.
- Regenerating lungs that would ordinarily be too damaged to transplant, vastly expanding the pool of organs available for transplant candidates.
- Designing ergonomic systems, such as more comfortable and supportive chairs and shoes that improve stability, provide all-day comfort and reduce the chance of falling.
- Developing soft contact lenses that users can wear for up to 30 days without cleaning.
- Reimagining automotive assembly lines to reduce injuries and chronic pain caused by working at awkward angles.
- Using computer models to optimize fiber type, length, stiffness and location to create a more effective toothbrush.

Recent advances in scientific discovery, engineering, computational modeling and technologies like 3D printing and bioreactors have led to the development of microphysiological systems: realistic, miniature models of organs and organ systems. These “organ-on-a-chip” systems can be used to grow and study thin slices of tissue, allowing researchers to closely examine both healthy and diseased states. Importantly, these human-cell-based platforms are reducing our reliance on animal models, which have both ethical and scientific limitations. By using human tissues, BME researchers can study how drugs and treatments actually behave in human biology, accelerating development while addressing growing worldwide concerns about animal testing. AI can enhance this process by analyzing complex datasets, identifying subtle patterns and predicting biological responses, making these platforms even more powerful.

Together, these innovations promise to reduce the cost and accelerate the pace of therapeutic development.



The economic case: Returns on investment

Every federal dollar invested in biomedical research returns $2.56 to the economy. This isn't theoretical. It's a measurable impact that has made the United States the dominant force in global health innovation.

One fact is certain about traditional biomedical devices: The United States dominates the industry. It is the global hub of biomedical engineering research, development, funding and scale-up. It is a major driver of American innovation and manufacturing.

Yet, because there are so many different types of medical devices, estimating their impact on the American economy is no simple task. Let's focus first on the market for conventional biomedical devices.

In 2021, Macro Policy Advisers undertook a thorough analysis of the industry for the Advanced Medical Technology Association. Using 2019 data, it found the medical device industry accounted for

- **$148.7 billion** in revenue,
- **$97.1 billion** in economic value-added,
- just under **400,000** direct employees earning **$28.8 billion** in payroll, and
- **$88,096** average wages — 49% higher than all industries and 18% higher than all manufacturing jobs.

WHY THESE NUMBERS MATTER

Most biomedical device companies are small — four out of five have fewer than 20 employees. Often, these small companies emerge directly from university labs, where biomedical engineers transform research discoveries into commercial ventures. This entrepreneurial pathway from lab bench to startup reflects the field's innovative culture and creates a dynamic ecosystem of emerging technologies.

Current market size

Based on a recent Ernst & Young industry report, the global medical technology market reached nearly $600 billion, with America commanding a market share of about 40%. This translates to about $240 billion in U.S. market value today.

Additionally, the United States leads in biomedical research and development. A robust ecosystem funds and commercializes innovative products, making America the preeminent producer of these technologies — a field that has overcome barriers to scaling up that have kept some domestic industries from investing in manufacturing.

The innovation ecosystem: How the pipeline works

America's dominance in biomedical devices and biology-based biomedical products has evolved over several decades.

This ecosystem draws top researchers and entrepreneurs from across the country and around the world, bringing to fruition thousands of innovative new products every year. It is composed of several distinct but overlapping segments.

RESEARCH: THE FOUNDATION

Research powers America's biomedical engineering enterprise. This is true for universities that spawn biomedical startups, small companies that have developed innovations outside of academia, and large companies with ongoing research and development programs.

Universities play a particularly critical role in biology-based products and systems because they do the following:

- Bring together varied expertise and specialized equipment needed to study life's finest details
- Provide platforms for biomedical engineers to collaborate with experts in AI, robotics, predictive models, advanced sensors, optoelectronics, nanotechnology and advanced imaging
- Enable partnerships with biologists and medical researchers at hospitals

The combination of robust funding and competition for grants has enabled American biomedical researchers to excel in many different leading technologies at the same time. It is the gold standard to which the rest of the world aspires.

FEDERAL SUPPORT SYSTEMS:

- National Institutes of Health (NIH): Through its diverse portfolio of institutes and centers, NIH supports biomedical engineering across virtually every health challenge, from biomedical devices and imaging to tissue engineering and nanotechnology delivery systems.
- National Science Foundation (NSF): Beyond direct biomedical programs like Engineering of Biomedical Systems and Smart Health and AI, NSF funds fundamental research in science and engineering whose medical applications often emerge unexpectedly years later. This basic research pipeline has proven essential for breakthrough discoveries.
- Department of Defense: DARPA and other DOD initiatives have supported major advances in mobile monitors, telemedicine, prosthetics, synthetic skin and battlefield injury robotics.

STARTUP FUNDING: FROM LAB TO MARKET

American researchers create numerous small companies to commercialize discoveries, accessing a broad range of investors — from private individuals and venture capitalists to corporate partnerships and public markets. They can also compete for federal grants reserved for scaling up promising technologies.

Many startups begin with only a handful of researchers. Nonetheless, such startups have attracted substantial investment from the United States and overseas. Between October 2020 and February 2024 (just over three years), investors poured more than $4.5 billion into 153 medical device deals, according to Camoin Associates, a large business development firm. American investors accounted for $3.1 billion, while the rest came from overseas investors anxious to buy into American biomedical innovation. According to Camoin, these investments generated about 17,000 jobs — a number likely to grow as these companies thrive and expand.

Beyond venture capital and federal grants, private foundations play crucial roles in biomedical engineering innovation. Organizations like the American Cancer Society, American Heart Association, Breakthrough T1D and Gates Foundation bridge basic research and clinical translation.

SCALE-UP: THE MANUFACTURING ADVANTAGE

Over the past two decades, America has sometimes struggled to fully commercialize discoveries from its world-class universities and research institutions into products manufactured domestically. This has proven true for such American-developed advanced technologies as personal computers, LCD and OLED displays and solar power. In other cases, such as semiconductors, 5G infrastructure, electric cars, robots and drones, America still makes products but is no longer an undisputed global leader.

Unlike other high-tech industries in which America has lost manufacturing leadership, biomedical devices remain an exception. This success stems from three main factors:

- Product characteristics: Many devices that are high-quality, low-volume systems competing on innovative features rather than cost
- Specialized ecosystem: Access to experienced product designers, software programmers and manufacturers who understand medical-grade requirements
- Regulatory and clinical expertise: Specialists who manage approval processes from experimental testing through human trials

GROWTH ENVIRONMENT: MULTIPLE PATHWAYS

The biomedical engineering marketplace offers investors numerous avenues to recoup their investment while successfully commercializing a new product. Some firms line up new investments and continue to grow as private companies. Others raise funds through initial public offerings.

Larger companies often acquire smaller companies, which are sometimes created at research institutions. This provides the innovation they need to fuel growth in exchange for expertise in scaling up production and distribution for their new acquisitions.

BMES BEYOND INNOVATION

Biomedical engineers serve critical roles across the entire health care ecosystem, ensuring public safety through regulatory processes and quality assurance, informing government policy and funding decisions and working as physicians. This engineering mindset across all sectors — innovation, translation, oversight and utilization — often serves as the ignition point for breakthrough advances.

THE PORTFOLIO APPROACH

Investing in research resembles investing in a portfolio of startup companies. Most look promising initially, but many will fail. Others pivot, using knowledge gained from one challenge to commercialize different solutions. A few achieve breakthrough success.

Addressing the investment question: Why “failures” drive success

Some argue that funding science and engineering research is wasteful because many experiments appear to fail. This perspective misunderstands how breakthroughs actually work.

THE NATURE OF DISCOVERY

Biological sciences and biomedical engineering have a long history of “failed” experiments that led to breakthroughs. In truth, scientists learn from experiments that are originally deemed failures. Indeed, many of our most profound innovations followed this path, such as:

> **Alexander Fleming** discovered penicillin after accidentally leaving a petri dish with bacterial samples uncovered. When he returned, he discovered a dish contaminated by mold — penicillin — had stopped the bacteria from growing. That observation led to the birth of antibiotics.
>
> **Kyriacos Athanasiou** at U.C. Irvine noticed that a graduate student’s failed attempt to grow cartilage on a synthetic scaffold produced a dark smudge outside the scaffold. That “failure” led to 25 years of developing a simpler method to grow cartilage without scaffolds and a bioreactor capable of producing cartilage for millions of implants.
>
> **Adam Engler** at the University of California spent decades studying the mechanical properties of scaffolds and tissues. Pivoting to cancer research, that fundamental knowledge revealed how cancer cells move from tumors into the bloodstream, developing a way to determine which cancers are likely to metastasize by measuring cell “stickiness.”

The list goes on and on. Researchers only discovered that resorbable surgical screws made with citric acid suppressed infection after running controlled tests on their behavior. Others found that mechanical forces could prompt heart cells to regenerate only after painstaking measurements of how damaged heart tissues responded to mechanical forces.

As these examples show, serendipity plus fundamental understanding is frequently the hallmark of discovery. Accidents lead to discovery. “Failures” lead to invention. Attempts to solve one problem often prove the key to another. This is the nature of discovery. It is especially true when dealing with the complexity of nature, where we don’t know what we don’t know. America’s outstanding biomedical engineering researchers need the room to fail, learn, course-correct and move forward. Along the way, they discover what they need to learn.

The promise ahead: Next-generation breakthroughs

Biomedical engineers are moving beyond mechanical and electromechanical devices toward biology-based systems that interact directly with cells, tissues and organs in unprecedented ways.

A FEW REVOLUTIONARY APPLICATIONS ON THE HORIZON

Cardiovascular disease: With direct and indirect costs exceeding $400 billion annually (according to the CDC), even small improvements in heart muscle regeneration could achieve significant impacts on patient quality of life and health care economics.

Cartilage regeneration: Addressing a $140 billion annual burden from osteoarthritis (according to the Osteoarthritis Action Alliance), promising bioreactor-grown cartilage techniques could replace worn cartilage early, improving joint performance and potentially reducing the need for the millions of knee, hip and shoulder replacement surgeries performed annually.

Organoids and drug testing: Microphysiological, "organ-on-a-chip" and organoid systems provide realistic platforms for drug screening, saving billions by identifying unsafe pharmaceuticals before expensive animal and human testing. Specifically, integrated organoids could reveal how medications affecting one organ might impact others.

Synthetic organs: Research is advancing toward full-scale lab-grown organs that produce critical hormones and proteins and emulate key functions. Autograph tissues grown from patients' own cells would eliminate immune system rejection and the vast array of anti-rejection drugs currently required. In the meantime, advances in synthetic support systems for renal replacement therapies, ventricular assist devices and extracorporeal membrane oxygenation (ECMO) systems continue to help patients live longer and better.

ECONOMIC IMPACT POTENTIAL

While assigning specific dollar figures to these emerging technologies remains premature, imagine implants that release insulin for years, freeing diabetics from pumps and syringes. Picture stroke and heart attack patients regaining strength and energy. Consider patients spared aggressive cancer treatments because their tumors are unlikely to metastasize.

Securing the future

American biomedical engineers have built a globally dominant industry that continues to expand, with breakthrough technologies moving from laboratories into clinical testing across the nation.

The pipeline connecting university research to patient care has proven its value through measurable economic returns and life-changing innovations. From pacemakers that evolved from car-battery-powered external devices to seamless implants smaller than matchboxes to AI-enabled monitoring systems that prevent medical emergencies, this ecosystem delivers results.

Yet the promise extends far beyond current achievements. Lab-grown cartilage, synthetic organs and biology-based therapeutic systems represent the next wave of innovations that will set new standards for not just length but quality of life, also known as healthspan.

THE CHOICE AHEAD

This isn't a speculative promise. Biomedical innovation is happening now in laboratories and startups nationwide, with advances poised to expand existing device markets while creating entirely new ones for biology-based biomedical systems. Realizing this potential requires sustained investment in the research that maintains America's leadership and keeps breakthrough innovations flowing. When support flows, innovation thrives. The next breakthrough that could help you and your community depends on decisions made today.

As lawmakers better understand the full biomedical engineering ecosystem — from research and development through manufacturing and delivery — they can direct funding to sustain America's innovation leadership. BMES is working to elevate the field's visibility and align it with national priorities by sharing compelling examples of breakthrough work from researchers and professionals across the country.

BMES is amplifying stories from BME professionals to build the public support that sustains innovation.

Share breakthrough examples of BME impact in everyday life