Strengthening America's Biotech Future: Strategies for Empowering U.S. Contract Manufacturing

Executive Summary

Background

The U.S. biotechnology industry is a dynamic ecosystem of roughly 3,000 companies, from startups to large enterprises, all focused on developing life-changing therapies. The sector has experienced explosive growth, with the global biotech market projected to reach $4.25 trillion by 2033, largely led by U.S. firms. This leadership ensures access to advanced medical treatments, supports American jobs, and drives exports.

To meet manufacturing demands, biotech companies rely on contract manufacturers for infrastructure, expertise, and regulatory support. These partners are especially vital for small to mid-size companies lacking in-house capabilities. As the industry aligns with national priorities to reshore manufacturing, contract manufacturers need government support to scale—through infrastructure investment, financial incentives, and workforce development.

The following recommendations directly support a robust contract manufacturing ecosystem thereby strengthening and reinforcing U.S, leadership in biotechnology innovation.

Key Economic Incentives & Infrastructure Support

The Service Provider – Contract Manufacturing Facilities

- Incentivize servicing low-volume contracts (e.g., preferential tax rates, depreciation benefits, etc.)
- Lower barriers to capital-intensive investments with incentives for facility and equipment buildouts
- Leverage government guarantees by expanding grant and credit tool programs for biotech manufacturing projects
- Reward technology adoption and innovation with incentives for advanced systems and pilot-scale facilities
- Encourage integrated end-to-end facilities through grants and tax benefits

The Customer – Biotech Companies

- Incentivize biotech firms to shift manufacturing to the U.S. through tax, capital, and IP benefits

Equipment & Critical Raw Materials Suppliers

- Ensure availability of biotech equipment and critical raw materials by funding and incentivizing domestic production
- Prioritize long-lead biotech equipment through a national list and incentives for domestic sourcing

The Combined Ecosystem

- Encourage regional biotech clusters by incentivizing shared infrastructure, workforce development, and expertise
- Facilitate access to land and utilities through grants and infrastructure support in development zones
- Address utilities and logistics barriers by improving infrastructure essential to biotech manufacturing operations
- Streamline environmental reviews to accelerate biotech facility construction while upholding safety standards

Workforce Development

- Establish standardized biomanufacturing education through national frameworks, degrees, and cGMP-aligned programs
- Fund biomanufacturing workforce development through grants, apprenticeships, and institutional training support
- Expand cross-training by funding accelerated programs to upskill science professionals in biomanufacturing

Federal Coordination

- Establish federal coordination office to unify biomanufacturing efforts across HHS, Commerce, and other agencies.

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The U.S. Biotechnology Ecosystem: The U.S. biotechnology industry is a vibrant and complex ecosystem made up of roughly 3,000 companies, ranging from small startups to large enterprises with thousands of employees. These organizations are united by a shared mission: to discover and develop life-changing therapies. The biotechnology industry is experiencing an extraordinary surge, marked by explosive market growth and groundbreaking innovation. From a modest $100 billion in the 1990s, the global biotech market skyrocketed to $1.55 trillion in 2023 and is projected to reach a staggering $4.25 trillion by 2033—and that global market is currently dominated by U.S. companies. America's biotech innovation leadership benefits all Americans— ensures Americans have access to the most advanced medical therapies, supports high-quality American jobs, and drives exports for economic growth.

Balancing Drug Development and Innovation: Despite this momentum, the journey from discovery to FDA approval is long and costly—typically spanning 10 to 15 years and requiring nearly $1 billion in investment. Out of every 10,000 compounds that enter the discovery phase, only one will make it through to approval, highlighting the immense scientific and financial hurdles involved. This expansion is fueled by record-breaking investment—more than $25 billion raised for U.S. companies in 2024 alone through venture capital and IPOs—driving rapid advancements across the sector. Therapeutic innovation is at the forefront, with a wave of FDA approvals for monoclonal antibodies, gene therapies, and cell-based treatments, ushering in a new era of precision medicine.

The Role of Contract Manufacturers: To navigate this demanding landscape, biotech companies increasingly rely on contract manufacturers. These strategic partners provide the physical infrastructure, expertise, and regulatory know-how needed to develop and manufacture complex therapies. Contract manufacturers support every stage of product lifecycle—from early research and clinical trials to commercial-scale production—allowing biotech firms to focus on innovation without having to build costly facilities or hire specialized staff. Their role is especially critical for small to mid-size companies that lack the resources to build and manage in-house manufacturing capabilities.

Aligning with National Priorities to Support Contract Manufacturers: American biotechnology companies of all sizes want to take part in the Trump Administration's drive to bring research, development, and manufacturing back to America. Since January 2025, close to half a trillion dollars has been committed to U.S. manufacturing from the biotech industry—driven mainly by larger, multi-national companies. But for smaller biotechnology companies to also take part, there must be sufficient contract manufacturing capacity within the United States. As service providers, contract manufacturers are not well positioned to quickly scale up without support. Infrastructure and supply chain investment, financial incentives, and workforce development programs are critical areas where government can assist. Success means American biotechnology companies choosing American-based contract manufacturers for developing new products and shifting existing product manufacturing back onshore.

Conclusion: Supporting contract manufacturers for biotechnology products is not just a strategic choice—it's a national imperative. A strong contract manufacturing ecosystem directly correlates to a strong biotechnology ecosystem—creating high-quality American jobs, driving exports that fuel economic growth, and securing our health supply chains to ensure that Americans have access to critical medicines when they need them. The following recommendations directly support a robust contract manufacturing ecosystem thereby strengthening and reinforcing US leadership in biotech innovation.

A. The Service Provider – Contract Manufacturing Facilities

1. Incentivize Servicing Low-Volume Contracts

Recommendation:	Rationale:
Apply preferential tax rates for contract manufacturers serving low-volume contracts or orphan sponsors. Implement accelerated depreciation for qualifying capital expenditures and expand interest deductibility for biotech infrastructure investments.	These policies reduce cost barriers, improve cash flow, and make it financially attractive to prioritize smaller U.S. innovators while expanding domestic capacity.

2. Lower Barriers to Making Capital-Intensive Investments

Recommendation:	Rationale:
Offer financial incentives, such as tax credits, targeted grants, or partial loan forgiveness for capital-intensive investment. These could include greenfield facility builds, buildouts of existing sites, purchasing of specialized equipment and upstream materials, etc.	Greenfield builds, site expansions, and capital investments carry high upfront risk but deliver resilient, future-ready facilities. Incentives de-risk private investment and anchor long-term capacity in the U.S.

3. Leverage Government Guarantees to Attract Private Investment

Recommendation:	Rationale:
Expand government-backed grant and credit tool programs tailored to biotechnology manufacturing projects. These could include structures like credit guarantees, flexible/convertible loan instruments, specialized mechanisms (e.g. DFC/DPA), etc.	Biomanufacturing requires significant upfront investment. Federal guarantees reduce capital costs, attract private investment, and accelerate growth in this strategic sector.

4. Reward Technology Adoption & Innovative Facilities

Recommendation:	Rationale:
Provide funding and tax incentives for adoption of advanced technologies (e.g. continuous processing, AI-driven quality systems) and support direct funding for pilot-scale (i.e. low production volume) facilities in emerging modalities such as cell and gene therapy or mRNA.	Cutting-edge technologies and early-scale capacity are essential for efficient production and rapid translation of scientific breakthroughs. Public support builds resilience and positions the U.S. as a global leader.

5. Encourage Integrated End-to-End Facilities

Recommendation:	Rationale:
Explicitly reward fully integrated contract manufacturing campuses that bring end-to-end capabilities (from the creation of drug substance through to final drug product) under one roof. Incentives may include preferential tax treatment and grants.	End-to-end integration reduces friction, eliminates the need for tech transfer across multiple contract manufacturers, lowers regulatory burden, and strengthens supply chain security. End-to-end models speed time-to-market and increase U.S. competitiveness.

B. The Customer – Biotech Companies

1. Incentivize Transferring Technology to the U.S.

Recommendation:	Rationale:
Provide incentives for biotech companies to choose U.S. contract manufacturers or move existing contract pipelines to the U.S. Incentives could include targeted tax credits for the incremental costs of transferring technology from one facility to another, access to other forms of capital, patent term extensions, additional exclusivity, federal procurement commitments, etc.	Technology transfers between facilities, including from international facilities to the U.S., require significant spend, such as on production batches, equipment upgrades, labor, validation, and regulatory documentation. Incentives reduce barriers to commercialization, encourage U.S. domestic scaling, and derisk capital commitment from investors.

C. Equipment & Critical Raw Materials Suppliers

1. Ensure Manufacturing Equipment and Raw Materials are Available

Recommendation:	Rationale:
Establish funding mechanisms and tax credits for upstream suppliers of critical biotechnology equipment and materials, including raw inputs, prioritizing domestic production.	Reliable access to specialized equipment and inputs is essential. Domestic support reduces reliance on international vendors, secures U.S. supply chains, and ensures timely access to essential equipment.

2. Prioritize Long-Lead Equipment and Materials

Recommendation:	Rationale:
Create a National Strategic Biomanufacturing Priority List for long-lead equipment and critical materials, with incentives for domestic sourcing and priority procurement under federal oversight.	Key equipment often has 18–24 month lead times. Federal prioritization shortens timelines and strengthens long-term security.

D. The Combined Ecosystem

1. Encourage Public-Private Manufacturing Clusters

Recommendation:	Rationale:
Promote development of regional contract manufacturer-anchored biotechnology manufacturing clusters through incentives for shared infrastructure, workforce, and collaborative innovation.	Clusters lower capital burdens, foster collaboration, and strengthen regional economies through localized supplier networks and talent pools. They accelerate product development by providing shared access to advanced facilities, expertise, and supply chains.

2. Facilitate Access to Land and Infrastructure

Recommendation:	Rationale:
Work with state and local governments to offer land grants, infrastructure support, and site development incentives in underutilized industrial or economic development zones.	Subsidizing land and infrastructure attracts biotech investment, creates jobs, and revitalizes regions while aligning with national innovation goals.

3. Address Major Utilities and Logistics Barriers

Recommendation:	Rationale:
Advance policies to improve utilities and transportation networks critical to biotech manufacturing operations.	Stable utilities and efficient logistics are essential. Coordinated State, Local, and Federal investment reduces risk and increases competitiveness of U.S. biotech hubs. Examples of utilities include power grid reliability, water and sewage systems, etc.

4. Streamline Environmental Review

Recommendation:	Rationale:
Work with state and local governments to simplify and expedite environmental review processes for biotechnology facility construction, while maintaining safety standards.	Long review timelines delay build-out and deter investment. Streamlining accelerates expansion and enhances public health readiness.

E. Workforce Development

1. Establish Standardized Educational Pathways for Biomanufacturing Careers

Recommendation:	Rationale:
Create a nationally coordinated framework for biomanufacturing education, including two-year degree programs, modular training, and micro-credentialing aligned with current Good Manufacturing Practice (cGMP) standards.	A standardized credential system ensures consistent training quality, accelerates workforce readiness, and enables mobility across biotech hubs. Flexible, stackable pathways will meet industry demand while expanding access to high-value careers for diverse learners.

2. Fund Workforce Development for Institutions and Learners

Recommendation:	Rationale:
Provide federal and state funding for accredited biomanufacturing training programs, including tuition grants, earn-and-learn apprenticeships, and institutional support for curriculum development and infrastructure.	Millions of Americans without college degrees represent an untapped workforce. Funding incentives reduce barriers to entry, promote inclusive economic growth, and empower educational institutions to build capacity and meet urgent labor needs.

3. Expand Cross-Training for Science and Technology Professionals

Recommendation:	Rationale:
Support accelerated certificate and retraining programs that equip current science and technology professionals with hands-on biomanufacturing and regulatory skills.	Retraining leverages existing technical talent and shortens time to workforce deployment. Applied coursework and apprenticeships provide industry-ready skills, strengthening the talent pipeline and maximizing return on prior education investments.

F. Coordination

1. Establish Federal Coordination

Recommendation:	Rationale:
Create a formal mechanism in the Federal government to coordinate these efforts across HHS, DoD, Commerce, and others (e.g., and interagency task force or a National Biomanufacturing Strategy Office).	Without central leadership, implementation of these recommendations risks duplication or gaps. A dedicated coordinating body ensures accountability and maximizes the return on federal investment.

About BIO

The Biotechnology Innovation Organization (BIO) is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies – all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. BIO also organizes the BIO International Convention and a series of annual conferences that drive partnerships, investment, and progress within the sector.

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Relevant Authorities

Relevant departments and agencies to lead on policy recommendations and implementation are listed in the table below.

Target	Recommendation	Congress	State/ Local	White House	HHS	DOD	DOE	DOC	USTR	USDT	SBA	USDA	EPA
Service Provider	Incentivize Serving Low-Volume Contracts	●	●										
	Lower Barriers to Making Capital-Intensive Investments	●	●										
	Leverage Government Guarantees to Attract Private Investment	●	●					●		●	●	●	
	Reward Technology Adoption & Innovative Facilities	●	●					●					
	Encourage Integrated End-to-End Facilities	●	●										
Customers - Biotech Companies	Incentivize Transferring Technology to the U.S.	●						●					
Equipment Manufacturers	Ensure Manufacturing Equipment and Raw Materials are Available	●		●				●					
	Prioritize Long-Lead Equipment and Materials	●		●	●	●	●				●		
Combined Ecosystem	Encourage Public-Private Manufacturing Clusters	●	●			●		●					

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	Facilitate Access to Land and Infrastructure	●	●										
	Address Major Utilities and Logistics Barriers	●	●	●			●						
	Streamline Environmental Review		●	●	●								●
Workforce Development	Establish Standardized Educational Pathways for Biomanufacturing Careers	●	●										
	Fund Workforce Development for Institutions and Learners	●	●										
	Expand Cross-Training for Science and Technology Professionals	●	●										
Coordination	Establish Federal Coordination	●		●									