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Pharmaceuticals Manufacturing Industry Landscape Report

Pharmaceutical and Medicine Manufacturing: NAICS 3254

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Contents

Pharma Industry Overview

The North American Industry Classification System (NAICS) code 325 represents the Chemical Manufacturing industry, which includes pharmaceutical manufacturing activities. Within this sector, NAICS 3254 designates Pharmaceutical (Pharma) and Medicine Manufacturing, encompassing the core processes used to create therapeutic, diagnostic, and preventative medical products. More specifically, NAICS 32541 defines the industry's central production activities. These range from the manufacture of medicinal and botanical products to pharmaceutical preparations, in-vitro diagnostic substances, and biologics. This sector is a vital component of the broader bioscience economy, encompassing the development, production, quality assurance, and distribution of pharmaceutical products, including prescription medications, over-the-counter drugs, biological therapies, and in-vitro diagnostic substances.

Pharma manufacturing involves the chemical and biological transformation of raw ingredients into finished medical products intended to diagnose, treat, prevent, or manage human and animal diseases. The manufacturing process spans multiple stages, including the synthesis of active pharmaceutical ingredients, formulation into dosage forms (such as tablets, capsules, injectables, or creams), quality testing, and packaging. These operations are conducted in highly controlled environments regulated by the United States Food and Drug Administration (FDA) under current Good Manufacturing Practices (cGMP), with a focus on product integrity, safety, and traceability.

Pennsylvania is among the nation's leading states for pharmaceutical manufacturing, with a strong base of multinational pharmaceutical companies, biotechnology firms, and contract development and manufacturing organizations. The Greater Philadelphia region, in particular, is a nationally recognized life sciences corridor, home to major pharmaceutical production facilities, innovation campuses, and research institutions. Central and western Pennsylvania are also emerging as key locations for advanced biomanufacturing and logistics. These geographic concentrations reinforce Pennsylvania's position as a core hub for pharmaceutical innovation, production, and global supply chain integration.

The Pharma Manufacturing industry intersects with multiple critical infrastructure sectors identified by the Cybersecurity and Infrastructure Security Agency, represented in Figure 1. It is deeply integrated with the Healthcare and Public Health sector, providing the foundational inputs—including therapeutics, vaccines, and diagnostics—essential to both routine and emergency medical care. It also depends on the Chemical sector for the supply of specialized reagents, solvents, and excipients that enable drug formulation and purification processes. The Water sector plays a similarly vital role, as pharmaceutical manufacturing is highly water-intensive, requiring purified water for compounding, equipment sterilization, and environmental controls. The Energy sector, meanwhile, ensures reliable, continuous power supply for production facilities, especially those operating cleanrooms, automated systems, and temperature-controlled environments.

Distribution and logistics are supported by the Transportation Systems sector, as the movement of pharmaceutical products often requires specialized cold chain infrastructure and expedited freight networks to ensure product stability and delivery timelines. Advances in pharmaceutical production have also made the industry increasingly reliant on Information Technology (IT), including data analytics, electronic batch records, and automated process controls. As a result, secure digital infrastructure and cybersecurity protections are essential. Moreover, the Critical Manufacturing sector supplies the precision equipment and custom systems used in high-compliance production environments, including bioreactors, isolators, filtration units, and packaging machinery.

The Pharmaceutical industry's outputs also extend beyond the commercial market. They are integral to national defense, emergency preparedness, and global public health. Pennsylvania-based pharmaceutical manufacturers support the United States Strategic National Stockpile, pandemic response campaigns, and international vaccine distribution efforts, underscoring the industry's importance to domestic and global health resilience.

This report will cover Pharma industry activity throughout the state of Pennsylvania, with segmentation by the Pennsylvania Manufacturing Extension Partnership (PAMEP)

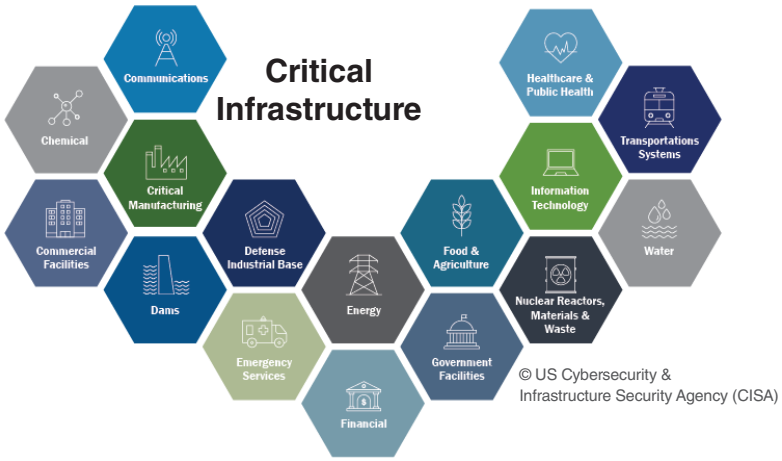

Figure 1

Pharmaceutical Manufacturing (NAICS 3254)

Pennsylvania Pharma Manufacturing – Entities

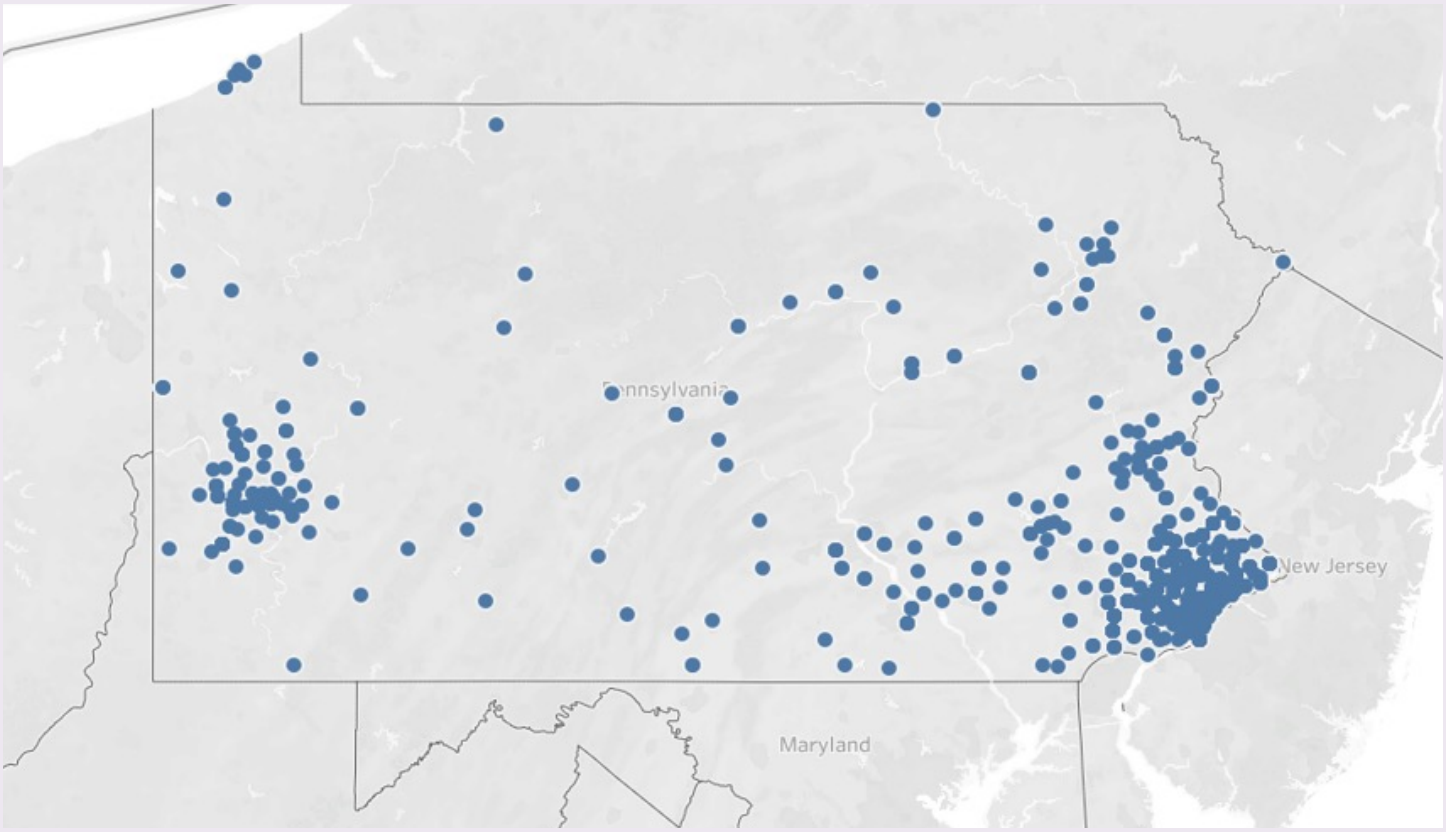

Figure 2: Represents 32541 NAICS Codes: Pharmaceutical and Medicine Manufacturing in Pennsylvania.

Pharma Industry Landscape

Industry Summary

Pharma is vital to the strength of Pennsylvania's economy and plays a key role in supporting the nation's healthcare, public health, and innovation infrastructure.

- In February 2025, Pennsylvania exported $995.7 million worth of chemical products (classified under NAICS 325) to global markets.
- Brand Name Pharmaceutical Manufacturing in Pennsylvania ranks among the top nationally, with 79 establishments (9th highest), $10.8 billion in projected 2025 revenue (8th highest, contributing 4.1% of national revenue), and 7,476 employees (11th highest). The state has seen robust growth with a 5.2% revenue compound annual growth rate (CAGR) from 2020 to 2025 and a 4.8% employment CAGR, underscoring its strong and sustained role in the U.S. pharmaceutical landscape.
- Generic Pharmaceutical Manufacturing in Pennsylvania ranks 7th nationally for the number of establishments (23 in 2025), despite slight annual declines in the establishment count (-0.8%). The state's pharmaceutical manufacturers are projected to contribute $7.3 billion in revenue in 2025, accounting for 14.4% of the national industry total and ranking the state as the second highest in the U.S. While employment has declined by 2.2% over the past five years, Pennsylvania still employs 6,500 workers, the second most nationwide, underscoring the state's strategic role in the generic pharmaceutical supply chain.
- Vitamin & Supplement Manufacturing in Pennsylvania ranks 13th nationally for the number of establishments (41 in 2025), representing 2.2% of the U.S. total. The state will contribute a projected $1.8 billion in 2025 revenue—4.5% of the national industry total—ranking 5th nationwide. With an estimated 1,329 employees, Pennsylvania also ranks 10th in employment. Despite modest revenue growth and stable establishment numbers, the sector's consistent workforce expansion underscores Pennsylvania's role as a mid-sized but steadily growing player in the national Vitamins & Supplements Manufacturing landscape.

The Pharma Manufacturing industry is comprised of the six-digit NAICS subsectors listed below.

Extended 32541 NAICS Codes: Pharmaceutical and Medicine Manufacturing

325411	Medicinal and Botanical Manufacturing
325412	Pharmaceutical Preparation Manufacturing
325413	In-Vitro Diagnostic Substance Manufacturing
325414	Biological Product (except Diagnostic) Manufacturing

Pennsylvania Pharma Segmented by NAICS Code

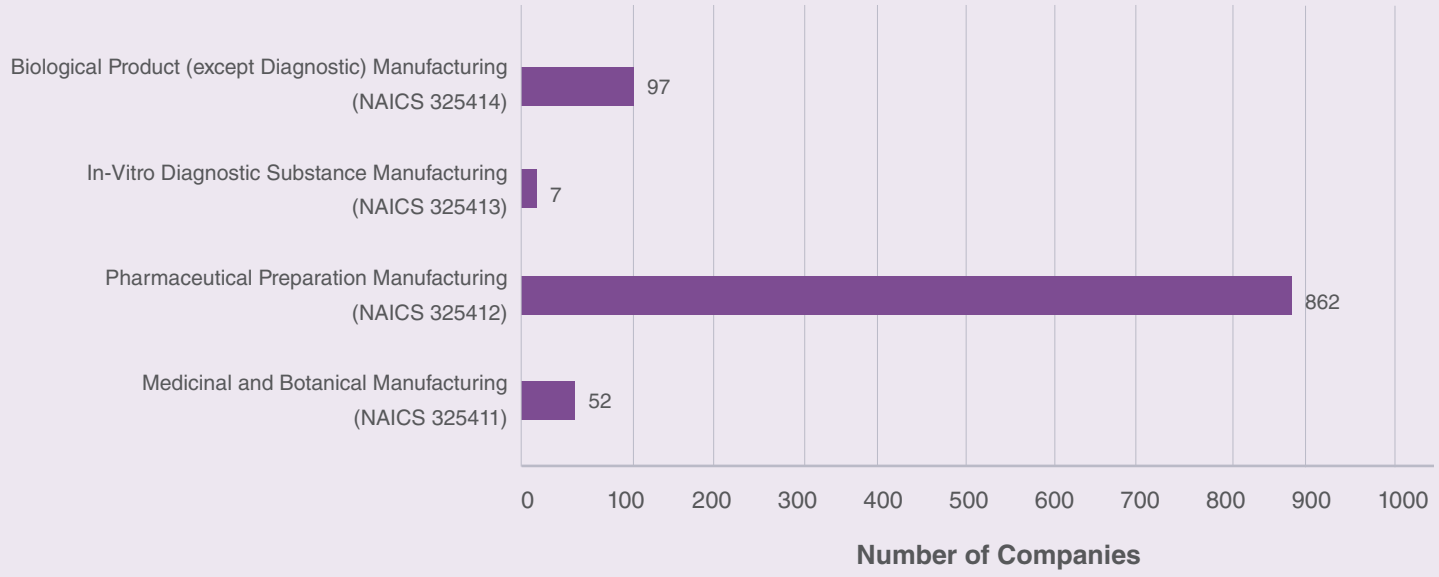

Figure 3: Pennsylvania Pharma Segmented by NAICS Code

Industry Demographics

This section provides Pharma Manufacturing industry demographics, including market size, revenue distribution across segments, establishment statistics, and critical market trends shaping the landscape. This exploration extends to industry profits, drivers, and the influence of external factors, offering an overview of the current state and future trajectory.

Pharma Manufacturing (NAICS 325) PA Real Gross Domestic Product: More than $23 billion (2023)

Pharma Manufacturing (NAICS 325) U.S. Gross Domestic Product: More than $531 billion (2023)

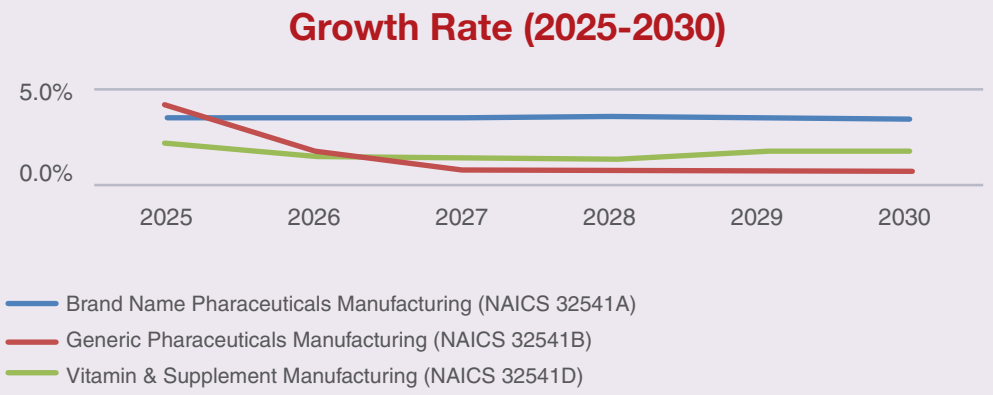

Figure 4: Growth Rates from 2025 - 2030

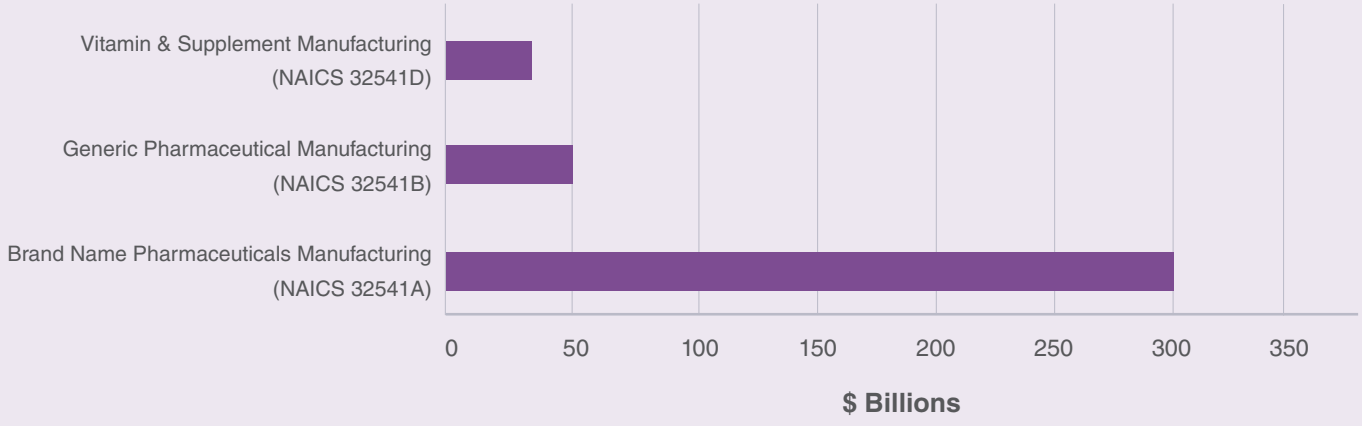

Figure 5: U.S. Pharma Manufacturing Revenue by Segment

Industry Demographics

Pennsylvania Employee Distribution by Establishment Size

There are more than 36,000 total employees in the Pharma Manufacturing industry in Pennsylvania. Figure 6 below illustrates the distribution of Pharma Manufacturing establishments by employment size. The vast majority (71%) of establishments employ fewer than 10 people. Employers with 250 to 499 employees represent 2%, with 1% being large employers with more than 500 employees.

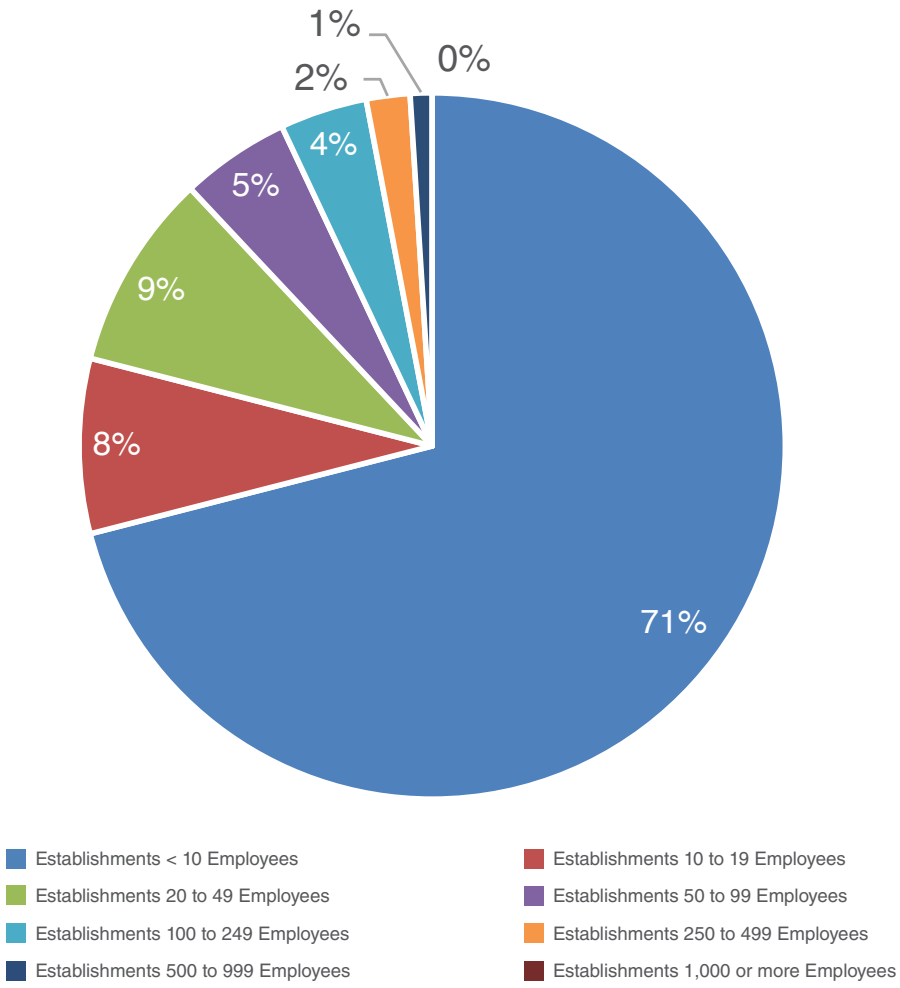

Figure 6: Pharmaceutical and Medicine Manufacturing in Pennsylvania by Company Size

Industry Demographics

Workforce

Workforce Trends

- United States
  - **Labor productivity index (output per hour):** Increased by 1.8% in 2023. This marked a significant rebound from prior declines between 2019 and 2022.
  - **Labor index (total labor hours):** Decreased by 0.2% in 2023, indicating slightly reduced labor input despite higher output.
  - **Output index (real output):** Rose by 2.8% in 2023, showing production gains across the sector.
- Pennsylvania
  - **Employment change (2022 to 2023):** Decreased by 1.6%, representing a loss of 338 jobs in the state's Pharmaceutical Manufacturing sector.
  - **Average annual wage change (2022 to 2023)** Increased by 5.3%, significantly outpacing the state's all-industry average of 2.9%.
- **Wages as a percentage of total revenue in 2025 in the U.S.:**
  - **Brand Name Pharmaceutical Manufacturing:** 9.84%
  - **Generic Pharmaceutical Manufacturing:** 12.92%
  - **Vitamin & Supplement Manufacturing:** 12.02%
- **Talent and Workforce Dynamics:** Workforce availability, skill alignment, and wage trends are fundamental cost drivers for Pennsylvania pharma.
  - **Employment Trends:** In 2023, NAICS 3254 (Pharmaceutical Manufacturing) employment declined by 1.6% (–338 jobs), even as average wages rose 5.3%—indicating a tightening market for specialized talent.
  - **Labor Costs:** Pharma wages outpace state averages by 33%, and wage pressure is rising amid increased demand for high-skill roles.
  - **Skills Gaps:** 44% of Pennsylvania manufacturers cite workforce skills as a barrier to tech adoption. Critical roles include CGT operators, regulatory staff, AI/data experts, and advanced manufacturing technicians.
  - **Efforts to address gaps include:** Workforce and Economic Development Network of Pennsylvania (WEDnetPA) for incumbent worker training, Career Connect internships, High Priority Occupations (HPO) planning by the Pennsylvania Department of Labor, and Workforce initiatives by Life Sciences PA, West Philadelphia Skills Initiative (WPSI), and Lehigh Valley Economic Development Corporation (LVEDC).

Workforce Challenges

- **Talent Shortages and Critical Skill Gaps:** Pennsylvania's pharmaceutical labor market is grappling with a high degree of specialization that outpaces the current supply of appropriately skilled workers. The state's leading position in cell and gene therapy (CGT), centered in Philadelphia's "Cellicon Valley", has created surging demand for workers proficient in aseptic processing, viral vector manufacturing, biologics quality control, and GMP compliance for advanced therapies. Many of these skills are rare nationally, let alone locally, prompting concerns about persistent bottlenecks in workforce availability.
- Simultaneously, the widespread adoption of **Pharma 4.0 principles**—including automation, robotics, Manufacturing Execution Systems (MES), and data-driven optimization—is reshaping manufacturing workforce requirements. Companies like GSK and Merck are heavily investing in "smart" facilities that rely on technicians skilled in DeltaV process control systems, Enterprise Resource Planning (ERP) software (e.g., Systems, Applications, and Products in Data Processing (SAP)), and digital twin technologies. This evolution demands a digitally fluent workforce capable of adapting to the convergence of operational technology (OT) and information technology (IT).
- The integration of **Artificial Intelligence (AI), machine learning (ML), and exploration into Industry 6.0** further compounds the challenge. There is growing demand for professionals in data science, bioinformatics, and AI application development—roles that require cross-disciplinary expertise not traditionally abundant in life sciences hiring pools.

Industry Demographics

- **Regional Talent Competition:** The geographic concentration of the Pharmaceutical industry in Southeastern Pennsylvania and the Pittsburgh region intensifies competition for talent. With firms like GSK, Merck, Johnson & Johnson, and Pfizer operating in close proximity to a dense network of Contract Development and Manufacturing Organizations (CDMOs), Contract Research Organizations (CROs), and health systems (e.g., Penn Medicine, University of Pittsburgh Medical Center (UPMC)), recruitment pressures have escalated. This leads to wage inflation and poses challenges for talent retention, especially for small or emerging firms competing against larger players.
- **Structural Workforce Misalignment:** The skills gap identified by the Pennsylvania Manufacturing Advisory Council reflects a broader misalignment between traditional workforce capabilities and the rapidly advancing technological demands of the Pharmaceutical industry. While the state's education system produces a robust supply of graduates, translating these into job-ready workers—especially for CGT and AI-based manufacturing—is a persistent issue. Upskilling and retraining are now essential strategies, particularly for filling mid-level technical roles that support advanced production environments.
- **Long-Term Competitiveness Risks:** Though average wages in the sector surged by 5.3% in 2023—more than double the state average—this wage pressure presents a potential risk to Pennsylvania's cost competitiveness. If unaddressed, sustained labor shortages and escalating compensation expectations may divert future investment to lower-cost regions. Balancing innovation incentives with scalable workforce solutions remains critical.

External Market Forces

- **Economic Pressures:** State- and national-level policies are generating new cost constraints and strategic challenges. The **Inflation Reduction Act (IRA)** introduced federal drug pricing reforms, such as Medicare negotiation and rebate requirements, which are expected to affect revenue projections and Research and Development (R&D) prioritization for companies with strong Medicare portfolios (e.g., Merck and GSK). While reducing out-of-pocket costs for tens of thousands of Pennsylvanians, these measures may dampen investment in certain drug categories and early-stage development efforts. Similarly, state-level affordability reforms (e.g., Act 77) expand oversight of Pharmacy Benefit Managers (PBMs) while aiming to control drug costs and protect pharmacy access, but they introduce new compliance obligations for payers and supply chain stakeholders.
  - At the same time, Pennsylvania offers cost-competitive operational conditions relative to peer Northeast hubs. Manufacturing hubs like King of Prussia and Pittsburgh report lower facility operating costs compared to Boston or New Jersey. The state's Revitalizing Industrial Sites for Employment (RISE) PA grant program and energy efficiency incentives further reduce overhead, particularly for energy-intensive operations. Global pressures like cheaper labor and Active Pharmaceutical Ingredient (API) sourcing abroad, however, continue to influence cost models and challenge local competitiveness.
- **Geopolitical Risk and National Security Drivers:** The proposed BIOSECURE Act, which restricts federal collaboration with entities using biotechnology services from foreign adversaries, poses a direct threat to Chinese-owned CDMOs like WuXi AppTec in Philadelphia. The law may accelerate a shift toward supply chain reshoring and diversification, benefiting domestic CDMOs such as SK Pharmteco, Catalent, and PCI Pharma Services. Moreover, pandemic-era lessons and federal biodefense strategies are reinforcing national security imperatives for onshore production of essential medicines and APIs. Pennsylvania, with its robust Pharmaceutical Manufacturing base and distribution infrastructure (e.g., Cencora HQ), is well-positioned to attract future investment aligned with these goals.
- **Regulatory Pressures:** The Drug Supply Chain Security Act (DSCSA) final enforcement took effect in late 2024, requiring pharmaceutical manufacturing firms to implement electronic traceability systems across the supply chain. This has created significant data management and technological integration demands. Concurrently, the FDA's heightened cybersecurity mandates for connected medical devices and combination products are intensifying expectations for vulnerability management, software transparency, and secure product design. Pennsylvania companies—particularly those adopting Pharma 4.0 digitalization strategies—must navigate these regulatory demands while ensuring GMP compliance and maintaining operational resilience.
  - At the state level, Pennsylvania's environmental regulations, including hazardous- and medical waste rules, and water discharge permits, add further complexity and cost to pharmaceutical manufacturing operations. Companies must dedicate capital and personnel to ensure compliance with evolving Department of Environmental Protection (DEP) standards.

Industry Demographics

- **Demographic and Social Dynamics:** Pennsylvania's aging population drives demand for chronic disease treatments and specialty pharmaceuticals. This demographic shift, however, also magnifies the pressure on affordability, especially as many older adults live on fixed incomes and rely on Medicare—a payer increasingly empowered to negotiate drug prices under the Inflation Reduction Act (IRA). The healthcare affordability crisis in the state, with more than half of adults delaying care due to cost, underscores the urgency for value-driven pharmaceutical innovation.
  - Parallel to these trends, there is rising consumer empowerment and engagement, with patients expecting greater transparency, digital access, and personalized care. Major Pennsylvania health systems like Penn Medicine, UPMC, and Geisinger are adopting telehealth, remote patient monitoring, and AI-driven tools to meet these expectations. Pharmaceutical companies must align with this shift by providing digital therapeutics, real-world data integrations, and supportive services that complement clinical treatment and enhance adherence.
  - Environmental, Social, and Governance (ESG) criteria and community engagement priorities, meanwhile, are becoming strategic imperatives. Companies such as GSK, Merck, Bayer, and West Pharmaceutical Services have embedded ambitious sustainability goals into their Pennsylvania operations, addressing not only emissions but also social determinants of health (SDOH) and workforce inclusion. These efforts enhance trust, mitigate reputational risk, and support long-term market access in an increasingly values-driven healthcare economy.

Innovations in Technology

AI and Machine Learning (AI/ML) in Pennsylvania R&D: Pennsylvania is rapidly emerging as a hub for AI-driven pharmaceutical innovation, leveraging its concentration of world-class research institutions, a strong pharma industry base, and robust computational infrastructure.

- **GSK Philadelphia AI Hub:** GSK operates a dedicated AI/ML group in Philadelphia focused on interpreting large-scale omics data to enhance target identification and RNA therapeutic development. This local initiative complements GSK's global $13.5B R&D investment.
- **Penn Medicine's AI in Drug Repurposing:** Penn researchers used machine learning to repurpose adalimumab for idiopathic multicentric Castleman's disease (iMCD), a rare illness—work now scaled by the nonprofit Every Cure. Penn is also piloting AI scribes to automate clinical documentation.
- **Carnegie Mellon University (CMU):** CMU's Auton Lab and NSF AI Institute apply ML to public health, diagnostics and drug safety. The Pittsburgh Supercomputing Center supports convergence AI/High Performance Computing (HPC) research. CMU's Cloud Lab and Regional Autonomous Patient Safety (RAPS) initiative explore automated and AI-enhanced scientific workflows.
- **University of Pittsburgh (Pitt):** Pitt's Computational Pathology & Ai Center of Excellence (CPACE), in partnership with Leidos, develops AI tools for digital pathology and cardiovascular diagnostics. A $10M investment is building a pipeline of AI-powered healthcare innovations and workforce training.
- **University of Pennsylvania (Penn):** Penn leverages National Institutes of Health (NIH)-funded datasets for AI/ML research and digital tool development. Integrated with Penn's presence in "Cellicon Valley," these efforts support translational innovation in CGT and diagnostics.
- **Bayer & ConcertAI:** Bayer's partnership with ConcertAI applies AI to vast oncology datasets (e.g., CancerLinQ) to optimize clinical trial design, predict treatment outcomes, and streamline precision oncology development.

Smart Manufacturing and Pharma 4.0: Pennsylvania is leading the U.S. transition toward "Pharma 4.0," integrating AI, the Internet of Things (IoT), robotics, and digital twins across pharmaceutical operations.

- **GSK Marietta Expansion:** GSK's $800M project embeds AI-enabled predictive maintenance, robotics, digital twins, and smart utilities. This facility is a prototype for next-gen vaccine- and therapeutic manufacturing.
- **Merck's Pharma 4.0 Vision:** Merck, in partnership with Purdue University, is developing autonomous systems, AI-powered quality analytics, and smart sterile manufacturing—technologies likely to influence its West Point and Upper Gwynedd sites.
- **AI in Supply Chain & Quality:** AI is enhancing logistics at Cencora, predictive scheduling at GSK, and quality control via anomaly detection and machine vision. Tools like Lighthouse AI support regulatory compliance in complex pharmaceutical supply chains.

Industry Demographics

AI-Enabled Clinical Trials: Pennsylvania's health systems are applying AI to transform clinical research, making trials more efficient, accessible, and data-rich.

- **UPMC Enterprises:** UPMC is using AI for patient recruitment, real-time data monitoring, and digital twins for trial simulation. Their Ahavi platform enables advanced analytics using real-world data.
- **Penn Medicine:** Penn's integration of ambient scribes and digital patient interaction tools (e.g., MyChart, MyCap) enhances participant engagement and trial data quality.
- **CMU-Pitt-UPMC Health Data Alliance:** AI/ML applications mine Electronic Health Records (EHRs) and claims data to detect trends and adverse events, informing safer, more efficient trials.

Telehealth, RPM, and Digital Engagement: Pennsylvania health systems are national leaders in implementing digital care models and patient engagement technologies.

- **UPMC:** Recognized at College of Healthcare Information Management Executives (CHIME) Level 10, UPMC integrates telehealth, eConsults, Remote Patient Monitoring (RPM), and Digital Health Navigator (DHN) programs to close digital equity gaps.
- **Penn Medicine:** Offers home chemotherapy, AI-drafted portal messages, and digitally coordinated care. Tools like MyPennMedicine facilitate eConsent, Patient-Reported Outcomes (PROs), and virtual visits.
- **Geisinger:** Partners with Best Buy's Geek Squad for at-home RPM device deployment. Its ConnectedCare 365 program spans 14 clinical areas with strong adherence and outcome improvements.
- **Highmark Health:** Their Living Health platform integrates Google Cloud-powered AI with 35 digital tools to deliver personalized, proactive member engagement.

Real-World Evidence (RWE) and Clinical Trials: Digital tools and AI are enabling new forms of clinical research rooted in real-world data.

- **RPM and Portals as RWE Engines:** Devices and apps deployed by UPMC, Geisinger, Penn, and Highmark collect vast patient data streams, useful for outcome research and post-market surveillance.
- **AI for Trial Acceleration:** UPMC uses AI for trial simulation, predictive recruitment, and adherence tracking. Middleware like Clinical Pipe streamlines EHR-to- Electronic Data Capture (EDC) integration.
- **Pharma 4.0, Continuous Manufacturing, and Advanced Tech: Pennsylvania's Pharma Manufacturing industry is undergoing a digital transformation:**
- **Continuous Manufacturing (CM):** GSK's Marietta site integrates AI, digital twins, and robotics in a seamless CM workflow. Merck's Purdue partnership explores similar systems for sterile injectables.
- **Automation and Robotics:** Robotics are being adopted in sterile fill-finish, packaging, and high-containment environments across Pennsylvania manufacturing sites.
- **3D Printing:** Adare Pharma's collaboration with Laxxon Medical brings screen printing to oral dosage form innovation.
- **Defense Advanced Research Projects Agency (DARPA)-Inspired Innovations:** Programs like Point-of-Deployment (PoD) and Biological Manufacturing on Demand (Bio-MOD) may influence Pennsylvania's adoption of mobile, on-demand manufacturing units and digital regulatory frameworks.
- **CDMOs/CROs Driving Advanced Manufacturing:** Pennsylvania's rich ecosystem of CDMOs and CROs enables cutting-edge production and research capabilities.
- **CBM/SK Pharmteco:** Focused on end-to-end CGT manufacturing in King of Prussia with proprietary viral vector platforms and real-time data tools.
- **Catalent, Adare, PCI, Abzena, Almac:** These firms provide everything from clinical packaging to complex biomanufacturing. Adare leads in taste masking and 3D printing; PCI is expanding injectable/device capabilities.
- **WuXi AppTec:** A key CGT services provider in Philadelphia facing regulatory uncertainty under the proposed BIOSECURE Act, which may reshape the competitive landscape.

Industry Demographics

Decentralized and Hybrid Trials: Digital trial components are expanding across Pennsylvania:

- **Penn Medicine:** Offers eConsent (DocuSign, REDCap), remote data capture (MyCap, Advance App), and EMR integration (Clinical Pipe). These tools support hybrid and decentralized trial formats.
- **Decentralized Clinical Trial (DCT)-Focused CROs:** Firms like Curavit and Frontage lead in managing DCTs, leveraging Pennsylvania's diverse population and advanced healthcare infrastructure.
- **Academic Studies:** Universities are adopting decentralized models for biobanking and registries, facilitating broader participation and data diversity.

State Policy and Support: Pennsylvania actively supports innovation through:

- **PA Innovation Fund:** $50M program with $30M earmarked for life sciences commercialization;
- **R&D Tax Credit:** Expanded to $60M, with industry advocates seeking $120M to meet oversubscription;
- **Life Sciences Greenhouses & Ben Franklin Technology Partners:** Key players in funding and mentoring startups and translating research into products; and
- **AdvancePA, RISE PA, EDGE:** State and federal-backed programs supporting job creation, manufacturing decarbonization, and tech-based economic development.
- These activities underscore Pennsylvania's success in attracting and retaining life sciences investment, significantly aided by proactive state-level initiatives. The Shapiro Administration's economic development strategy, implemented through the BusinessPA team, leverages tools like the PA SITES program for site development, Pennsylvania First grants, Pennsylvania Industrial Development Authority (PIDA) loans, workforce development grants (WEDnetPA), and tax credits (AdvancePA, R&D Tax Credit) to incentivize growth.

Mergers & Acquisitions

The period between 2023 and early 2025 witnessed substantial investment flowing into Pennsylvania's Pharmaceutical and Life Sciences sectors, primarily characterized by strategic expansions and state-supported relocations, rather than large-scale acquisitions of Pennsylvania-based companies.

- **Adare Pharma Solutions:** Relocated its global headquarters from New Jersey to Philadelphia and is undertaking a $16.8 million expansion of its two existing Philadelphia manufacturing and packaging facilities. The move, supported by nearly $3 million in state funding (PIDA loan, grants), is expected to create 115 new jobs and retain 200.
- **BioTechnique (PSC Biotech):** Relocated its pharmaceutical contract manufacturing operations from Wisconsin to a former Unilife facility in York County. This $22 million project, supported by state incentives including grants and a PIDA loan, is expected to create 100 jobs.
- **Catalent:** The global CDMO, with key sites in Philadelphia and Malvern, was acquired by Novo Holdings for $16.5 billion (enterprise value). Announced in February 2024 and closed in December of that year, this deal saw three non-Pennsylvania sites sold to Novo Nordisk, but Novo Holdings retains Catalent's remaining global network, including its Pennsylvania facilities.
- **GSK:** Announced an $800 million expansion of its Marietta facility in Lancaster County, supported by $21 million in state investment. This project, which broke ground in April 2025, aims to build new R&D and manufacturing facilities for vaccines and medicines, creating more than 200 jobs and retaining thousands more statewide. GSK acquired Boston-based IDRx, a clinical-stage company focused on GIST (a type of gastrointestinal cancer), for up to $1.15 billion. This 2025 deal adds to GSK's oncology pipeline. This is relevant given GSK's extensive R&D and manufacturing presence in Pennsylvania.
- **Merck:** Acquired California-based Imago BioSciences, which focuses on hematology, for $1.35 billion. The deal, which closed in the first quarter of 2023, strengthens Merck's pipeline and will impacting its significant Pennsylvania operations.
- **Nucleus RadioPharma:** Is establishing a new facility in Spring House (Montgomery County) as part of its strategy to regionalize the production of radiopharmaceuticals.
- **PCI Pharma Services:** This Philadelphia-headquartered CDMO has seen significant private equity interest, with Kohlberg and Mubadala acquiring a majority stake in 2020, following Partners Group's acquisition from Frazier Healthcare Partners in 2016. This highlights ongoing investor confidence in the Pharma services sector within Pennsylvania.

- **Roche:** Announced a $50 billion, five-year investment plan for the U.S., including potential new manufacturing and research sites in several states, explicitly mentioning Pennsylvania as a possibility.
- **Other expansions include:** PCI ($365M globally), Almac ($65M clinical capacity), and Abzena ($5M bioconjugation).

Renewable Energy and Sustainable Practices

Regulatory Framework and State Incentives: Pennsylvania's Pharmaceutical industry operates within a stringent environmental regulatory environment shaped by the Pennsylvania DEP, which enforces state-specific rules and incorporates relevant federal standards. Key Regulatory Areas include:

- **Hazardous Waste Management:** Pennsylvania has adopted federal Resource Conservation and Recovery Act (RCRA) regulations, including the Universal Waste Rule and special standards for hazardous waste pharmaceuticals (40 CFR Part 266 Subpart P), prohibiting sewer disposal and setting handling standards for healthcare-related facilities and reverse distributors.
- **Regulated Medical and Chemotherapeutic Waste (RMCW):** Governed by 25 Pa. Code Chapter 284, this mandates DEP-issued licenses for transporters and permits for processing facilities, directly impacting pharma R&D and manufacturing waste disposal.
- **RISE PA Grant Program:** Funded by $396 million from the Environmental Protection Agency (EPA) through the Inflation Reduction Act, RISE PA supports industrial decarbonization with grants covering:
- 30%–50% of project costs and includes additional bonuses for higher green house gas (GHG) reductions, fair labor practices, or low-income and disadvantaged communities (LIDAC) benefit.
- Eligible projects include energy efficiency, low-carbon fuel switching, on-site renewables, industrial electrification, and carbon capture, utilization, and storage (CCUS).

Additional Incentives:

- **Reduced-Cost Energy Audits:** For manufacturers under 500 employees and $250M in sales, subsidized Level II American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) audits help identify savings.
- **Federal Investment Tax Credit (ITC):** Solar projects may qualify for enhanced ITC rates based on domestic content and location in energy communities.
- **Past State Support:** Grants like those from Department of Community and Economic Development (DCED) to Merck (Upper Gwynedd) exemplify state commitment to renewable energy deployment.

Corporate Sustainability Initiatives in Pennsylvania: Global pharmaceutical firms with major operations in Pennsylvania are embedding sustainability within their corporate strategies and local facilities.

- **GSK (Marietta):** Targets 100% renewable electricity by 2025 and net-zero emissions by 2045 (Science Based Targets initiative (SBTi) approved).
- **Initiatives:** Member of RE100 and EV100; supply chain emissions tackled via sustainable procurement and airfreight reduction; Leadership in Energy and Environmental Design (LEED) Silver features at Marietta include solar panels, water/energy reclamation, electric heat, and biodiversity promotion.
- **Merck (Upper Gwynedd):** Targets Carbon neutrality and 100% renewable energy by 2025.
- **Projects:** Installed 1.5 MW solar array—funded in part by American Recovery and Reinvestment Act (ARRA) and DCED—providing 14% of campus energy; surplus power is returned to the Philadelphia Electric Company (PECO) grid. The site is recognized for conservation and adaptive reuse.
- **Bayer (Myerstown):** Goal to reduce Scope 1 & 2 emissions by 42% by 2029, achieve climate neutrality by 2030 (sites), and be net-zero across the value chain by 2050. Myerstown facility operations fall under these commitments.
- **West Pharmaceutical Services (Exton):** In 2023, achieved 13.6% GHG reduction, 31% renewable electricity use, and 79% of waste diverted from landfills.
- **Goals:** West Pharmaceutical Services aims to be 100% landfill-free by 2030.
- **Community Engagement:** The company is an official sustainability partner of the Philadelphia Eagles.

Industry Demographics

Strategic Impact on Pennsylvania's Industry: Sustainability regulations and incentives, combined with ambitious corporate goals, are reshaping pharmaceutical operations in Pennsylvania. Key impacts include:

- Integration of clean energy and circular economy principles into facility design and manufacturing processes;
- Increased adoption of low-emission technologies supported by programs like RISE PA and federal ITCs; and
- Long-term cost savings and competitive positioning for companies adopting green practices amid tightening environmental, social, and governance (ESG) expectations

Supply Chain

Key Hubs, Providers, and Infrastructure: Pennsylvania's pharmaceutical supply chain is supported by a mature and strategically positioned logistics ecosystem. Key logistics clusters in the Lehigh Valley (Allentown/Bethlehem/Easton) and Greater Philadelphia capitalize on proximity to major population centers and intermodal transportation networks. Major providers include:

- Cencora (AmerisourceBergen) – Headquartered in Conshohocken, Cencora operates more than 40 distribution centers nationwide and serves as a cornerstone of wholesale and specialty distribution, offering services from ordering to analytics-driven inventory management.
- Kuehne+Nagel – Maintains logistics offices in Philadelphia, Bethlehem, Carlisle, and Pittsburgh, with 24/7 pharmaceutical services.
- Hub Group – Operates a major fulfillment center in Allentown, focused on e-commerce and pharma logistics.
- Geodis – Offers cold-chain and specialized healthcare logistics across Pennsylvania.
- CDMO-Linked Logistics – Companies like Adare Pharma Solutions and PCI Pharma Services provide integrated distribution and packaging services directly from facilities in Philadelphia.
- General Providers – Firms like DF Young, BDP International, Apex Health Services, and NFI support pharma supply chains with warehousing, fulfillment, and transition logistics.
- Pennsylvania's logistical footprint enables seamless service across the full spectrum, from bulk wholesale to clinical trial fulfillment and final-mile delivery for advanced therapies.

Technology and DSCSA Compliance: Technology adoption in pharmaceutical logistics is accelerating, driven by both operational needs and federal mandates—most notably the DSCSA. DSCSA Compliance Requirements (effective November. 27, 2024) include:

- **Serialization:** Application of unique product identifiers (2D barcodes) to unit and case-level packaging;
- **Electronic Data Exchange:** Use of Electronic Product Code Information Services (EPCIS) to share transaction data- Transaction Information (TI) and Transaction Statement (TS)- among supply chain actors;
- **Verification Systems:** Tools to validate identifiers and manage returns or suspicious product; and
- **Illegitimate Product Response:** Mandatory quarantine, investigation, and reporting protocols.

Pennsylvania-based stakeholders like Adare Pharma Solutions and UPM Pharmaceuticals, and service providers like Excellis Health Solutions, are actively implementing these systems, creating a rich data environment that enables further optimization.

- **Digital Transformation and AI Integration:** DSCSA compliance is laying the groundwork for advanced digital infrastructure, setting the stage for AI and data analytics to transform pharmaceutical logistics.
- **AI/ML Applications in Pharma Supply Chains:** Demand forecasting, inventory and capacity optimization, anomaly detection in quality assurance, predictive maintenance exist at GSK's Marietta site and others.
- **Smart Manufacturing and Digital Factories:**
  - GSK's $800M investment integrates digital twins, AI-enabled scheduling, Manufacturing Execution Systems (MES) systems, robotics, and energy-efficient automation.
  - DARPA-backed initiatives (PoD, Bio-MOD, SCOPE, EQUIP-A-Pharma) explore on-demand, small-batch, agile manufacturing—potential future models for advanced pharmaceuticals.

Industry Demographics

- **Advanced Materials and Packaging Innovations:** Secure packaging (Radio-Frequency Identification (RFID), tamper-evident features), aseptic spray drying, and custom polymers enhance both logistics integrity and therapeutic stability.
- **Cybersecurity in Interconnected Systems:** As digital integration increases, cybersecurity has become critical for operational continuity and data integrity.
- **Cybersecurity in Pharma Manufacturing:** Pharma firms face escalating cyber threats—ransomware, intellectual property (IP) theft, and OT/ industrial control system (ICS) compromise—especially as IT-OT convergence removes traditional network boundaries. For Pennsylvania pharma firms, effective cybersecurity involves asset inventory and vulnerability management, network segmentation, continuous threat monitoring, and cross-functional governance integrating IT, OT, and quality teams.

Pennsylvania-Based Initiatives and Impact: National trends toward resilience and reshoring are directly shaping investment within the Commonwealth. Examples:

- **GSK (Marietta):** Expanding domestic vaccine production.
- **Adare Pharma:** Relocated headquarters to Philadelphia; investing in packaging/warehouse capacity.
- **BioTechnique (York):** Moved operations from Wisconsin to Pennsylvania to expand sterile injectable manufacturing.
- **Roche and Eli Lilly:** Large-scale reshoring efforts that could bring future projects to Pennsylvania.
- **Nucleus RadioPharma (Spring House):** Establishing localized production for radiopharmaceuticals.
- **State-Level Support:**
  - **RISE PA:** Funds decarbonization and facility upgrades.
  - **DSCSA Implementation:** Drives digitization across manufacturing and logistics.
  - **Strong CDMO/CRO Base:** Companies like Catalent, Almac, PCI, and WuXi provide turnkey service options to mitigate supply chain risk.
- Supply Chain Modernization & Resilience: In the wake of COVID-19 and ongoing geopolitical instability, supply chain resilience has become a national priority. With over 90% of U.S. sterile injectable inputs sourced from China or India, the risk of global disruptions remains high. In response, the U.S. government is leveraging Executive Order 14017, the National Biodefense Strategy, and the Defense Production Act to expand domestic manufacturing of APIs and medical countermeasures (MCMs). Strategies such as onshoring, near-shoring, and friend-shoring are being deployed to reduce dependency on fragile international supply chains.
  - Pennsylvania is a direct beneficiary of these efforts, with recent developments including Adare Pharma relocating its headquarters to Philadelphia, BioTechnique moving operations from Wisconsin to York County, GSK committing its largest U.S. investment to Marietta, and major reshoring investments in the state by Roche, Merck, and Eli Lilly. Modern supply chains require digital tools—AI for forecasting and inventory, serialization for DSCSA compliance, and potential deployment of DARPA-modeled agile manufacturing (e.g., PoD, Bio-MOD, SCOPE). Pennsylvania's logistics strengths and Cencora's national footprint position the state as a resilient distribution hub. Despite the high investment, modernization is critical for long-term operational security and federal contracting competitiveness.
- **Logistics and Distribution Strength;** Pennsylvania's location in the Northeast corridor supports rapid access to major markets. Distribution infrastructure is anchored by:
  - **Cencora (formerly AmerisourceBergen):** Headquarters in Conshohocken, 26 U.S. centers.
  - **Kuehne+Nagel, Hub Group:** Fulfillment centers statewide.
  - **PCI, Adare:** End-to-end packaging and distribution.
- The DSCSA, effective November 2024, requires serialization and electronic tracking across the supply chain. Pennsylvania's firms—manufacturers and distributors alike—are investing to meet compliance, improving supply chain security and resilience.
- In terms of economic impact, Pharma manufacturing supports hundreds of thousands of jobs and 7,200 in-state vendors, contributing nearly $8B to the local economy. Life sciences wholesaling alone generates $86.4B annually. Pennsylvania's 10-year strategy targets life sciences as a driver of gross domestic product (GDP) and job growth.

Industry Demographics

Regulatory and Standards Landscape

- **National Institute of Standards and Technology (NIST) Cybersecurity Framework (CSF) and SP 800-82 Rev. 3:** Foundational guides for OT security practices.
- **International Society of Automation (ISA) / International Electrotechnical Commission (ISA/IEC) 62443:** International standards for industrial automation and secure product development.
- **Cybersecurity and Infrastructure Security Agency (CISA):** Offers sector-specific guidance, threat alerts, and vulnerability scanning.
- **FDA (Section 524B):** Under FD&C Act Section 524B, requires extensive cybersecurity protocols for "cyber devices," including SPDF design, threat modeling, postmarket surveillance, and Software Bills of Materials (SBOMs). Compliance with NIST CSF and IEC 62443 adds further burden.
- **Best Practices:** Network segmentation (IT/OT isolation), multi-factor access control, vulnerability and patch management, incident response and third-party risk management, and employee training and awareness.
- **Supply Chain Security:** The DSCSA mandated unit-level drug traceability by November 2024. This requires serialization, EPCIS exchange, verification systems, and exception handling protocols—all substantial tech and process investments.
- **BIOSECURE Act:** If enacted, it would prohibit federal contract recipients from engaging with Chinese biotech firms like WuXi AppTec (heavily present in Philadelphia). Transitioning to new suppliers could disrupt timelines and increase costs.
- **Regulatory Landscape and Guidance:** The FDA's 2023 guidance for "cyber devices" emphasizes secure product design, threat modeling, and software bill of materials (SBOM) requirements.
- **Pennsylvania-Specific Needs:** Support for small and medium-sized enterprises (SMEs), particularly those without in-house cybersecurity teams, is essential. Partnerships with state agencies or industry groups like Life Sciences Pennsylvania (LSPA) could play a critical role in improving cybersecurity maturity statewide.
- **Additional state-level pressures:** include environmental compliance (hazardous waste, water, emissions) and the implementation of Act 77, Pennsylvania's new pharmacy benefit manager (PBM) oversight law, which adds transparency and regulatory complexity to market access.

Resilience and National Security Drivers: Supply chain resilience has become a national priority, with Pennsylvania playing a key role in efforts to mitigate global risks and prevent drug shortages.

- **Geopolitical Tensions:** Trade disputes, regional conflicts, and the "weaponization" of medicines threaten global supply stability.
- **National Security Policies:** The National Biodefense Strategy, EO 14017, and the BIOSECURE Act frame pharmaceutical supply as a critical defense issue.
- **Strategic Responses:**
  - **Supplier Diversification:** Engaging multiple or domestic suppliers to reduce single-source dependency.
  - **Near-shoring and Reshoring:** Rebuilding U.S. capacity for APIs, essential medicines, and sterile injectables.
  - **Technology Integration:** Use of AI, DSCSA-based traceability, and digital factory infrastructure.
  - **Public-Private Investment:** Leveraging federal (e.g., Defense Production Act (DPA), Biomedical Advanced Research and Development Authority (BARDA)) and state-level programs (RISE PA, PIDA) to support infrastructure buildout.

Consumer Trends

Demographics and Patient Health Priorities: Pennsylvania's aging population is reshaping pharmaceutical demand across the Commonwealth. With 3.4 million residents aged 60+, Pennsylvania ranks fifth nationally for older adult population. Projections suggest older adults will soon outnumber those under 20, due to rising life expectancies and declining birth rates. This demographic shift drives high and sustained demand for therapies addressing:

- Chronic conditions (e.g., diabetes, cardiovascular disease);
- Neurodegenerative disorders (e.g., Alzheimer's);

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- Oncological needs, as the state sees ~78,000 new cancer cases annually; and
- Preventative care, including adult vaccines.

Health equity is a growing concern. Rural areas, where ~540,000 residents live in "pharmacy deserts," report higher rates of skipped care and medication rationing due to cost. Tailored strategies—mobile units, telehealth expansion, and rural pharmacy support—are needed to address geographic barriers.

In addition, social determinants of health (SDOH) significantly affect outcomes. Factors such as economic hardship, social isolation, low health literacy, and limited transportation or digital access among older adults are especially prevalent and correlate with poorer health outcomes. Understanding these factors is essential for equitable pharmaceutical access and effective public health strategies.

- **Digital Health Adoption:** The digital transformation of healthcare is rapidly advancing across Pennsylvania, led by the state's major health systems and shaped by federal policy and pandemic-era reforms. Key Trends and Innovations:
- **UPMC (Level 10 "Most Wired"):** Deployed a DHN program that improved portal adoption; 98% of patients rated the program helpful.
- **Penn Medicine:** Pioneered AI-assisted message drafting via the MyChart portal, implemented ambient listening for clinical notes, and expanded home-based infusion care.
- **These technologies aim to:** Enhance clinician efficiency, improve patient-provider communication, support at-home care models, and increase patient autonomy and engagement.
- **Digital Divide Challenges:** Older adults, rural residents, and lower-income populations face barriers to digital health tool adoption due to limited digital literacy or broadband access. Programs like UPMC's DHN illustrate successful mitigation strategies but highlight the ongoing need for equity-focused digital inclusion efforts.

Patient Engagement and Experience: Patients increasingly expect convenient, tech-enabled care. Health systems are responding with a mix of human-centered design and digital automation.

- **Penn Medicine:** Integrated AI tools to manage more than 6 million annual patient messages; piloted tech to improve scheduling and reduce clinician burden.
- **UPMC:** Uses predictive analytics and patient engagement platforms to proactively support care continuity.
- **Statewide Consolidation:** Health systems like UPMC, Geisinger, Highmark-AHN, and Jefferson Health are expanding through integration, aiming for greater financial and operational efficiency, improved digital infrastructure, and broader service reach—including to vulnerable populations.
- **Digital engagement:** Via portals, telehealth, and apps, this is central to this evolution, enabling systems to compete on patient experience and access.

Affordability and Consumer Trust: Affordability is the most pressing healthcare concern for Pennsylvanians.

- 57% report healthcare affordability burdens.
- 83% worry about future healthcare costs.
- 51% delay or forgo care due to cost.
- 33% have medical debt or made basic-needs sacrifices to pay medical bills.
- Prescription drug prices are a major contributor. State- and federal policy efforts aim to relieve this burden.
- Federal Measures (Inflation Reduction Act):
  - Medicare price negotiations (beginning 2026)
  - $2,000 annual cap on Medicare Part D out-of-pocket costs (benefits ~73,000 Pennsylvanians)
  - $35 insulin copay cap (benefits ~154,000)
  - Expanded "Extra Help" eligibility (~23,000 new beneficiaries)
- **State Measures (Act 77 of 2024):** Regulates PBMs, bans patient steering and clawbacks, authorizes audits and transparency reporting, and seeks to reduce prices and protect local pharmacies (over 70 closures since 2024).

- **Trust and Perception:** Nationally, only 40% of individuals trust pharmaceutical manufacturers. In Pennsylvania, trust is closely tied to affordability and access. The tangible success of reforms like Act 77 and the IRA will likely shape future public sentiment toward the pharmaceutical industry in the Commonwealth.

Current Cost Trends

R&D Investment Landscape: Pharmaceutical R&D is both capital and time-intensive, with development timelines exceeding a decade and costs often surpassing $2 billion per new drug. Pennsylvania is deeply embedded in this high-investment landscape, supported by elite academic institutions and a robust private-sector presence, yet it faces challenges in commercialization and funding stability.

- **Academic Research Strength:** Pennsylvania ranks 4th nationally in higher education R&D expenditures, with nearly $5 billion in 2020, largely focused on life sciences. Penn and Pitt are major NIH funding recipients—$691.2M and $661.2M respectively in FY2024—with Penn's total federal funding exceeding $1B. This fuels significant innovation, particularly in fields like CGT.
- **Corporate R&D Footprint:**
  - Merck employs around 14,000 individuals in Pennsylvania, with its West Point facility serving as its global manufacturing flagship and Upper Gwynedd hosting U.S. R&D and Human Health headquarters. Merck has invested over $3B in its Pennsylvania operations.
  - GSK, headquartered in Philadelphia, is investing up to $800M in its Marietta site, including a new R&D pilot plant.
  - Other key players include J&J/Janssen, Bayer, and Teva, with each maintaining significant operations in the state.
- **Challenges:** Pennsylvania ranks 11th in venture capital inflow, 43rd in startup density, and 48th in new entrepreneurship. Translating academic discovery into commercial output is a key hurdle. Additionally, reliance on federal grants, especially NIH funding, creates vulnerability. Recent proposals to cap indirect cost reimbursements threatened nearly $240M in funding for Penn alone, highlighting the need for stable policy and enhanced commercialization pathways.

Manufacturing Costs & Operations in Pennsylvania

Pennsylvania's Pharmaceutical manufacturing base includes both large-scale and specialized operations. Cost drivers include labor, facility investment, energy, regulatory compliance, and adoption of new technologies. Major sites & investments:

- **GSK (Marietta):** Is undergoing $800M expansion to double capacity, add sterile manufacturing and R&D capabilities, and integrate smart manufacturing tools (digital twins, robotics, AI).
- **Merck (West Point):** Is the largest global facility for Merck, spanning 400 acres and producing vaccines, biologics, and pharmaceuticals.
- **Bayer (Myerstown):** Recent $44M expansion for over-the-counter (OTC) packaging.
- **BioTechnique (York):** Specializes in sterile injectables, including high-potency compounds.
- **Generics Sector:** Is still present but under pressure from national consolidation trends.
- **Labor & Facility Costs:** Pharma labor costs in Pennsylvania are ~33% higher than state averages, reflecting a skilled workforce.

NAICS 3254 saw a 5.3% wage increase in 2023 despite slight employment decline, indicating a tight labor market. Comparative site studies show the state to be cost-competitive:

- **Horsham Township:** $14.9M annual cost for a hypothetical R&D center is cheaper than Cambridge, Massachusetts or Princeton, New Jersey.
- **Philadelphia and Pittsburgh:** Ranks in the lower middle among 25 global manufacturing hubs for operating costs.
- **Energy & Sustainability:** Pennsylvania ranks 18th lowest nationally in industrial electricity rates (6.65¢/kWh). The RISE PA grant program ($396M) supports energy efficiency and renewables. Merck and GSK have integrated solar and water-saving technology at their facilities.

Industry Demographics

- **Efficiency Trends:** Nearly 90% of Pennsylvania manufacturers are investing in automation. GSK's expansion integrates AI-enabled scheduling and predictive maintenance. Firms like Adare use Lean/Six Sigma to boost productivity and cut waste.

CDMO Market Dynamics: Pennsylvania is a CDMO/CRO powerhouse, enabling pharmaceutical innovation and manufacturing across the product lifecycle. Key players:

- **Catalent (Philadelphia, Malvern):** Global CDMO was recently acquired for $16.5B by Novo Holdings.
- **Adare Pharma Solutions:** Headquarters relocated to Philadelphia; investing $16.8M in expansion.
- **PCI Pharma Services:** Global headquarters are in Philadelphia; invested $365M in new technologies.
- **WuXi AppTec:** Major CGT operations are in the Philadelphia Navy Yard.
- **Almac Group:** Claims multiple sites and a recent $65M expansion.
- **Other Notables:** Include Quotient Sciences, SK Pharmteco (CBM), Frontage Labs, Abzena, and BioTechnique.
- **Growth Drivers:** CGT demand is driving exponential growth (projected to grow from $5B in 2023 to $43B by 2032). CDMOs offer critical services in process development, vector production, fill-finish, and analytics. Pennsylvania's "Cellicon Valley" brand enhances its appeal for CGT manufacturing partnerships.
- **Risks & Geopolitics:** The proposed BIOSECURE Act could disrupt WuXi operations in Philadelphia by restricting federally funded work with Chinese CDMOs. WuXi is reportedly considering divestiture. This could open opportunities for domestic CDMOs at the risk of short-term service gaps.
- **Cost Factors:** Warehousing, inventory management, transport, and DSCSA compliance are key expenses. Automation and analytics are increasingly used to optimize operations. While specific costs are proprietary, Pennsylvania's dense healthcare market and infrastructure provide scale advantages and logistical efficiencies.

Future Cost Trends

Inflationary Pressures and Pricing Dynamics: Rising input costs across labor, energy, materials, and equipment continue to pressure pharmaceutical manufacturers. While specific inflation rates for pharma inputs aren't detailed, the broader economic climate necessitates strategic cost control.

The IRA of 2022 introduces systemic changes to pharmaceutical pricing, particularly for Medicare-exposed products.

- **Medicare Price Negotiation:** For the first time, Medicare negotiated prices for ten high-cost drugs without competition, yielding reductions of 38–79% from 2023 list prices, effective in 2026. This introduces price compression and revenue uncertainty for manufacturers targeting the Medicare market. While advocates highlight cost savings, Pharmaceutical Research and Manufacturers of America (PhRMA) argues it could suppress innovation. The Congressional Budget Office (CBO) estimates a modest reduction in future drug development.
- **Inflation Rebates:** Manufacturers must pay rebates if drug prices rise faster than inflation, disincentivizing steep price hikes for legacy drugs.
- **Medicare Part D Cap:** A $2,000 annual out-of-pocket cap (starting in 2025) will benefit roughly 73,000 Pennsylvanians annually, potentially increasing drug utilization and shifting payer costs.
- **Insulin Copay Cap:** Insulin copays have been capped at $35/month since 2023, impacting about 154,000 Medicare beneficiaries in Pennsylvania.

These provisions create complex downstream effects. The Pennsylvania Society of Health-System Pharmacists (PSHP) has flagged issues with the rebate-based model for delivering negotiated prices. Providers may face financial strain from fronting drug acquisition costs at wholesale prices while awaiting uncertain rebates. This is especially burdensome for safety-net hospitals. Manufacturers must reassess pricing and access strategies as IRA provisions reshape the reimbursement landscape.

- **Advanced Therapies (CGT):** Philadelphia's "Cellicon Valley" has cemented Pennsylvania as a global CGT hub, anchored by institutions like Penn and Children's Hospital of Philadelphia (CHOP) and commercialized through Spark Therapeutics, Adaptimmune, and spinouts like Tmunity, Carisma, Passage Bio, and iECURE. CGTs are transformative but costly.

- Personalized treatments, complex vectors (adeno-associated virus (AAV), lentivirus), and GMP-compliant facilities drive high per-patient costs.
- Specialized CDMOs (e.g., WuXi AppTec, Center for Breakthrough Medicines, Catalent) provide vector production, fill-finish, and analytics—at premium prices.
- CGT scale-up demands vast capital. Manufacturing, workforce specialization, and logistics complexity (e.g., cold chain) amplify expenses. Since 2013, over $4B in venture capital has been invested in Philadelphia's CGT firms, and NIH grants continue to support academic research.
- While growth is strong, long-term viability hinges on reducing costs via process innovations and securing viable reimbursement models. Managing CGT's economic burden is a defining industry challenge in Pennsylvania.

Industry Profits and Drivers

Industry Drivers

- **Cellicon Valley and the Rise of Cell & Gene Therapy:** Pennsylvania's pharmaceutical strength is driven by scientific innovation, most visibly embodied in Cellicon Valley—Philadelphia's globally recognized CGT hub. Built on foundational research from Penn and Children's Hospital of Philadelphia (CHOP), the region's CGT ecosystem emerged from landmark advances in chimeric antigen receptor T-cell (CAR-T) therapy and gene vector research (James Wilson). These discoveries catalyzed a commercial transformation.
  - **Major breakthroughs followed:** Spark Therapeutics—spun out of CHOP and now part of Roche—secured the first FDA-approved gene therapy for an inherited disease. Numerous Penn spinouts have advanced diverse CGT technologies:
    - Tmunity Therapeutics (CAR-T).
    - Capstan Therapeutics (in vivo CAR-T via messenger RNA (mRNA)/ lipid nanoparticles (LNP)).
    - Carisma Therapeutics (CAR-macrophages).
    - Passage Bio (central nervous system (CNS) gene therapies).
    - Verismo Therapeutics (CAR-T platforms).
    - iECURE (in vivo gene insertion for liver diseases).
- Other companies, like Integral Molecular, contribute to R&D with antibody discovery platforms and major federal contracts.
  - The CGT boom fuels competition for talent, venture capital (life sciences accounted for 20% of all VC funding in one recent year), and demand for advanced CDMO/CRO services. WuXi AppTec's CGT operations in the Navy Yard and the Center for Breakthrough Medicines in King of Prussia exemplify this supply-side growth. The region is projected to add 7,600–11,300 new CGT jobs by 2033.
  - This success stems from synergies between academic research (Penn, CHOP, Wistar), technology commercialization (PCI Ventures), state-supported incubators (Life Sciences Greenhouses), and a maturing services sector. These elements create a reinforcing innovation loop, anchoring Pennsylvania's leadership in CGT.
- **University Research Engines:** Outside CGT, Pennsylvania's pharmaceutical innovation pipeline is sustained by its research universities. In FY2023, Pitt ranked sixth and Penn fifth nationally in NIH funding, receiving $661M and $691M, respectively. In FY2024, Penn's total federal research funding exceeded $1B. Pitt's annual research expenditures top $1.2B, focused largely on health sciences.
  - Key strengths include infectious disease, vaccine R&D, oncology, neuroscience, and psychiatric research, each of which is foundational to emerging therapeutics. Every $1 of NIH funding generates an estimated $2.56 in economic activity, highlighting the downstream impact.
  - However, this innovation engine faces a critical funding threat. Proposals to cap reimbursement for indirect costs (F&A), which fund infrastructure, compliance, and safety, could slash budgets at Penn and Pitt by hundreds of millions annually. For Penn, a 15% cap could mean a $240M annual loss. These cuts would imperil lab operations, staffing, and innovation output—posing a systemic risk to the state's biopharma competitiveness.

Industry Demographics

Addressing Unmet Medical Needs

Pennsylvania's aging population drives demand for treatments addressing cancer, Alzheimer's, diabetes, and chronic illness.

- The state's strategic plan, "Aging Our Way, PA," prioritizes equitable healthcare access, long-term support, caregiver resources, and digital inclusion. Pennsylvania's pharmaceutical ecosystem is directly aligned:
  - Pitt excels in psychiatry, internal medicine, and neuro research;
  - Penn leads in cancer immunotherapy and gene therapies; and
  - GSK's respiratory syncytial virus (RSV) and shingles vaccines target aging populations.

This demographic-healthcare alignment offers both market opportunity and social impact for companies focused on aging-related therapies.

- Pennsylvania institutions support nearly 250 immuno-oncology clinical trials. CHOP and Penn continue to pioneer CGT.
- Pitt's Center for Vaccine Research and GSK's Marietta site are leaders in vaccine innovation.
- State policy also prioritizes rare disease research, enhancing the impact of targeted therapies.
- To address this, Pennsylvania has enacted Biomarker Testing Coverage mandates and Act 77 (2024) PBM transparency reforms.
- Federal support via the IRA includes Medicare drug price negotiations, a $2,000 annual cap on Part D out-of-pocket costs (starting in 2025), a $35 insulin monthly cap, and expanded Affordable Care Act (ACA) subsidies helping 346,000 residents.
- Digital health—via Penn, UPMC, and other systems—is improving access, though disparities in tech adoption persist. Balancing affordability with innovation incentives remains a central challenge for policymakers and industry alike.

Key National Defense Trends Affecting Pharma Manufacturing

- **Biosecurity Imperatives and MCM Needs**: National security strategy increasingly prioritizes biosecurity and pandemic preparedness, driving federal investment in MCMs. Pennsylvania's pharmaceutical sector, which is home to advanced research institutions, CDMOs, and major vaccine producers, stands to play a pivotal role.
- **Alignment with the National Biodefense Strategy:** The 2022 update to the U.S. National Biodefense Strategy outlines a comprehensive approach to mitigating biological threats, encompassing human, animal, and environmental health. The strategy emphasizes five core goals: improving risk awareness and detection, preventing bio incidents, ensuring preparedness to reduce impact, enabling rapid response, and supporting recovery. Crucially for pharma manufacturers, it stresses the need for scalable, agile manufacturing of therapeutics and vaccines and robust domestic supply chains for critical items, including MCMs and personal protective equipment (PPE).
- Pennsylvania is well aligned with these goals. Institutions like the University of Pennsylvania and the University of Pittsburgh are advancing pathogen research and novel countermeasures. GSK's Marietta facility provides significant vaccine capacity, and a strong network of CDMOs (e.g., Adare Pharma, PCI Pharma, and others) supports biologics, sterile injectables, and emerging modalities like CGT. State initiatives, such as investments in neurodegenerative disease research, also contribute to broader biosecurity priorities.
- **PHEMCE and BARDA's Role in MCM Preparedness:** The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), led by the U.S. Department of Health and Human Services (HHS) through Administration for Strategic Preparedness and Response (ASPR) and BARDA, is the federal coordination hub for MCM planning and procurement. It involves the Centers for Disease Control and Prevention (CDC), FDA, NIH and U.S. Department of Defense (DoD), and it targets threats from CBRN agents to pandemics and emerging diseases.
  - BARDA funds advanced R&D, scale-up, and procurement of MCMs. Between FY2023–2027, projected PHEMCE funding needs are $79.5 billion, but expected shortfalls may exceed $46 billion. A persistent challenge is the Strategic National Stockpile (SNS), where ongoing maintenance, like replenishing expiring MCMs, is often underfunded, leading to gaps in national preparedness for threats such as anthrax or smallpox.
  - Pennsylvania companies are positioned to support SNS needs. Janssen, with Pennsylvania-based operations, played a critical role in COVID-19 vaccine development. Persistent underfunding, however, may limit federal procurement, constraining Pennsylvania manufacturers' ability to fully leverage their capabilities.
- **Federal and State Incentives Fuel Growth:** The DoD leverages the DPA to support domestic capacity, including a $69.3M award to CONTINUUS Pharmaceuticals and a $410M loan to National Resilience Inc. for end-to-end biologics manufacturing.
- Technology Spillover from Defense Investments DoD and DARPA fund R&D with commercial relevance—AI, advanced materials, and agile pharma manufacturing.
  - **Battlefield Medicine and Bio-MOD**: Develop deployable, on-demand drug manufacturing platforms.
  - **SCOPE:** Aims to simplify drug synthesis.
  - **EQUIP-A-Pharma:** Seeks to modernize regulatory frameworks for flexible manufacturing.
  - **Dual-Use Potential & Gaps:** AI tools developed for military logistics could support pharma supply chains, but tech transfer mechanisms remain fragmented. A coordinated state or regional approach could link Pennsylvania companies to DoD innovations to leverage public R&D for commercial advantage.
- These innovations address core pharmaceutical challenges (speed, scale, cost, compliance) and have high commercial potential.

Leading Pennsylvania Manufacturers within NAICS 325

This section documents the leading players in the Pharmaceutical Manufacturing industry with operations in Pennsylvania and sorted alphabetically. Leading companies were selected based on revenue estimates.

Pennsylvania NAICS 325: Chemical Manufacturing

- **Almac Group Incorporated** (Souderton)
- **Cephalon LLC** (West Chester)
- **Colorcon, Inc**. (West Point)
- **CSL Behring L.L.C.** (King OF Prussia)
- **Endo Health Solutions Inc.** (Malvern)
- **Endo, Inc.** (Malvern)
- **Frontage Laboratories, Inc.** (Exton)
- **GlaxoSmithKline LLC** (Philadelphia)
- **Harmony Biosciences Holdings, Inc.** (Plymouth Meeting)
- **Janssen Biotech, Inc.** (Horsham)
- **Krystal Biotech, Inc.** (Pittsburgh)
- **Lannett Company, Inc.** (Trevose)
- **Madrigal Pharmaceuticals, Inc**. (West Conshohocken)
- **Mylan Inc.** (Canonsburg)
- **Piramal Critical Care, Inc.** (Bethlehem)
- **Sanofi Pasteur Inc.** (Swiftwater)
- **Spark Therapeutics, Inc.** (Philadelphia)
- **Viatris Inc.** (Canonsburg)

Pharma Manufacturing Buyers and Suppliers Relationships

Suppliers

Chemical Manufacturing (Active Pharmaceutical Ingredients - APIs)
Biological Product Manufacturing
Specialty Chemical Manufacturing
Glass Product Manufacturing (vials, ampoules)
Plastic Packaging Manufacturing
Label & Carton Printing Services
Lab Equipment & Analytical Instrument Manufacturing
Pharmaceutical Machinery & Equipment Wholesaling
Cold Chain Logistics Providers
Contract Research Organizations (CROs)
Contract Development and Manufacturing Organizations (CDMOs)
Utilities
Cleanroom Supplies and Environmental Controls
Livestock/Biological Feedstock (for biologics or vaccine production)

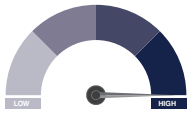
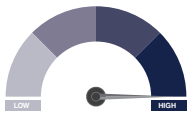
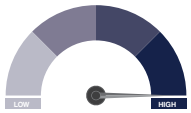
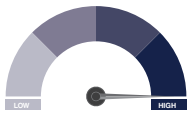
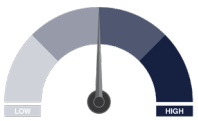
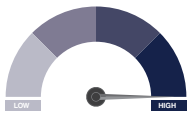
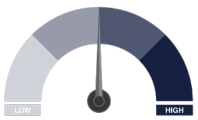
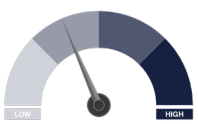
Pharmaceutical Manufacturing

Buyers

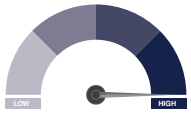
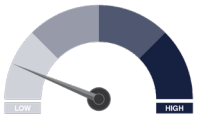
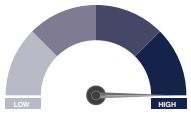
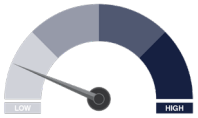
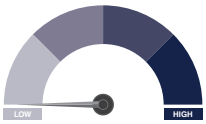
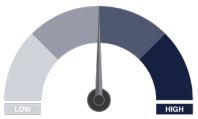
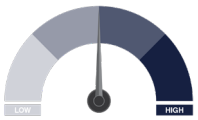
Hospitals
Pharmacies (Retail & Mail Order)
Veterinary Clinics
Government Health Agencies (e.g., CDC, NIH, DoD)
Wholesalers & Distributors
Clinical Research Organizations
Health Maintenance Organizations (HMOs)
Public Health Systems
Export Markets (International Distributors)
Specialty Clinics (e.g., Oncology, Fertility, Pain Management)
Insurance Companies (Formulary Management)
Pharmacy Benefit Managers (PBMs)
Compounding Pharmacies
Emergency Preparedness Stockpiles
Academic Research Institutions

* Industries within Critical Infrastructure highlighted in **RED**

Pharma Manufacturing Impact on Critical Industries

Critical Industry Sector as defined by Cybersecurity & Infrastructure Security Agency (CISA)	What the Critical Industry Provides to Pharma Manufacturing	Impact of Critical Industry on Pharma Manufacturing	U.S. Growth Rate (2023)
Communications – interconnected industry using terrestrial, satellite, and wireless transmission system	- Provides real-time coordination across production, distribution, and compliance systems through telecommunications networks. - Supports industrial control systems and secure data sharing essential for pharmaceutical quality and traceability. - Enables remote facility monitoring, tele maintenance, and digital records management.		1.43%
Chemical - manufactures, stores, uses, and transports potentially dangerous chemicals	- Supplies base chemicals, reagents, solvents, and excipients used in pharmaceutical formulations. - Supports synthesis of APIs and intermediates. - Critical to the purification, testing, and preservation processes in drug manufacturing.		-1%
Commercial Facilities - diverse range of sites that draw large crowds of people for shopping, business, entertainment, or lodging	- Includes physical infrastructure for pharmaceutical R&D, production, and warehousing. - Supports cold chain logistics and climate-controlled storage for temperature-sensitive drugs. - Provides retail pharmacy space and distribution centers facilitating access to medicine.		3.4%
Critical Manufacturing - significant manufacturing industries that may be susceptible to manmade and natural disasters	- Produces specialized pharmaceutical machinery such as reactors, filtration systems, and isolators. - Supports packaging and labeling automation technologies. - Supplies spare parts, sensors, and monitoring systems essential for cGMP-compliant production.		-2%
Dams - delivers critical water retention and control services	- Ensures stable water supply for industrial processes like formulation, equipment sterilization, and cooling. - Contributes hydroelectric power to pharma operations in energy-diverse regions. - Supports flood control to protect manufacturing assets.		6%
Defense Industrial Base - research and development, design, production, delivery, and maintenance of military weapons systems, subsystems, and components or parts, to meet U.S. military requirements	- Collaborates with pharma manufacturers to produce medical countermeasures. - Funds R&D for vaccines and treatments critical to national security. - Enables rapid scale-up of emergency drug production through DOD partnerships.		8%
Emergency Services - community highly-skilled, trained personnel, along with the physical and cyber resources, that provide a wide range of prevention, preparedness, response, and recovery services	- Protects pharma facilities during hazardous events, fires, or chemical spills. - Provides rapid emergency medical services (EMS) response to protect life and prevent facility downtime. - Coordinates secure medicine transport during disasters or public health emergencies.		5.8%
Energy - protects a multifaceted web of electricity, oil, and natural gas resources and assets to maintain steady energy supplies	- Delivers continuous electric power required for cleanrooms, automation, and cold storage. - Provides natural gas for steam generation, sterilization, and high-energy manufacturing steps. - Enables uninterrupted operations through grid and backup power infrastructure.		9.3%
Financial Services - depository institutions, providers of investment products, insurance companies, other credit and financing organizations, and the providers of the critical financial utilities and services that support these functions	- Offers capital financing for facility development and expansion. - Provides risk mitigation tools such as insurance against supply chain disruption. - Supports global pharma trade via credit, payments, and foreign exchange systems.		7.7%

Pharma Manufacturing Impact on Critical Industries

Critical Industry Sector as defined by Cybersecurity & Infrastructure Security Agency (CISA)	What the Critical Industry Provides to Pharma Manufacturing	Impact of Critical Industry on Pharma Manufacturing	U.S. Growth Rate (2023)
Food and Agriculture - composed of farms, restaurants, and registered food manufacturing, processing, and storage facilities	- Supplies biological ingredients used in drugs and vaccines (e.g., eggs for flu vaccine, heparin from livestock). - Provides fermentation feedstocks (e.g., sugars) used in microbial drug production. - Contributes excipients like gelatin, lactose, and starch from agricultural sources.		3.1%
Government Facilities - a wide variety of buildings, located in the United States and overseas, that are owned or leased by federal, state, local, and tribal governments	- Hosts public labs and regulatory agencies (e.g., FDA, NIH) supporting compliance and R&D. - Provides infrastructure for SNS and emergency coordination. - Regulates clinical trials, facility licensing, and post-market surveillance.		1.6%
Healthcare and Public Health - protects all sectors of the economy from hazards such as terrorism, infectious disease outbreaks, and natural disasters	- Drives pharmaceutical demand based on population health needs. - Collaborates in surveillance, reporting, and preparedness planning. - Ensures distribution and administration of pharmaceutical products during crises.		6%
Information Technology - produce and provide hardware, software, and information technology systems and services	- Powers MES, batch records, and digital quality systems. - Enables predictive maintenance, sensor networks, and bioinformatics tools. - Provides cybersecurity frameworks for protecting intellectual property and production data.		8.2%
Nuclear Reactors, Materials and Waste - America's civilian nuclear infrastructure	- Supplies radioisotopes for diagnostic imaging and cancer treatments. - Supports sterilization of medical equipment and certain drugs. - Ensures proper disposal of radioactive materials used in pharma processes.		1.4%
Transportation Systems - Aviation, Highway and Motor Carrier, Maritime Transportation System, Mass Transit and Passenger Rail, Freight Rail, and Postal and Shipping	- Facilitates inbound logistics (chemicals, vials, components) and outbound pharma distribution. - Provides air freight and cold-chain services for temperature-sensitive products. - Supports secure transport of controlled substances and high-value goods.		8.8%
Water - public drinking water systems and wastewater treatment systems	- Delivers potable and high-purity water essential for drug formulation and cleaning. - Enables steam generation and heating, ventilation, and air conditioning (HVAC) regulation in good manufacturing practice (GMP) environments. - Treats pharmaceutical wastewater to meet regulatory and environmental standards.		6.8%

Supply Chain Partners

The Pharma Manufacturing supply chain depends on a number of suppliers for raw materials, components, technologies, and infrastructure services. It also serves a broad spectrum of demand industries, including healthcare providers, government agencies, national defense contractors, and specialized retailers. Below is an overview of the major input supplier and end-use demand sectors, organized by category:

Major Supply Industries

- **Biological Product (except Diagnostic) Manufacturing (NAICS 325414):** Supplies biologic inputs used in vaccine and therapeutic production.
- **Pharmaceutical Ingredient Manufacturing (NAICS 325412):** Provides APIs and excipients critical to drug formulation.
- **Chemical Manufacturing (NAICS 325199):** Supplies specialty chemicals, solvents, reagents, and synthesis agents used in pharmaceutical R&D and production.
- **Glass Product Manufacturing (NAICS 327212):** Produces vials, ampoules, and containers for injectable and oral dosage forms.
- **Plastic Packaging Manufacturing (NAICS 326199):** Provides blister packs, syringes, and other drug delivery and packaging materials.
- **Pharmaceutical Machinery Manufacturing (NAICS 333248):** Delivers equipment for drug formulation, filling, sterilization, and packaging.
- **Cleanroom HVAC and Environmental Controls (NAICS 238220):** Supplies systems critical for maintaining sterile environments in GMP-compliant facilities.
- **Cold Chain Logistics (NAICS 493120):** Supports temperature-controlled transport and storage of vaccines, biologics, and other sensitive products.
- **CROs & CDMOs (NAICS 541714/325412)**: Provide R&D services, clinical trial support, and contract-based drug manufacturing expertise.
- **Utilities (NAICS 221310/221122):** Deliver essential water and power services for pharmaceutical production and compliance.

Major Demand Industries: Pharma Manufacturers are strategic partners to U.S. defense contractors and the Department of Defense (DoD), playing a critical role in sustaining the Defense Industrial Base (DIB). They also support numerous other essential infrastructure sectors by ensuring reliable access to life-saving medicines, vaccines, and therapeutics. Pharma Manufacturers also supply other critical infrastructure sectors, including:

- **Hospitals and Surgical Centers (NAICS 622110):** Require a continuous supply of pharmaceuticals for inpatient and outpatient care.
- **Retail Pharmacies and Drug Stores (NAICS 446110):** Major distribution points for prescription and over-the-counter pharmaceuticals.
- **Veterinary Clinics (NAICS 541940):** Purchase specialized pharmaceuticals for animal health.
- **Federal and Military Health Systems (NAICS 928110):** Depend on pharmaceutical manufacturers for active duty, veteran, and defense-related healthcare.
- **Long-Term Care Facilities and Nursing Homes (NAICS 623110):** Consume high volumes of chronic disease and supportive care medications.
- **Correctional Facilities (NAICS 922140):** Require reliable access to prescription drugs for incarcerated populations.
- **Emergency Preparedness & Disaster Relief (NAICS 624230):** Stockpile and deploy pharmaceuticals for rapid response scenarios, including pandemics and biothreats.
- **Insurance & Pharmacy Benefit Managers (NAICS 524114):** Influence purchasing and distribution based on formulary management.
- **Clinical Research Institutions (NAICS 541715):** Use investigational drugs in early-stage and late-phase clinical trials.
- **Public Health Agencies (NAICS 923120):** Procure vaccines, therapeutics, and strategic stockpile materials for public health initiatives.

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