



The Outsourcing of CQV and GMP Automation Services

Playing the Capital Spending and AI Adoption Cycle in Pharma and Biotech Manufacturing

October 2026

Table of Contents

Key Takeaways on the Commissioning, Qualification, and Validation (CQV) and GMP Automation Services Marketplace	6
Section 1: The Marketplace for CQV Outsourcing Services	7
Section 2: Good Manufacturing Practice (GMP) Automation and Digital Manufacturing Services	30
Section 3: Valuation and M&A Considerations	45
Section 4: Profiles of Select Service and Software Providers	57
Appendix: Bourne Partners Overview	65



Donald Hooker, CFA
Director of Research
dhooker@bourne-partners.com
+1 980.414.0945



Jeremy Johnson
Senior Managing Director, Head of IB
jjohnson@bourne-partners.com
+1 704.201.2323



James West
Managing Director
jwest@bourne-partners.com
+44 7456.427.468



Jake Curtis
Director
jcurtis@bourne-partners.com
+1 980.372.2566



Ryan Silvester
Vice President
rsilvester@bourne-partners.com
+1 980.372.7450



Nick Triantafyllides
Vice President
nickt@bourne-partners.com
+1 980.372.7567



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Pharma Services and Technology Expertise



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Clinical & Drug Discovery Services

Full-Service & Specialty CROs
Site Networks / SMOs
Patient Recruitment
Patient Engagement & Retention
Patient Logistics & Payments
eClinical (eCOA, ePRO, IRT, EDC, CTMS, RBQM)
Pharma, CRO, & Site Technology
RWD, RWE, & Data Analytics
Hub & Patient Support Services
Life Sciences Consulting



Commercialization Services

Market Access
Medical Communications & Education
Healthcare Marketing / Advertising
Commercial Patient / HCP Engagement
Market Access & Pricing, HEOR, & RWE
Medical & Regulatory Affairs
Post-Market Safety & Pharmacovigilance



Pharma
Services



Pharma /
Therapeutics



Healthcare
Services

Select Pharma Services Transactions

JLL Partners

has acquired

CAI

Buy-Side M&A

PROJECT FARMA

a subsidiary of
**PRECISION
MEDICINE
GROUP**

a portfolio company of
Blackstone

has been acquired by
PerkinElmer
a portfolio company of
NMC
NEW MOUNTAIN CAPITAL

**Lifecore
BIOMEDICAL**

has entered into a
definitive agreement to
be acquired by

Webster
Equity Partners

Sell-Side M&A

**SUMMIT
BIOSCIENCES INC.**

has been acquired by

Kindeva
DRUG DELIVERY

a portfolio company of
ALTAIIS

Sell-Side M&A

TAPEMARK

has been acquired by

LTS
TRANSDERMAL MARKETLEADER

Sell-Side M&A

Afton Scientific

has sold a
majority stake to

ACP

Sell-Side M&A

Foreword

Anshul Mangal, President, Pharma Specialty Services, PerkinElmer

Pharma and biotech manufacturing are facing one of the most significant periods of infrastructure investment in decades. Across the industry, companies are preparing to meet growing demand for increasingly complex therapies by rapidly expanding domestic capacity. In the last two years alone, major pharmaceutical companies have announced over \$500 billion in new US manufacturing investments. Realizing the value of that investment will depend on how effectively new facilities move from construction into reliable and compliant production.

Key workstreams like commissioning, qualification and validation (CQV) may account for only 5–10% of direct project costs for a typical pharma manufacturing expansion, but final drug product cannot be released commercially until that work is complete. This work begins well before a facility is built and continues until the facility is operational. Its influence on the overall project is substantial, helping determine whether production can begin without unnecessary delays or risk.

Meanwhile, manufacturing expansion is becoming ever more complex through the increase of automation and the integration of data. More digital manufacturing networks require tighter integration within a validated environment, as disconnected CQV and good manufacturing practice (GMP) automation workstreams can leave gaps in accountability, documentation, testing, and scheduling at the handoffs. By connecting these workstreams earlier in the project lifecycle, teams can reduce friction and prepare facilities for the demands of modern manufacturing.



Anshul Mangal
*President, Pharma Specialty Services
at PerkinElmer*

Key Figures

\$500bn+

Of new US manufacturing capital investment announced by pharma and biotech companies over just the past two years

5–10%

CQV share of direct project costs, yet product cannot be released until complete

Foreword (Continued)

Executing these critical areas for operational readiness requires deep specialist expertise across CQV, automation, and manufacturing. Meeting regulatory expectations is another important piece of the puzzle, requiring seamless coordination across functional teams and site operations. At a time when specialist talent remains constrained, experienced partners can help companies scale manufacturing capability efficiently while maintaining the quality and compliance standards the industry requires.

At PerkinElmer, we have combined the expertise of three global pharma solution providers, OneSource, Project Farma, and SimoTech, into a single Pharma Specialty Services platform to ensure there are fewer handoffs and stronger continuity across the entire R&D and manufacturing lifecycle. Connecting these services is especially important as facilities become more digital and technically complex, helping life science innovators operate reliably, meet regulatory requirements, and produce at scale.

Looking ahead, digital tools and AI will continue to add another layer of complexity to pharma manufacturing. Before AI can create value in a regulated environment, the underlying systems, data flows, and controls must be connected and validated. Many sites are still working through legacy systems, fragmented data, and paper-based processes — groundwork that will support the safe and effective use of AI tools in regulated environments.

As this investment cycle continues, success will increasingly be measured not simply by how much new capacity is built, but by how effectively that capacity is brought online and operated over time. For patients, new manufacturing capacity only matters when it translates into safe, reliable and timely access to critical medicines. This report examines the market supporting that work, and the capabilities companies will need to bring new capacity online successfully as pharmaceutical manufacturing continues to evolve.

“Success will increasingly be measured not simply by how much new capacity is built, but by how effectively that capacity is brought online and operated over time.”

One Integrated Platform

OneSource

Project Farma

SimoTech

Now one Pharma Specialty
Services platform

Anshul Mangal

President, Pharma Specialty Services
PerkinElmer
Founder of Project Farma

Bourne Partners Takeaways on CQV/GMP Automation Services

Looking ahead, **we see a multi-year period of strong revenue and earnings growth for providers of commissioning, qualification and validation (CQV) services** -- as well as for good manufacturing practice (GMP) automation and digital manufacturing. In our view, pharma and biotech manufacturing is in the early stages of a capital spending super-cycle that is being led by the United States, with new favorable regulations also coming out of Europe.

- 1 We believe that demand for outsourced CQV and GMP automation services generally tracks pharma and biotech capital spending trends** at a roughly two-to-three-year lag. Since early 2025, pharma companies have announced over \$500 billion of U.S. investment, driven by tariffs, shipping costs, and scrutiny into offshore production. Not all of this will be capital spending, of course, but even a fraction of it could lift demand for CQV and automation services for years. Also, the rising therapeutic complexity of the drugs in the development pipeline is implying more validation work per dollar of capital spending.
- 2 Artificial intelligence (AI) continues to be top-of-mind for pharma and biotech executives.** To be fully effective, AI requires structured data and connected systems that most pharma/biotech manufacturing facilities lack, and building them requires integration, migration, and validation work that goes largely to third parties. Also, if adopted as drafted, the European Commission's Annex 22 would turn AI used in critical GMP applications into recurring qualification and monitoring work.
- 3 We see a compelling case for combining CQV and GMP automation services on one platform.** An integrated provider removes the handoffs that cause rework and product launch delays, particularly as more manufacturing expansion projects are being designed with AI enablement in mind. **PerkinElmer** is the clearest example, acquiring **Project Farma** (CQV) in March 2025 and **SimoTech** (GMP automation) in September 2026. **Cognizant** and **NNIT** provide earlier examples.
- 4 The adoption and use of digital validation tools (DVTs) should reduce billable hours per project**, in our view. However, DVTs improve the economics of outsourcing. A small or mid-sized pharma or biotech manufacturer with only a few sites can rarely justify the cost of a DVT platform, while a CQV provider can spread out the cost, template library, and know-how across dozens of sites/projects. Also, providers that scale DVTs should gain market share and expand profit margins even if pricing falls.
- 5 We see CQV and GMP automation providers generally being valued in the low/mid-teens as a multiple of forward EBITDA** -- bracketing the valuations of public pharma services and engineering and technical consulting firms. Disclosed deal values have been limited, but a number of sponsor platforms are past their typical holding periods -- suggesting more deal activity ahead.



The Marketplace for CQV Outsourcing Services

What is Commissioning, Qualification, and Validation (CQV)?

Commissioning, qualification, and validation (CQV) is the documented, good manufacturing practice (GMP) work of demonstrating to regulators and others that a pharma or biotech manufacturing facility -- i.e., its clean utilities, equipment, and processes -- does what it was designed to do before the commercial production of a drug begins.

Commissioning is the engineering start-up and functional testing against design intent, including factory and site acceptance testing (FAT/SAT). It is executed under good engineering practice (GEP) rather than GMP, and covers issues like setting to work, balancing, loop checks, and turnover of facilities, utilities, and equipment to the end user. The work generally begins as initial construction completes, although FAT happens earlier, at the vendor's shop before equipment ships. Under a risk-based approach, documented commissioning can be leveraged into qualification instead of being repeated, assuming the testing is traceable to user requirements. This is where most of a capital project's schedule and cost savings are found, in our view.

Qualification is the quality-governed verification that follows. It runs from user requirements and design qualification (URS/DQ) through installation, operational, and performance qualification (IQ/OQ/PQ), confirming that systems are installed as designed, are operating across their intended ranges, and are performing reliably. Scope is set by risk assessment against the critical aspects that affect quality and safety, and documentation is approved by dedicated quality assurance staff, not the engineers. Most of this qualification work is done by the start of commercial production; however, change controls, periodic reviews, and re-qualifications continue for the life of the asset.

Validation then tests processes thereafter. This involves proving that the manufacturing process, e.g., cleaning between batches, the software that runs and records production, and the lab methods that check quality, are executed the same way every time -- ensuring every batch of product -- not just the first -- meets the quality standards set in advance. Formally it is a three-stage lifecycle: process design, process performance qualification (PPQ) on commercial-scale batches, and then continued process verification (CPV) that monitors output batch by batch in routine production. Validation is therefore an ongoing operating obligation, not a one-time activity at start-up.



How CQV Fits Within a Larger Pharma Manufacturing Project

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Varying Modalities of CQV Service Outsourcing

Commissioning, qualification, and validation (CQV) is expensive and occurs sporadically. Because of this, pharma and biotech companies tend to outsource CQV activities to third-parties rather than carry idle staff between projects. The form of this outsourcing can vary, depending on the need for specialization and the price sensitivity of the customer.

Pharma and biotech companies are able to do CQV work themselves in-house, of course, but the need for CQV services arrives in bursts and requires expensive engineering staff for short periods of time -- by our estimates, ~3 to 6 months for a single piece of equipment, ~6 to 12 months for a new manufacturing line, and ~12 to 18 months for a full facility. As indicated previously, the need for CQV work does not completely go away once a manufacturing facility starts commercial production since change controls, periodic re-qualifications, and revalidations will continue. However, this steady-state CQV work is a fraction of the initial/up-front work.

In our view, **this is a primary reason why CQV is mostly and increasingly outsourced to third-parties.** The inconsistency of the need for CQV work means that small/mid-sized manufacturers would otherwise have to hold idle staff between capital projects. So, manufacturers often outsource project-by-project and site-by-site. Contracts are typically priced on billable hours with traditional change-order mechanics, while more complex contracts can be priced on the achievement of milestones and readiness dates.

Various Modalities of CQV Outsourcing

The **"programmatic"** approach to CQV outsourcing involves the provider being fully responsible for protocol authorship, execution, and deviation resolution, often under multi-year master service agreements across a client's site network. Since the provider owns the deliverables and the schedule, this model can be priced to target dates and outcomes rather than to hourly rates. This creates the potential for higher profit margins than does hourly work.

"Flexible resourcing" is akin to a contract staffing model in which the CQV provider places specialist engineers under the client's control. Here, the client keeps the deliverables, the schedule, and the risk. Providers, in turn, compete on access to labor and speed of mobilization. Revenue is time-and-materials (hourly rates), and tracks headcount and utilization. Profit margins are thinner as a result. The upside is that this model scales quickly, and it can convert into program work.

"Bundled delivery" involves CQV being delivered from within a broader engineering, procurement, and construction management (EPCM) contract. This results in one provider having single accountability from design through startup. Execution is more seamless and often quicker given the integration. However, the trade-off is less independence. Also, the contractor treats CQV as a deadline to meet rather than a service to profit from.

Mapping the Marketplace of Third-Party CQV Providers

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CQV Services Offered Through Larger A/E/C Firms

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Key Factors Impacting CQV Outsourcing Over the Next 5 Years

Looking ahead, **we believe there is good visibility to high single digit annual growth in commissioning, qualification, and validation (CQV) spending** in the coming years, with an increasing mix going to third-party specialists. Key drivers include pharma capital spending, regulatory expectations, therapeutic complexity, labor, and digital validation tools.

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research@bourne-partners.com*

Super-Cycle in U.S. Pharma and Biotech Capital Spending

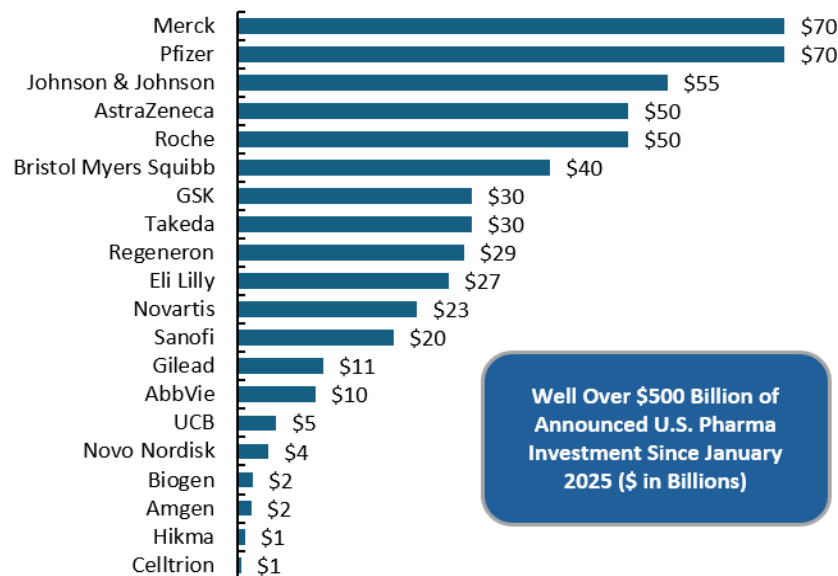
In our view, **the U.S. pharma and biotech industry is in the early innings of a multi-year capital spending “super-cycle”** that is being driven by recently announced tariffs on pharma imports by the Trump administration -- as well as by rising energy and transportation costs and elevated regulatory scrutiny into overseas manufacturing facilities. This, in turn, represents revenue opportunity for providers of commissioning, qualification, and validation (CQV) services.

We estimate that total capital spending by U.S. pharma companies and biotech firms -- including contract development and manufacturing organizations (CDMOs) -- has averaged \$40 billion to \$50 billion annually in recent years. Since early 2025, we have tracked public announcements of planned investments in domestic pharma manufacturing (and research and development) infrastructure totaling well over \$500 billion. Spread over a hypothetical five-year time horizon, this would imply well over \$100 billion of annual capital spending -- essentially double current spending levels.

As indicated previously, **every new facility, suite, utility system, cleanroom, and warehouse must be commissioned, qualified, and validated** before it can be used to manufacture a final drug product. This work generally falls toward the end of a construction or expansion project. We therefore expect demand for CQV work to track pharma and biotech manufacturing capital spending at roughly a two-to-three-year lag. These same facilities, suites, systems, cleanrooms, and warehouses also require ongoing re-qualifications, change controls, and computerized system validations for the rest of their useful lives.

The result is a two-stage revenue profile for CQV providers -- first an initial revenue spike tied to construction, startup, or expansion, and then recurring revenues tied to an underlying installed base.

Announced U.S. Pharma Manufacturing/Other Investments Since January 2025 (\$ Bils)
(All figures are publicly announced estimates of multi-year investment commitments)



**Well Over \$500 Billion of
Announced U.S. Pharma
Investment Since January
2025 (\$ in Billions)**

Bringing Pharma Manufacturing Back to the United States

Much of the aforementioned expected super-cycle of U.S. pharma and biotech manufacturing capital spending -- and the associated demand for commissioning, qualification, and validation (CQV) services -- is a function of the policy priorities of the current Trump administration. Since early in his second term, President Trump has used tariffs and Most Favored Nation (MFN) pricing agreements to "jawbone" pharma companies to shift their drug manufacturing onshore.

In April 2026, the Trump administration announced a new system of tariffs on branded pharma products (and patented pharma ingredients) under Section 232 of the *Trade Expansion Act*. Imports from certain countries that have already entered into trade agreements with the Trump administration (which separately already include their own pharma tariffs) are exempt -- as well as generics and biosimilars, orphan drugs, cell and gene therapies, antibody-drug conjugates, plasma-derived and fertility products, nuclear medicines, and other specialty therapeutics. *All other pharma related imports are subject to a 100% tariff.*

Pharma companies and biotech firms can avoid this tariff by entering into Most Favored Nation (MFN) deals that involve pricing concessions and a commitment to U.S.-based manufacturing infrastructure. By our count, twenty-six (26) pharma companies have entered into MFN agreements with the Trump administration. Separately, companies that sign onshoring agreements with the U.S. Department of Commerce, without an MFN deal, face a reduced 20% tariff rate. Applicants for this reduced tariff must submit onshoring plans, including product-level manufacturing locations, use of contract manufacturers, the share of portfolio to be produced onshore, and the percent of patented drugs made with U.S.-sourced ingredients.

Tariff Category	Tariff Rate	Bourne Partners Commentary
Most Favored Nation (MFN) Pricing and Onshoring Agreement with U.S. Department of Commerce	0%	Pharma/biotech company must agree to MFN pricing and enter into onshoring agreement with Commerce Department; Applies through January 2029
Onshoring Agreement (Only)	20%	Pharma/biotech company must commit to building U.S. manufacturing capacity via an agreement with the U.S. Department of Commerce
Existing Trade Deal Countries (e.g., European Union, Japan, South Korea, and Switzerland)	15%	Existing trade agreements that include a lower tariff rate on pharma imports
United Kingdom	10%	Existing favorable trade agreement with the United Kingdom
Generics, Biosimilars, and Orphan Drugs	0%	Fully exempt from tariffs, although recent commentary from the Trump administration suggests tariffs on generics and biosimilars could be coming
All Other Branded Pharmaceuticals	100%	Default tariff rate

Most Favored Nation Deals and Commitments to Onshore

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Rising Energy / Transportation Costs and Quality Concerns

We believe that there are other factors driving the current super-cycle in U.S. pharma and biotech capital spending outside of the trade policy of the Trump administration. This includes rising energy, shipping, and transportation costs as well as quality and regulatory concerns with overseas pharma/biotech manufacturers -- e.g., particularly in Asia/China.

Tariffs and trade policy are becoming critical drivers of where pharma manufacturing is being done. However, there are other factors to consider as well. We have heard commentary from various pharma executives about a number of different reasons as to why they are choosing to onshore their manufacturing to the United States (or Europe), regardless of tariffs. In fact, we suspect that many of the announcements of pharma manufacturing expansions in the United States over the past eighteen months were likely the result of decisions made well before President Trump was elected -- given the typical 12 to 36-month planning cycle for the typical greenfield construction of a new pharma manufacturing facility.

Most notably, **from 2019 to 2025, pharma companies have seen a 60%-75% increase in overseas shipping costs.** This is particularly impactful for medications requiring specialized storage. **Eli Lilly (NYSE-LLY)**, for instance, announced \$27 billion of domestic manufacturing investment in 2025. While this coincided with threats by the Trump administration to implement tariffs on pharma imports, we suspect that much of this decision may have been influenced by the increasing cold chain storage costs for GLP-1 drugs (~70% of which are consumed in the United States). And concerns about pharma shipping and transportation costs have only likely worsened in recent months given the ongoing war with Iran and concerns about shipping through the Strait of Hormuz.

Ocean Component	2019	2025	Pharma Executive Supply Chain Security Survey	
Dry Container (Baseline)	\$1,400 - \$2,500 / FEU	\$2,400 - \$3,200 / FEU	92% say risk has increased over past two years	94% expect risk to increase further
Reefer Multiplier	2-3x Dry Rates	2-3x Dry Rates		
Standard Reefer	\$3,000 - \$5,000 / FEU	\$5,500 - \$10,000 / FEU	57% product tampering as top in-transit issue	44% cite temperature control damage
Pharma Premium	+40%-60% Over Reefer	+40%-60% Over Reefer		
Pharma Cold Chain (Est)	\$5,000 - \$8,000 / FEU	\$8,000 - \$14,000 / FEU		
Result	~60%-75% Increase from 2019 to 2025			

Retrofitting Existing Manufacturing Facilities

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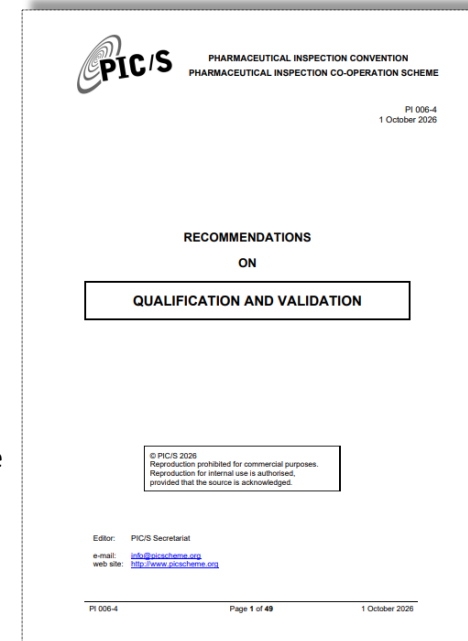
Rising and Expanding Regulatory Guidelines and Pressures

We see demand for commissioning, qualification, and validation (CQV) services also being driven by expanding regulatory guidelines and pressures. Most recently, this includes revised guidelines by the *Pharmaceutical Inspection Co-operation Scheme (PIC/S)*, replacing earlier guidelines that had been in place for almost twenty years.

The rising CQV guidelines are easiest to observe in the area of sterile manufacturing, in our opinion. The revised European Union Good Manufacturing Practice (EU GMP) Annex 1 took effect in August 2023, with its requirement on loading and unloading freeze-dryers (lyophilizers) following a year later. This was the first comprehensive overhaul of Annex 1 since 2008, and it called for a reorganization of sterile manufacturing around a single, plant-wide “Contamination Control Strategy” that management must review and keep current. The PIC/S adopted identical text on the same dates. So, the new Annex 1 standards now apply across most of the world. For a provider of CQV services, this means requalifying rooms and utilities, upgrading barriers and isolators, redesigning the trial runs that prove sterile lines stay clean, and generating fresh supporting data.

A bigger change came in July 2026 with the PIC/S publishing fully revised guidelines for CQV (“Recommendations on Qualification and Validation”), to be effective in October. The new guidelines are considerably broader than earlier guidelines, adding formal steps ahead of installation, operational, and performance qualification: the user requirements specification, design qualification, and factory and site acceptance testing. It also allows manufacturers and CQV providers to use a risk-based approach to test equipment that is still proven fit for use. Finally, the guidelines now apply to active pharmaceutical ingredients (APIs) and intermediates as well as finished drugs, and they add requalification, ongoing process verification, utilities qualification, transportation verification, and packaging validation.

Separately, **the European Medicines Agency (EMA) and PIC/S are currently drafting a revision of Annex 15**, the binding rule these recommendations sit under, to extend it to active substance manufacturers (the European term for API makers) and line it up with the risk-management principles of the International Council for Harmonisation (ICH) guideline Q9(R1). Notably, when a rule that defines a deliverable changes, every validation master plan, protocol template, and requalification cycle in the installed base becomes a new work item for a CQV provider.



Increasing Regulatory Inspection and Enforcement Activity

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research@bourne-partners.com*

Therapeutic Complexity Raises Validation Pressures

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Labor Shortages Should Play Well to CQV Outsourcing

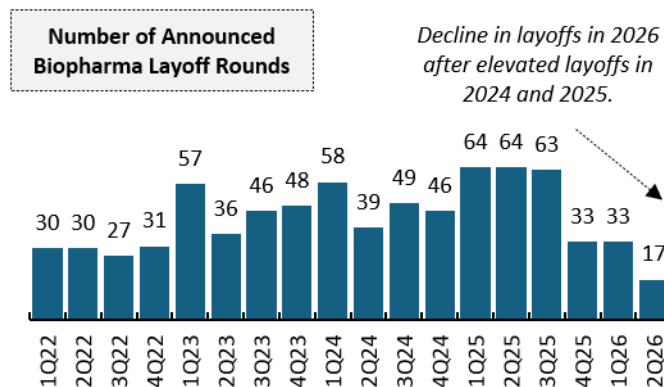
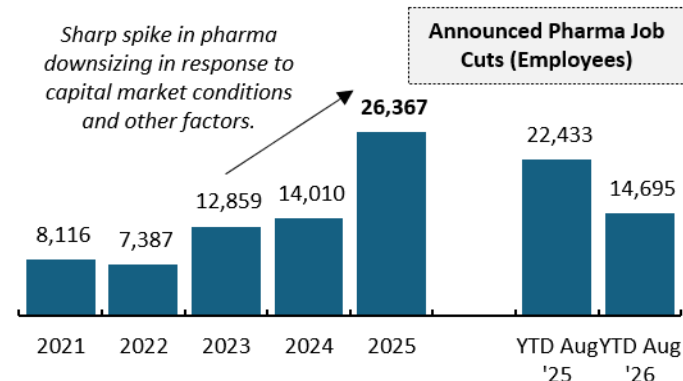
In recent years, **the pharma and biotech industry has gone through a period of heavy downsizing in response to capital market pressures**, adverse legislation/regulation, and patent expirations on high-revenue branded drugs, among other factors. This has resulted in a growing reliance on outsourcing by pharma and biotech firms, in our opinion. This, in turn, sets up strong demand for outsourced commissioning, qualification, and validation (CQV) services.

In our view, **the pace of pharma and biotech employee layoffs has declined in recent quarters. But this follows significant downsizing in 2024 and 2025.** Today, pharma companies are operating with much "leaner" organizations with little surplus staff -- just as they are looking to materially increase their U.S. manufacturing. Adding to this are the pressures of greater therapeutic/modality specialization coupled with an aging workforce. Of note, the shortage is often one of CQV experience rather than headcount, and experience can only be built over time.

Shortages of specialized CQV professionals regularly come up in our conversations with pharma executives as a bottleneck to manufacturing capacity expansion projects. CQV is also a peak-load need, not a steady run-rate, making internal teams costly to carry between projects. This, in turn, will likely lead to an increasing reliance on third-party outsourcing providers. Today, we believe well over half of CQV activity is outsourced and we see outsourcing steadily increasing over the next decade.

Geographic variances can also exacerbate CQV labor shortages, since experienced CQV professionals are often concentrated in a handful of regional hubs. Here, too, outsourcing has advantages. A multi-regional outsourcing provider can quickly mobilize travel-based teams from a more expansive pool of labor. These teams can execute a project in one region and then redeploy to execute another project in another region.

Biopharma Firms Significantly Reduced Their In-House Staff Since 2023 Due to Challenging Market Conditions



The Impact of Digital Validation Tools on CQV Spending

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Scenario Impact of DVT Adoption on an Individual CQV Project

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The Rapid Evolution of a DVT Vendor Landscape

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research@bourne-partners.com*

Digitization Analogs in Other Services (Non-Healthcare)

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Looking Ahead: The PreCheck Program and PDUFA VIII

One notable development that we are monitoring for providers of commissioning, qualification, and validation (CQV) services is the recently introduced “PreCheck” pilot program. This program, if made permanent, could accelerate the timing of revenues for CQV providers and reward CQV providers with regulatory affairs capabilities and experience.

The U.S. Food and Drug Administration (FDA) announced the PreCheck program in August 2025, following through on President Trump's May 2025 executive order directing the FDA to reduce the regulatory barriers to building new manufacturing facilities. We see the PreCheck program accelerating the pace at which pharma and biotech companies can stand up new domestic manufacturing capacity by giving them earlier and more frequent communication with the FDA on key topics such as facility design, construction, and pre-production readiness. It also streamlines the Chemistry, Manufacturing and Controls (CMC) section of a drug application that relies on a new manufacturing site and allows for pre-application meetings with FDA officials to avoid wasted time.

The durability of the PreCheck pilot program beyond the current Trump administration is questionable given that it was created in response to an executive order and it has no dedicated funding. In fact, the FDA has limited the PreCheck program to seven facilities given the resources needed to execute the program. However, we think there is a good chance many of the key elements of PreCheck are made permanent through the PDUFA VIII negotiations, which are nearing completion. According to the FDA, the proposed PDUFA VIII agreement includes a new CMC Facility Lifecycle Program with pre-submission meetings on manufacturing facilities ahead of evaluation and inspection, among other elements. PDUFA VIII must be passed by Congress by September 2027, and, if the proposed agreement stands, we believe that it could materially change the nature and timing of CQV revenues.

Specifically, in our view, **PreCheck is important to monitor because the FDA's pre-operational review covers much of the same work that CQV providers perform** -- facility and quality system design, a review of the final design before construction, equipment installation and qualification, and an assessment of readiness to begin production. So, under PreCheck, CQV providers could see some of their revenues pulled forward, as design decisions draw FDA feedback before construction. The documentation is then filed in a facility-specific Type V Drug Master File that the FDA actively assesses, and the manufacturer must keep the file current as equipment and processes change. This creates recurring work, and it favors CQV providers with regulatory experience. Partially offsetting this, early FDA feedback might prevent some of the design failures that generate follow-up remediation and requalification work for CQV providers today. And architecture, engineering, and construction (A/E/C) firms may become better positioned to bundle CQV into their design work, pushing CQV providers into (less attractive) subcontractor roles.

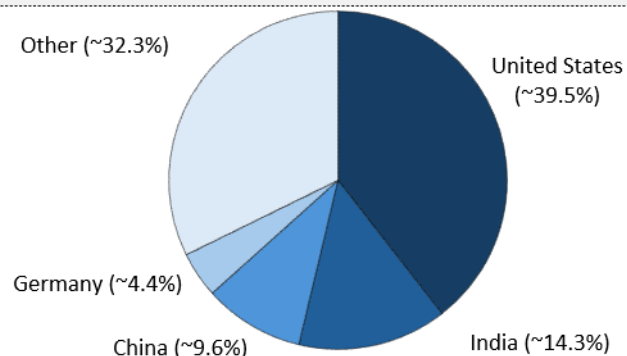
Looking Ahead: The BIOSECURE Act

Another topic that we are monitoring is the potential impact of the BIOSECURE Act on the ongoing regionalization of pharma manufacturing. In our opinion, depending on how circumstances play out, this legislation could drive incremental demand for commissioning, qualification, and validation (CQV) as pharma manufacturing is relocated.

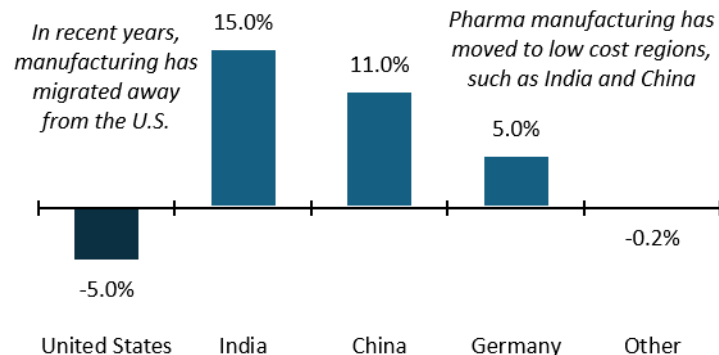
Enacted in December 2025, the **BIOSECURE Act bars U.S. federal government agencies from procuring biotechnology equipment or services from designated "biotechnology companies of concern,"** and from funding them through grants or loans. Contractors and grant recipients are likewise barred from using those companies to perform a federal award. The list of "biotechnology companies of concern" is set by the Department of Defense's 1260H list of Chinese military companies as well as a process overseen by the Office of Management and Budget. The initial list of "biotechnology companies of concern" is due by December 2026 with implementing guidance coming 180 days after that and federal procurement rules then being rewritten to carry the prohibition. Practically speaking, the prohibition would most likely go into operational effect in the mid-to-late 2028 timeframe.

The impact of the BIOSECURE Act on CQV activity depends on how aggressively the legislation is executed (and how the industry responds). If a pharma or biotech company moves drug substance or fill-finish away from a Chinese manufacturing site, for instance, the receiving site must be qualified, since transfers require Good Manufacturing Practice revalidation and FDA approval. Shifting production between manufacturers is itself resource-intensive and can require a prior-approval supplement where the change could affect the identity, strength, quality, purity, or potency of the product.

Breakdown of Pharma Manufacturing Facilities By Geography
(Excluding Medical Gas) in 2025



Change in Pharma and Biotech Manufacturing Facilities By
Geography, Excluding Medical Gas (from 2021 to 2025)



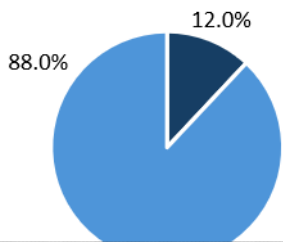
Looking Ahead: Are Tariffs Coming for Generic Drugs As Well?

To date, **tariffs by the Trump administration have focused on branded drugs while explicitly excluding generics and biosimilars**. Patented drugs, biologics and their ingredients now face a 100% tariff, while generics and biosimilars have been carved out. However, a recent Truth Social post from President Trump signals that this carve-out may be temporary.

In July 2026, President Trump announced -- informally, via Truth Social -- plans to extend tariffs on branded drugs to generics (and biosimilars). Per the Truth Social post, generics would stay duty-free for two years before facing a 100% tariff starting August 2028 (stepping up to 200% a year later). All of this is framed as a penalty on companies that do not manufacture domestically. Generics account for ~90% of all U.S. scripts filled, and the vast majority of generic drugs are manufactured abroad. Indian manufacturers alone supply ~47% of U.S. generics but only ~30% of import value, evidence of how thin the pricing cushion is. Chinese firms, in turn, dominate the upstream supply of active pharmaceutical ingredients (APIs), such as amoxicillin and heparin.

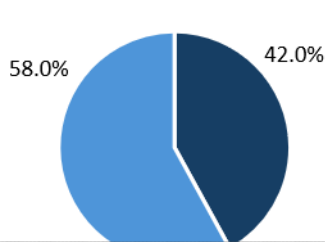
The reality of imposing tariffs on generic drugs is much more complicated than imposing tariffs on branded drugs. The economics of generic manufacturing are unforgiving, with razor-thin margins -- so layering a tariff onto that cost base could push manufacturers out of the market rather than encourage them to reshore. And this, in turn, could exacerbate drug shortages in oncology, anesthesia, and sterile injectables -- where U.S. supply is already most fragile. Accordingly, we will be closely watching for commentary from the *U.S. Department of Commerce* (due in April 2027) on if/how it recommends potentially extending Section 232 tariffs to generic drugs.

Percent of Generic Drugs (Solid Oral Dose)
Made in the U.S. Versus Outside of the U.S.



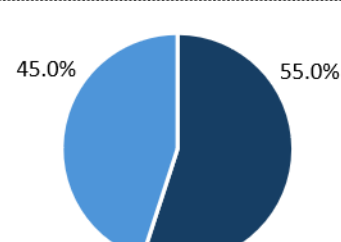
■ Manufactured in the United States
■ Manufactured Outside of the United States

Percent of Generic Drugs (Sterile Injectable)
Made in the U.S. Versus Outside of the U.S.



■ Manufactured in the United States
■ Manufactured Outside of the United States

Percent of Branded Drugs (All Forms)
Made in the U.S. Versus Outside of the U.S.



■ Manufactured in the United States
■ Manufactured Outside of the United States



Good Manufacturing Practice (GMP) Automation and Digital Manufacturing Services

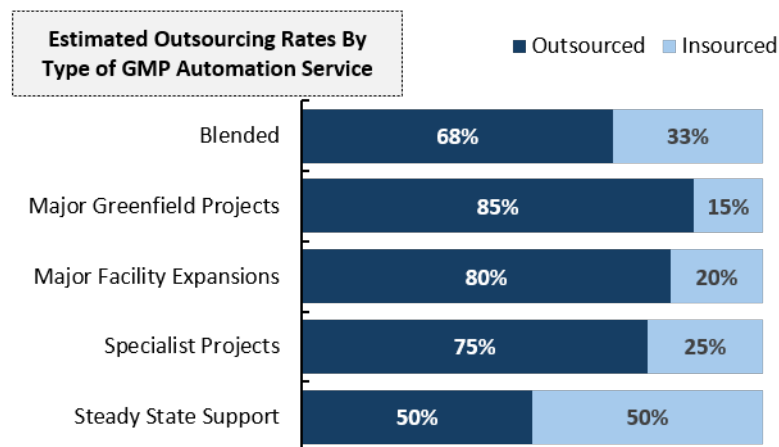
GMP Automation and Digital Manufacturing Services

In parallel to commissioning, qualification, and validation (CQV), **we see a similar period of accelerated demand for good manufacturing practice (GMP) automation and digital manufacturing services** from third-party providers in the coming years -- driven by many of the same dynamics as well as the rise of artificial intelligence (AI).

We define providers of GMP automation services as engineering firms that build and support the automation and information technology (IT) systems inside a pharma or biotech manufacturing facility. A modern plant is not operated by hand, of course. Software applications are installed that control the tanks, valves, temperatures and timing, and every batch must be recorded in a form that regulators will accept. Automation services providers write the specifications, configure the control software and electronic batch records, and connect the equipment and instruments. Also, many automation services providers remain with their customers to support systems day to day, handle changes and upgrades, and help turn digital manufacturing data into useful insight.

Most GMP automation services (we ballpark 75%+) are procured from outsourced third-party providers, although there is no official third-party data on the topic. Outsourcing rates are highest for greenfield builds and expansions, where the work is inherently non-recurring. Pharma companies and biotech firms typically cannot justify carrying permanent headcount for this type of work. This is particularly the case for facilities owned/operated by contract development and manufacturing organizations (CDMOs). Large pharma companies would tend to outsource less since they often have the scale to justify having an in-house automation team.

Regulation defines GMP automation services. EU GMP Annex 15 establishes the rules for qualifying facilities, equipment and utilities, and it explicitly contemplates validation protocols being supplied by a third party, provided that the customer confirms their suitability before approval. The computer systems these providers build fall under Annex 11, which requires that they be validated and kept in a validated state. A proposed revision to Annex 11 requires the manufacturer to be fully responsible for work it contracts out. Because of this, most pharma customers audit their vendor before relying on any vendor documentation and they contract for the vendor's support during regulatory inspections.



Mapping the Marketplace for GMP Automation Services

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Integrating GMP Automation with CQV Services

We are seeing a trend of good manufacturing practice (GMP) automation and digital manufacturing services being integrated with commissioning, qualification, and validation (CQV) services under a common platform. In our view, pharma companies prefer to purchase from a one-stop-shop provider and providers, in turn, benefit from labor synergies.

We do think there is value in being an independent GMP automation services specialist. An independent provider is not tied to a control system or equipment vendor, so it can recommend the technical answer that fits the process rather than the one it sells, and it can work across the full installed base rather than being tied to a single platform. That widens the addressable market, because most plants run distributed control systems, manufacturing execution systems, and supervisory control and data acquisition (SCADA) platforms from several vendors. This also positions the provider for technology selection, acceptance testing, and upgrade related work. Control systems age out of vendor support, forcing the pharma/biotech manufacturer to replace and requalify systems.

However, in our view, **providers that can offer GMP automation services integrated with CQV services have three advantages.**

- **Simplified Contracting.** Offering both GMP automation and CQV services allows the provider to cover the full technical scope of a manufacturing expansion project. This is generally how pharma and biotech companies prefer to procure services because it simplifies the contracting process for the customer and it holds one provider responsible for project controls, automation, and qualification. This mitigates the risk of having multiple handoffs between different vendors.
- **Pricing/Cost Efficiencies.** Both GMP automation and CQV services draw on the same pool of technical labor. So, a provider that offers both services can benefit from labor (utilization and recruiting) efficiencies as well as cross-selling synergies.
- **Diversified Revenues.** CQV work is lumpy, while automation and GMP IT work continues into support, upgrades, and lifecycle management once the plant is running. This lengthens the provider's presence at a manufacturing site and makes the provider the incumbent for the next CQV project that comes along.

PerkinElmer is the clearest recent example of this type of integration. It acquired **Project Farma** (CQV services) in March 2025 and **SimoTech** (GMP automation services) in September 2026, folding both into a single pharma services platform. **Cognizant (NASDAQ-CTSH)** reached the same outcome earlier, buying **Zenith Technologies** in 2019 -- consulting, automation, and manufacturing site services on one platform -- then adding industrial data and intelligence firm **TQS Integration** in 2021. **NNIT** similarly rolled up **Halfmann Goetsch Partner** (2019), **Excellis Health Solutions** (2020), **SL Controls** (2021), and **prime4services** (2022).

Handoff Risks Between GMP Automation and CQV Providers

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The Key Catalyst: Artificial Intelligence (AI)

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Integrating the Technology Stack Is Labor, Not Software

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How AI Is Disrupting Pharma/Biotech Manufacturing

Over time, **we see artificial intelligence (AI) becoming foundational to the Quality-by-Design (QbD) strategies** of pharma companies, biotech firms, and contract development and manufacturing organizations (CDMOs). Simply stated, AI is able to generate real-time insights from large datasets and offer predictive insights into complex manufacturing processes.

For decades, **guidelines by the International Council for Harmonisation (ICH) have explicitly encouraged the use of QbD strategies in pharma (and biotech) manufacturing**. Although the ICH has no direct legal authority, it reflects the global consensus of industry and government on the best practices in drug manufacturing, and regulators around the world often reference ICH guidelines when establishing and enforcing their own good manufacturing practices (GMPs).

QbD involves the systematic integration of quality/risk management into manufacturing processes. For the manufacturer, this, in turn, requires a deep *a priori* understanding of the critical process parameters and quality attributes of a specific product as well as perspectives on the variables that could impact the quality and consistency of production. Of course, the concept of QbD predates the use of AI, *but we see AI significantly enabling QbD approaches in multiple (overlapping) ways*.

Example AI Use Cases in Drug Manufacturing

- 1 **Process Analytical Technology (PAT)**. AI-enabled PAT can detect subtle product and process deviations during manufacturing that might otherwise be missed by conventional monitoring technologies. For automation services providers, this, in turn, requires qualified instruments, validated data paths, and documented critical process parameters.
- 2 **Digital Twins**. AI can facilitate the use of computer-based virtual simulations to allow manufacturers to plan new product launches by predictively addressing problems before they occur in the real world (avoiding trial-and-error experiments).
- 3 **Computer Vision**. AI-enabled computer vision systems collect and feed image data to AI applications that, in turn, are trained to detect undesired variability in product output -- e.g., defects, contamination, and/or packaging issues.
- 4 **Predictive Maintenance**. AI can be part of a predictive approach to maintenance for sensitive facility and equipment by evaluating data inputs. This can help to reduce unplanned downtime and lower equipment upkeep/repair costs.

Each of the AI use cases above runs on validated software systems that good manufacturing practice (GMP) automation services providers must build and qualify. None of these use cases is a simple software purchase. Instead, each involves the coordination of sensors and data paths that need to be qualified, models that need to be tested, and records that regulators will need to accept.

AI-Enabled Process Analytical Technology

We view Process Analytical Technology (PAT) to be at the heart of quality-by-design (QbD). For good manufacturing practice (GMP) automation services providers, PAT is the most relevant of the AI use cases. Real-time release testing depends on qualified instruments, validated data paths into the historian, and documented critical process parameters.

Over 20 years ago, **the U.S. Food and Drug Administration (FDA) introduced the concept of PAT to provide pharma manufacturers with clear regulatory safe harbors to adopt modern QbD manufacturing processes** that are commonly used in other industries. The FDA wanted to encourage pharma manufacturers to move away from quality control management that relies on end-product testing, instead moving towards proactive real-time monitoring of predefined critical process parameters (CPPs) and critical quality attributes (CQAs). This, in turn, requires the identification of CPPs and CQAs, the systematic deployment of analytical monitoring tools against these CPPs and CQAs, and the documentation of manufacturing processes. This has further led to a shift in regulatory inspections away from end-product batch testing and towards the risk-based monitoring of manufacturing processes.

AI-enabled PAT systems can aggregate and analyze data, in real-time, from spectroscopic devices, pressure monitors, temperature sensors, flow meters, and other monitoring tools to identify deviations and nuances in CPPs and CQAs that would otherwise be challenging (if not impossible) for a human to detect. This allows the pharma manufacturer to forecast product quality before the manufacturing is complete, and, importantly, make proactive adjustments, as needed. This also allows for real-time release testing in which drug products are released based on real-time process data rather than based on end-product lab testing. All of this facilitates more rapid production cycles, improved equipment effectiveness, lower rates of batch failures, and less raw material waste.

Examples of Process Analytical Technology

- **Near-Infrared (NIR) Spectroscopy** helps identify variations in chemical composition in tablets
- **Raman Spectroscopy** measures molecular structures to ensure a drug stays within specified parameters
- **Fourier Transform Infrared (FTIR) Spectroscopy** monitors chemical bonds during reactions
- **Chromatography** provides detailed chemical analysis of in-process and finished pharma products
- **Particle Size Analyzers** measure particle size for the analysis of dissolution and bioavailability
- **Process Sensors** provide real-time tracking of CPPs such as temperature, pressure, pH, etc



AI-Enabled “Digital Twins” for Process Optimization

In our view, there is an attractive opportunity for pharma companies, biotech firms, and contract development and manufacturing organizations (CDMOs) to use artificial intelligence (AI) to create “digital twins” (i.e., virtual simulations) to optimize production processes and equipment, such as a bioreactor, a fermentation process, or a cell culture system.

AI-powered “digital twin” technologies allow manufacturers to predictively address problems before they occur in the real world, thereby avoiding the need for time-consuming and costly trial-and-error experimentation. A key feature of a “digital twin” is a continuous refinement of the simulation, over time, based on continuous/real-time collection of data from sensors and Internet of Things (IoT) devices. For the good manufacturing practice (GMP) automation services provider, the creation and use of a digital twin involves sensors and data paths, all of which require continuous specification, integration, and qualification work.

It is difficult to generalize the financial return on investment (ROI) of digital twin technologies in pharma manufacturing because situations will vary significantly. However, we commonly hear of significant efficiency gains, including some CDMOs being able to eliminate as much as 70% of trial-and-error experiments with digital twin systems. The production of medicine can involve many thousands (or millions) of variables. There are certainly significant upfront costs for the adoption of necessary AI software, sensors, and hardware, and there are ongoing costs to maintain this. Also, access to (and the retention of) the necessary skilled labor can be a challenge as well. Even still, for successful use cases, we commonly hear of payback periods of less than a few years given the significant savings that can come from accelerated production timelines, reduced batch failures, and regulatory efficiency.

Scenario: Digital Twin Tech ROI in Biopharma Manufacturing					
\$ in Millions	Year 1	Year 2	Year 3	Year 4	Year 5
Savings from Reduced Batch Failures	3.0	3.0	3.0	3.0	3.0
Downtime Avoidance	1.0	1.0	1.0	1.0	1.0
Accelerated Production Scale-Up	3.0	2.0	1.0	-	-
Regulatory Efficiency	1.0	1.0	1.0	1.0	1.0
Financial Benefits of Digital Twin Tech	\$8.0	\$7.0	\$6.0	\$5.0	\$5.0
Upfront Capital Investment	(8.0)	-	-	-	-
Operating Costs	(1.5)	(1.5)	(1.5)	(1.5)	(1.5)
Cost of Digital Twin Tech	(\$9.5)	(\$1.5)	(\$1.5)	(\$1.5)	(\$1.5)
Cumulative Net Financial Benefits	(\$1.5)	\$4.0	\$8.5	\$12.0	\$15.5



AI-Enabled Computer Vision in Pharma Manufacturing

Computer vision systems come up over and over again in our conversations as another top use case for artificial intelligence (AI) in pharma manufacturing. Over the past five years, the use of AI-enabled computer vision technologies by pharma companies, biotech firms, and contract development and manufacturing organizations (CDMOs) has noticeably increased, and we expect these technologies to be common by the end of the coming decade.

Computer vision systems involve the deployment of high-resolution cameras, specialized lighting, sensors, and other imaging tools that can collect and feed pixel data to AI algorithms that, in turn, are trained to detect variability in product output -- e.g., defects, contamination, and/or packaging issues. These systems can be a powerful tool to improve quality management given the ability of AI to operate with a speed, accuracy, and objectivity that is well beyond that which is possible by a human inspector.

The return-on-investment (ROI) for an AI-backed computer vision system will vary by scenario, of course. However, we commonly hear of 20%-40% reductions in product quality costs, driven by less defective output, fewer manual inspections, and fewer regulatory interventions (e.g., product recalls or fines). Also, vision systems can track personnel and workflows to identify process inefficiencies and compliance issues. These AI-enabled computer vision systems can be expensive to set up, but payback is often quick. We typically hear of payback on investment within a couple of years.

Scenario ROI on AI-Backed Computer Vision in Pharma Manufacturing Operations	Annual Baseline	AI Efficiency Gains (%)	AI Efficiency Gains (\$)
Annual Product Output	500,000,000		
x Defect Rate	2%		
= Defective Product	10,000,000		
x Cost per Tablet (Materials and Labor)	0.10		
= Cost of Defective Product	\$1,000,000	x	25% = \$250,000
Number of Humans Involved in Manual Inspection	20		
x Annual Wage Per Employee (Inspector)	50,000		
= Cost of Manual Inspections	\$1,000,000	x	25% = \$250,000
Cost of Regulatory Interventions (e.g., Recalls)	\$4,000,000	x	35% = \$1,400,000
Product Quality Related Costs	\$6,000,000	31.7%	\$1,900,000

We commonly hear that AI-backed computer vision in pharma manufacturing can reduce product quality related costs by 20%-40% annually through the reduction in defective product, manual labor, and product recalls.



AI-Enabled Predictive Equipment Maintenance

We hear more and more cases of artificial intelligence (AI) being used by pharma companies and contract development and manufacturing organizations (CDMOs) to proactively identify needs for maintenance on facilities and equipment. This helps to avoid unplanned equipment failures, costly production downtime, and potential product quality issues.

Using AI for predictive facility and equipment maintenance is not a “futuristic” idea for pharma manufacturing, in our view. An increasing number of manufacturers are evaluating opportunities to use AI to be more proactive with facility and equipment capital and maintenance investments. Traditional maintenance relies on scheduled maintenance at predetermined intervals or reactive maintenance based on the occurrence of an equipment failure. By contrast, AI-enabled predictive maintenance involves the aggregation and analysis of data from sensors, e.g., vibration monitors, temperature sensors, pressure gauges, electrical current measurements, and acoustic sensors. Notably, where these technologies do not directly affect product quality, they fall outside draft Annex 22’s definition of a critical GMP application. So, this work is data engineering and integration rather than model qualification.

The objective is to maximize overall equipment effectiveness (OEE) by highlighting nuances in facility and equipment performance that might otherwise go unnoticed by a human observer. This can allow for tailored maintenance schedules, issues being proactively addressed during normal maintenance downtime periods, and better documentation to support future compliance and regulatory audits. Financially, for the pharma and biotech manufacturer (and CDMO), this can improve capacity and output, and most case studies we have reviewed show high returns on investment with short payback periods.

Scenario: AI-Based Predictive Maintenance Systems are particularly relevant for sterile filling lines given the potential for high downtime and product quality risk

Reduction in Unplanned Downtime	30 Hours	x	\$125k/ Hour	=	3,750,000
Reduction in Maintenance Costs	~\$ 1 Mil Baseline	x	20% Cut	=	200,000
Reduction in Lost Product	One Event Avoided	x	\$2 Mil Per Event	=	2,000,000
Improvement in Throughput	\$25 Mil Annually	x	2% Improvement	=	500,000
=Sum of Total Benefits					\$6,450,000
less: Operating Cost of AI System					(150,000)
=Net Annual Benefit					\$6,300,000

Use Cases for AI Predictive Maintenance

- Bioreactors and Fermenters
- Lyophilizers (Freeze-Dryers)
- Tablet Presses and Encapsulators
- Aseptic Filling Lines and Isolators
- HVAC / Environmental Control Systems
- Water for Injection
- Purified Water Systems
- Autoclaves
- Sterilization Equipment

Qualified/Cross-Functional Staff as a Prerequisite for AI

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Regulation Turns AI Ambition Into GMP Services Work

Regulation is what turns artificial intelligence (AI) strategies into recurring services work. The European Commission's draft Annex 22 proposes treating any AI model used in a critical good manufacturing practice (GMP) application as a system that must be qualified and monitored. That makes AI adoption billable work for automation service providers.

Draft Annex 22 sits on top of Annex 11 and covers any AI model that directly affects patient safety, product quality, or data integrity. It applies only to models that are static and deterministic after training (i.e., give the same answer to the same question). Models that keep learning during use, and models that can give different answers, such as generative AI and large language models, are outside its scope and are not to be used in critical GMP work. Automated visual inspection is the clearest case: trained on images, then frozen before use. The first wave of regulated AI is vision, sorting, and prediction tasks inside validated control and production systems -- exactly the systems that third-party GMP automation service providers build and qualify today.

Four provisions matter most commercially, in our view. First, the manufacturing site must review the model paperwork whether the site built the model itself or bought it from a third party. So, buying an AI model moves the validation work to the site rather than removing it. Second, staff who have seen the test data cannot train the same model unless paired with a colleague who has not -- favoring independent providers. Third, performance monitoring continues after start-up, so the work repeats instead of ending at handover. Finally, one system can hold several models, and each one needs its own stated use, pass criteria, and test evidence.

If Adopted as Drafted, Annex 22 Would Require	The Work Each Requirement Creates for Service Providers
Intended use and input sample space documented before testing	Requirements definition with site process experts
Test metrics and acceptance criteria approved before testing	Baseline study of the manual process being replaced
Test data representative, labelled, and independent of training	Data governance, labelling checks, and a controlled repository
Testing planned, executed, and documented; deviations investigated	Protocol authoring and execution -- core CQV work, applied to models
Explainability and confidence scores captured during testing	Automation engineering to capture, log, and qualify attribution
Change and configuration control before deployment	Change control across the model, the system, and the process
Ongoing monitoring of model performance and input drift	Recurring site work -- continuous model surveillance

Why European Rules Reach U.S. Pharma/Biotech Manufacturers

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Valuation and M&A Considerations

A modern conference room with a large wooden table and black leather chairs, overlooking a city skyline through floor-to-ceiling windows. The text "Valuation and M&A Considerations" is overlaid on the left side of the image.

Valuation Drivers for CQV (and Automation) Service Providers

Pharma and biotech companies are increasingly outsourcing commissioning, qualification, and validation (CQV) to third-party specialists. Selections of outsourcing providers, in turn, are generally driven by technical expertise, customer incumbency, access to sufficient labor resources, geographic proximity, and digital/artificial intelligence (AI) capabilities.



Domain Expertise. In our view, outsourced CQV providers compete primarily on their perceived reputation for technical expertise in specific therapeutic modalities, because CQV protocols are modality-specific. Sterile fill-finish, cell and gene therapy, biologics, and active pharmaceutical ingredients (API) each carry different regulatory expectations. A provider that has a track record of effectively qualifying the same equipment before is more likely to write cleaner protocols and anticipate inspector questions. This results in fewer failed qualification delays.



Customer Incumbency. A preexisting relationship is a key competitive factor when pursuing a project, and customers typically give recurring business to their preferred providers. CQV work is performed inside the client's quality systems, under its procedures and documentation standards, so switching carries cost and risk. Incumbents can also reuse commissioning data to satisfy qualification requirements across sites, avoiding duplicative testing. So, incumbency often predicts the next award.



Access to Labor Resources. A client commissioning a facility often requires dozens of qualified engineers on site. Only providers with bench depth can absorb this demand and then redeploy staff as the project winds down. Scale also enables multi-site agreements large pharma now favors as it consolidates vendor lists, and it allows for greater standardization across those sites. Smaller firms can win single projects, but they rarely qualify for enterprise programs. This limits their growth.



Geographic Presence. Because CQV is an on-site activity with short lead times, geographic density and the ability to mobilize rapidly are key. Sometimes whoever can put qualified people at a site quickly can win on availability alone. Engineers must also be present for months at a time, so travel and per diems can impact costs and margins. Finally, providers clustered near established biomanufacturing hubs staff faster and more cheaply than those flying teams in, lowering execution risk.



Digital Validation Tools (DVTs). Paperless digital validation platforms cut protocol execution hours, shorten review cycles, strengthen data integrity, and audit scrutiny, while AI-assisted authoring and deviation review compress them further. This improves profit margins of CQV providers and allows a CQV outsourcing provider to deliver more projects with fewer people. Fully embedding DVTs also reframes CQV services toward a managed service with recurring software-like revenue.

Pharma Services as a Starting Point for Valuation

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Non-Healthcare Comparisons for CQV Providers

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Non-Healthcare Comparisons for Automation Services

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Premium Valuations for Pharma Services

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Observations on M&A Activity in the CQV Space

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Observations on M&A in the Automation Services Space

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Select Acquisitions: CQV and Automation Services (1 of 4)

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Select Acquisitions: CQV and Automation Services (2 of 4)

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Select Acquisitions: CQV and Automation Services (3 of 4)

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Profiles of Select Service and Software Providers

Select CQV, Automation Services, and DVT Providers (1 of 7)

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Select CQV, Automation Services, and DVT Providers (2 of 7)

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Select CQV, Automation Services, and DVT Providers (6 of 7)

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Select CQV, Automation Services, and DVT Providers (7 of 7)

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A modern office interior with a large conference table and chairs, overlooking a city skyline through floor-to-ceiling windows. The scene is dimly lit, with the primary light source being the natural light from the windows, which shows a cityscape with various buildings, including one with a prominent triangular roof. The office furniture consists of a dark wood conference table and black leather chairs with chrome frames. The overall atmosphere is professional and contemporary.

Appendix: Bourne Partners Overview

Bourne Partners Overview

Since 2001, Bourne Partners has been offering a unique perspective and unmatched expertise while remaining highly focused on fulfilling the needs of established healthcare and life sciences companies across the globe

Our Passion

*“Working with **great people** and **great companies** to achieve **extraordinary results.**”*

Bourne Partners Investment Banking

Mergers & Acquisitions	
<i>Sell-Side Advisory</i>	<i>Buy-Side Advisory</i>
<i>Company & Product Focus</i>	<i>\$100M - \$1B+ Enterprise Value</i>
Capital Advisory Services	
<i>Equity Capital Raising</i>	<i>Debt Capital Raising</i>
<i>Alternative Financing Options</i>	<i>\$100M+ Capital Raises</i>

Highly-Focused Firm



Pharma
Services &
Technology

Healthcare
Services &
Technology

Pharma &
Pharmacy
Services

Value-Add Advisors with a Global Reach

\$20B+

Transaction
Value

15

Years of Average
Tenure at Bourne¹

25+

Year Track
Record

Six

Continents
Reached

Research and Thought Leadership at Bourne Partners



Donald Hooker, CFA
Director of Research

Over twenty years of experience as a publishing sell-side equity analyst at UBS, Morgan Stanley, KeyBanc Capital Markets, and Capital One, among others

Extensive background in healthcare services, pharma services, and healthcare information technology

Joined Bourne Partners in July 2024 to build out a research function

Morgan Stanley



The Bourne Partners Perspective

With 20+ years of exclusive industry and capital markets coverage, we are committed to providing insights to clients. We provide cutting-edge thought leadership on all things Pharma, Pharma Services, Healthcare Services, and Consumer Health.



Clinical Trial Technologies Marketplace Update

Perspectives on Recent Trends in Artificial Intelligence (AI) Adoption in Clinical Trials

April 2026



CDMO Marketplace Update

Perspectives on Recent Trends in Digital and Artificial Intelligence (AI) Adoption by CDMOs

February 2026



Home and Alternate Site Infusion Therapy Marketplace Update

Perspectives and Research into Recent Trends Impacting the Infusion Therapy Space

December 2025



The Evolving Landscape of Pharma Services and Technology

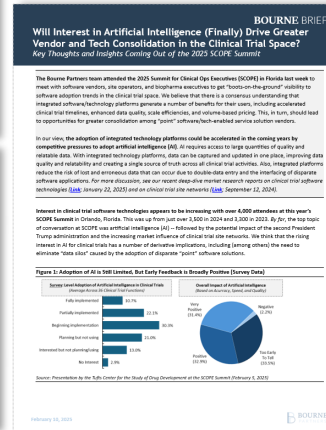
Key Takeaways from the CPhA Americas 2026 Conference

Last week, the Bourne Partners team attended the 2026 CPhA Americas Conference in Philadelphia to meet with executives at a broad range of pharma services and technology companies to get their world-view perspectives on the various disruptive forces that are reshaping drug development and manufacturing today. The dominant theme that came up over and over again at the Conference was the ongoing regulatory (including of pharma manufacturing and services). The consensus view is that the regulatory environment is becoming increasingly complex and costly. We see this trend amplifying an ongoing capital spending "gap" among U.S. domestic pharma companies and service firms. Continued development and manufacturing capabilities (CDMOs), in particular, are especially well positioned to benefit here – nearly every CDMO we met with cited rising customer interest in domestic manufacturing. This increasing demand should also drive demand for U.S.-based contract packaging and sterilization providers (who sponsor prefer these functions to sit close to their manufacturing sites).

Another major topic of conversation at the CPhA Americas Conference was the rising therapeutic complexity of the drug development pipeline. The conference, created by the Infectious Diseases Act (IDA) of 2022 and the Drug Research Act (DRA) of 2023, clearly shows the development of biologics and orphan drugs with longer periods of protection from仿制品 price negotiations. This has broad implications for the pharma services landscape. Sites capable and prepared to handle CDMOs and device manufacturers. Specialized contract packaging and packaging providers should also benefit from this, given their ability to handle the smaller, high-risk, high-cost, and fully isolated unit product lines. Finally, software and professional services providers should see incremental demand for their products and services as rising therapeutic complexity requires more efficient data management and domain expertise. For more, see our recent Bourne Partners Deep Dive Report: [CDMO Marketplaces Update and Perspectives on Trends in Digital and AI Adoption](#) (February 2026).

Key Takeaways at a Glance

1. **Manufacturing Reprogramming:** Tariffs and post-COVID supply-chain resilience are driving a multi-year retooling of contract manufacturing. "Just-in-time" in the United States, domestic CDMOs, packaging, sterilization, and CQV-related services will be major beneficiaries, in our opinion.
2. **Therapeutic Complexity:** Increased interest in recent legislation is having the drug development pipeline become longer and more complex. This has broad implications for the pharma services landscape, especially packaging, sterilization, and software/IT services.
3. **CDMO Regulatory Readiness:** Looking forward across the top drug review risks at the FDA is creating uncertainty, likely putting a premium on all-related, commercial-stage assets and established service platforms.
4. **Artificial Intelligence (AI):** The promise of AI has been a source of interest every executive we spoke with. Most, if not all, of the companies we met with are developing AI strategies – and many have built out teams internally to implement AI technologies. However, the real-world impact of AI will remain uncertain.
5. **Executive Perspectives:** Conversations with various management teams across CDMOs, packaging, sterilization, consulting, and software agencies reinforced each of the above themes above.



Will Interest in Artificial Intelligence (Finally) Drive Greater Vendor and Tech Consolidation in the Clinical Trial Space?

Key Thoughts and Insights Gaining Out of the 2025 SCCTE Summit

The Bourne Partners team attended the 2025 Summit for Clinical Data Executives (SCCTE) in Florida last week to meet with executives from leading technology providers, data scientists, and regulatory experts. The conference was a key event for the clinical trial industry, focusing on the challenges and opportunities of digital transformation. The consensus view is that the regulatory environment is becoming increasingly complex and costly. We see this trend amplifying an ongoing capital spending "gap" among U.S. domestic pharma companies and service firms. Continued development and manufacturing capabilities (CDMOs), in particular, are especially well positioned to benefit here – nearly every CDMO we met with cited rising customer interest in domestic manufacturing. This increasing demand should also drive demand for U.S.-based contract packaging and sterilization providers (who sponsor prefer these functions to sit close to their manufacturing sites).

In our view, the adoption of integrated technology platforms could be accelerated in the coming years by competitive pressures and other artificial intelligence (AI). It requires access to large quantities of quality and reliable data. With integrated technology platforms, data can be processed and analyzed in real time, improving data quality and reliability and creating a source of rich insights at clinical trial activities. Also, integrated platforms reduce the risk of lost and erroneous data that can occur due to double data entry and the interfacing of disparate software applications. For more discussion, see our recent deep-dive market research report on clinical trial software technology [Link](#) (January 22, 2025) and our clinical trial software [Link](#) (September 12, 2024).

Interest in clinical trial software technology appears to be increasing with over 6,000 attendees at this year's SCCTE Summit in Orlando, Florida. This was up from just over 5,000 attendees at last year's SCCTE Summit. At the top table of conversation at SCCTE was artificial intelligence (AI). Followed by the potential impact of the recent President Trump administration and the increasing market pressure of clinical trial on networks, the focus that the drug industry is on for clinical trials has a number of alternative regulations, including limiting access to the network "data silos" caused by the adoption of disparate "point" software solutions.



Source: Prepared by the authors for the SCCTE Summit in Orlando, Florida, September 12, 2024.



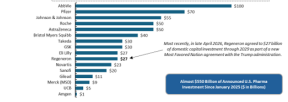
Playing the Supercycle in U.S. Pharma Manufacturing and Artificial Intelligence (AI) Adoption

Key Takeaways from the 2026 Interphex Conference

The Bourne Partners team recently attended the 2026 Interphex Conference in New York City to get real-world insights from pharma executives about the trends that are reshaping their businesses. The consistent observation across our meetings is the positive demand environment for contract pharmaceutical services – particularly those associated with pharma and biotech manufacturing capacity expansion. In our view, the U.S. pharma and biotech industry is currently in the early stages of a multi-year capital spending "super-cycle" that is being driven by recently announced health care reform legislation by the Trump administration, rising energy and transportation costs, elevated regulatory scrutiny into overseas manufacturing facilities, and an increasing therapeutically complex drug development pipeline. In fact, over the past year alone, we have tracked public announcements of planned capital investments in domestic pharma manufacturing totaling about \$200 billion.

Another major topic of conversation at the Interphex Conference was the opportunity to take advantage of emerging artificial intelligence (AI) to modernize pharma manufacturing in ways that prior investments in traditional automation have failed. While there is a cultural battle, a reshaping of pharma manufacturing capacity to the United States could provide a "window of opportunity" for the design of new manufacturing facilities with AI-enhanced in mind. For more discussion, see our recent Bourne Partners Deep Dive Report: [CDMO Marketplaces Update and Perspectives on Trends in Digital and AI Adoption](#) (February 2026).

Figure 1: Massive Pending Capital Spending Wave Among Major Pharma Companies



Source: Prepared by the authors for the 2026 Interphex Conference in New York City, February 2026.



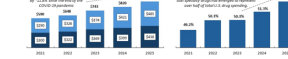
Updated Thoughts and Hopes for a U.S. Biologics Marketplace

Take-Aways from the 2026 Association for Accessible Medicines (AAM) Conference

The Bourne Partners team recently attended the Association for Accessible Medicines (AAM) Conference in Miami, Florida to hear perspectives on the biopharmaceutical and generic drug environment in the United States – not just as on the broader issue of prescription drug prices and affordability, but also on the specific issue of biologics. The consensus view is that the regulatory environment is becoming increasingly complex and costly. We see this trend amplifying an ongoing capital spending "gap" among U.S. domestic pharma companies and service firms. Continued development and manufacturing capabilities (CDMOs), in particular, are especially well positioned to benefit here – nearly every CDMO we met with cited rising customer interest in domestic manufacturing. This increasing demand should also drive demand for U.S.-based contract packaging and sterilization providers (who sponsor prefer these functions to sit close to their manufacturing sites).

The AAM Conference gave us a number of reasons to be hopeful that the U.S. biopharmaceutical market could meaningfully open up in the coming years. This, in turn, could have positive implications for the pharma services companies involved in drug commercialization and market access. There was considerable discussion at the Conference about the potential for a new wave of drug production by the U.S. Food and Drug Administration (FDA) as a result of the regulatory and market access challenges facing biopharmaceuticals. In our view, this guidance could result in biopharmaceutical companies being in a better position to also discuss around ways to improve market access for biopharmaceuticals. However, we have heard that the FDA has been particularly cautious in its recent guidance on biologics, and we believe that the FDA's recent guidance could result in biopharmaceutical companies being in a better position to also discuss around ways to improve market access for biopharmaceuticals. However, we have heard that the FDA has been particularly cautious in its recent guidance on biologics, and we believe that the FDA's recent guidance could result in biopharmaceutical companies being in a better position to also discuss around ways to improve market access for biopharmaceuticals.

Figure 1: Specialty (Single-Dose) Drug Average for Over 50% of Total U.S. Drug Spending (and Rising)



Source: Prepared by the authors for the 2026 Association for Accessible Medicines (AAM) Conference in Miami, Florida, February 2026.

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Sector Expertise and Dedicated Coverage Teams

Pharma Services & Technology

Representative Clinical Solutions

- Pharma, Site, Biotech, CRO, and Lab Technologies
- Full-Service & Specialty CROs
- SMOs & Clinical Research Site Networks
- Patient Recruitment & Engagement
- Clinical Regulatory Consulting & Strategy Services

Representative Supply Chain Solutions

- Full-Service & Specialty CMOs & CDMOs
- Biostorage, Distribution & Logistics Services
- Commercial Lab & Analytical Services
- Contract Packaging & Labeling
- Manufacturing Consulting & Strategy Services

Representative Commercialization Solutions

- HCP, Patient & Omnichannel Engagement
- Market Access & Pricing, HEOR, RWE
- Medcomms & Healthcare Marketing / Advertising
- Medical & Regulatory Affairs & Pharmacovigilance
- Patient Support & Hub Services



James West
Managing Director
jwest@bourne-partners.com
+44 7456.427.468



Jake Curtis
Director
jcurtis@bourne-partners.com
+1.980.372.2566



Ryan Silvester
Vice President
rsilvester@bourne-partners.com
+1.980.372.7450

Therapeutics

Representative Focus Areas

- Commercial-Stage Specialty & Rare Disease
- Biopharma Therapeutics
- Generic Pharma
- Legacy / Established Brands
- 505(b)(2)
- De-Risked Clinical Stage Biotech
- Cell & Gene Therapies
- Medical Devices

Representative Solutions

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- Debt & Equity Financing
- Synthetic Royalty / Revenue Interest Financing
- Royalty Monetization
- Priority Review Voucher (PRV) Monetization & Financing



Carson Riley
Managing Director
criley@bourne-partners.com
+1.980.372.2551



Oliver White
Associate
owhite@bourne-partners.com
+1.980.372.7851



Luke Habecker
Associate
lhabecker@bourne-partners.com
+1.980.372.2593

Healthcare Services & Technology

Representative Healthcare Services

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- Behavioral Health
- Managed Care
- Physician Practice Management
- Alternate Site

Representative Outsourced Services

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- Home Medical Supplies & DME
- Labs & Lab Services
- Staffing
- Virtual Care-Enablement & Provider Technology

Representative Pharmacy Services

- Infusion Services
- 503A Compounding Pharmacy
- 503B Hospital Outsourcing
- Specialty and Retail Pharmacy
- Medication Management & Adherence



Aaron Olson
Managing Director
aolson@bourne-partners.com
+1.917.763.8972



Brennan Hockaday
Associate
bhockaday@bourne-partners.com
+1.980.463.9088

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