# JOINT VENTURE CONTRACT SERVICES – A CDMO'S APPROACH TO BEING A TRUE PARTNER

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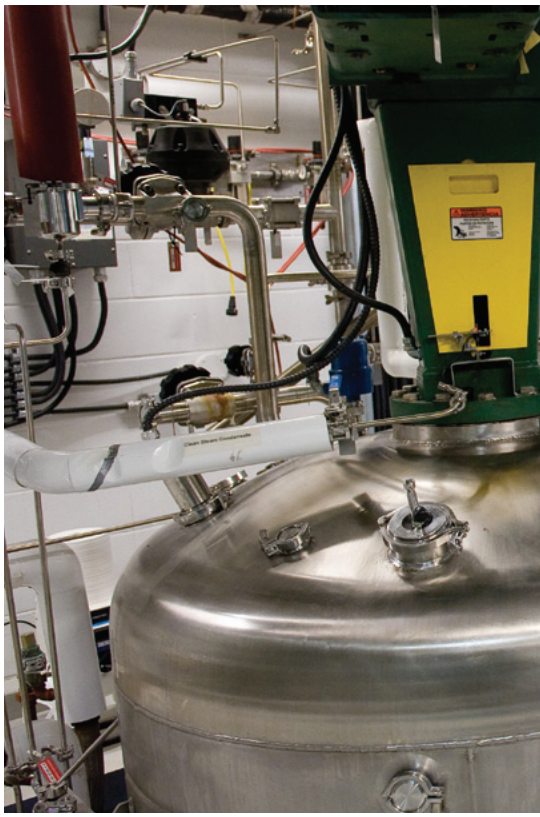
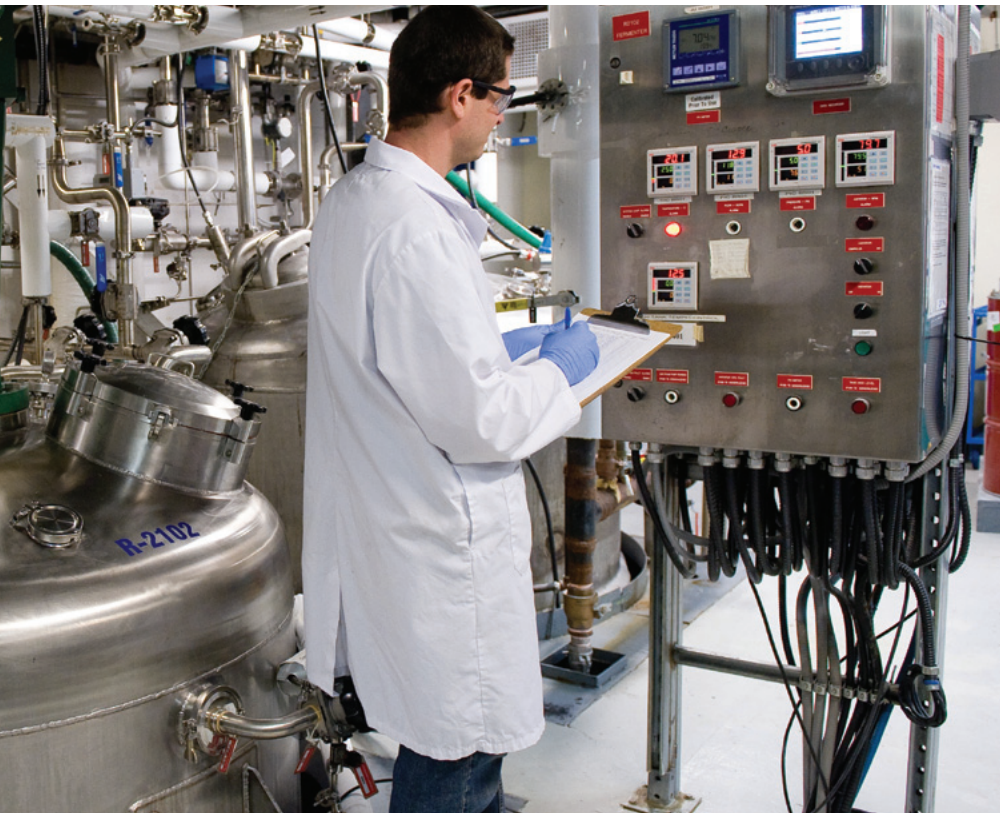


The active pharmaceutical ingredient (API) is the key functional component of a pharmaceutical formulation, rendering efficacy to the final drug product. Driven by the aging population, public and government demands for affordable drugs, reimbursement pressure and expansion of the emerging market, the pharmaceutical market is expanding rapidly. With this, the global market for APIs will rise steadily, meeting the increased need for medicines across the board. The market is expected to reach $198.8 billion by 2022, growing from $121.4 billion in 2014 at a compound annual growth rate (CAGR) of 6.4%.[1]

APIs are manufactured in-house or outsourced to contract development and manufacturing organizations (CDMOs/CMOs). Largely due to its low profit margin, pharmaceutical/biotech companies are often inclined to rely on contract manufacturing to achieve production efficiency and economies of scale, especially for small-molecule APIs. This trend is evident in 2016 Nice Insight CDMO Outsourcing Survey results. With respect to small-molecule API contract manufacturing, 56% of the buyer respondents indicated that their companies had contracted or planned to contract with CDMOs/CMOs for manufacturing services at clinical scale and 33% at commercial scale. Midsized pharmaceutical/biotech companies are slightly more inclined to outsource their manufacturing needs both at the clinical scale (60%) and commercial scale (38%). In addition, 63% of the respondents reported that their companies




had contracted or planned to contract with CDMOs/CMOs for research & development and/or manufacturing services for advanced intermediates. Big pharmaceutical/biotech companies showed the highest level of interest (67%), followed by emerging (65%), midsized (59%) and small (57%) pharmaceutical/biotech companies.[2]

The pharmaceutical industry's growing preference for contract manufacturing is good news for CDMOs as API manufacturing accounts for the largest business segment for CDMOs.[3] However, as pharmaceutical/biotech companies are racing for novel therapeutics, the APIs are becoming more complex, posing serious challenges to a CDMO's technical expertise and competency. Additionally, the drug developers have become more cautious in selecting contract manufacturers. A CDMO/CMO's ability to produce quality APIs at scale, ensuring supply chain security and final product quality, is critical in winning a contract. To keep pace with the evolving pharmaceutical industry, CDMOs must take a customer-centered approach to understand their changing needs and long-term goals, and be willing to invest and adapt new capabilities to meet specific demands. To stand out in the competitive outsourcing market, BioVectra has been implementing several strategies to maintain competitive advantage including expanding competencies and capacities, developing niche capabilities and becoming, more than ever, a true strategic partner.

## BEING AN INTEGRATED SERVICE PROVIDER

For drug developers, the benefit of a CDMO with fully integrated service capabilities is manifold. First, it simplifies the drug development value chain. Better communication, enhanced project management and seamless scale-up occur as products advance through each stage. Additionally, time and cost savings are achieved through technology transfer between different service providers. Indeed, many pharmaceutical/biotech companies are interested in having a long-term relationship with a single service provider (or a few) rather than transactional relationships with many. As seen in the 2016 Nice Insight CDMO Outsourcing Survey, less than one third of the respondents (31%) are seeking a tactical service provider when selecting a CDMO/CMO. The rest of the respondents are seeking a relationship beyond transactional, with 43% seeking a preferred provider and 26% seeking a strategic partner.[2]

Building on 45 years of experience, BioVectra has developed full-service capabilities for cGMP custom API manufacturing in both synthetic chemistry and microbial/fungal fermentation. A suite of ancillary capabilities complementary to GMP manufacturing are also in place, including raw material in-process and final product testing; process research, development and optimization; analytical method transfer and development; stability testing; process and analytical method validation; batch record/SOP preparation; assurance of regulatory compliance; and custom packaging and labeling, as well as state-of-the-art inventory management. With these capabilities, BioVectra is poised to serve pharmaceutical/biotech companies as a long-term partner to take their complex molecules, small or large, from lab (grams) to pilot (multi-kilogram) to commercial scale (metric ton).

## STRENGTHENING CORE COMPETENCY AND EXPANDING MANUFACTURING CAPACITY

In response to pharmaceutical/biotech companies' increasing outsourcing demands, the outsourcing market has witnessed a wave of infrastructure renovation, capacity expansion and mergers and acquisitions lately.

BioVectra has also been actively investing in infrastructure upgrades and is constantly enhancing core competencies. The company is adding an additional 30,000 liters of fermentation capacity and installing improved downstream purification equipment in its newly acquired API manufacturing facility in Nova Scotia, Canada. This expansion makes BioVectra the CDMO with one of the most extensive ranges of fermentation and downstream purification capabilities in North America.[3] This improved purification capacity is also designed to

THE PARTNERSHIP BUSINESS MODEL ALLOWS BIOVECTRA **TO EXPAND SERVICE COMPETENCIES AND DELIVER ON CLIENT EXPECTATIONS.**

support isolation and purification of potent intermediates and APIs. Additional investment plans include several new pre-clinical fermentation and potent chemistry suites.[4] This series of self-financed expansion is driven by the demand for more microbial/fungal fermentation capacity.

### DEVELOPING NICHE CAPABILITIES

As APIs are becoming more diversified and complex, specialized capabilities are often required to produce them. One such niche is the capability to produce high-potency APIs (HPAPIs). HPAPIs can be a small molecule, biologic or a hybrid of the two such as an antibody drug conjugate, a fast-growing class of targeted therapy applied primarily in cancer treatments. According to Roots Analysis, over 25% of total drugs worldwide are classified as highly potent.[5] Additionally, a significant fraction of pipeline drug candidates contain HPAPIs, resulting in growing demand for their production. In Nice Insight's 2016 survey, 51% of the respondents reported their companies acquired or planned to acquire service for high-potency compounds capabilities and 40% acquired or planned to acquire service for cytotoxic compounds capabilities.[2]

However, due to their high potency and, most likely, cytotoxicity, manufacturing HPAPIs require specialized facility design, equipment, operation, process control and safety to achieve the desired level of containment. To meet these challenges, BioVectra has placed significant investment in equipment and technologies designed for process containment, potent handling training and extensive industrial hygiene and environment monitoring systems. Both BioVectra's fermentation and chemical processing suites are equipped to handle potent substances. Over the past decade, BioVectra has manufactured more than 10 HPAPIs and established the capability to handle products with an occupational exposure limit below 20 ng/m$^3$.

Other niche capabilities BioVectra offers are custom functionalization of methoxy-polyethylene glycol (MPEG). PEGylation is a broadly used technology to improve the pharmacokinetic profile of therapeutic agents and extend their half-life, and is especially useful in developing biological therapeutics. With a secured, unique supply chain of the starting material, BioVectra is able to produce cGMP MPEG derivatives tailored to clients' specifications using proprietary, scalable technology. Combined with its expertise in bio-conjugation, BioVectra is able to achieve PEGylation efficiency required by clients. Its capability to handle, process and quantify APIs under cGMP differentiates BioVectra from other players in this market.

### BEING A TRUE STRATEGIC PARTNER

Under today's stringent regulatory environment, quality is the top concern in every drug maker's mind and thus the primary criteria for selecting a CDMO/CMO rather than cost. In Nice Insight's 2016 CDMO Outsourcing Survey, the first reason for respondents' companies to engage contract service providers is to improve quality, followed by improving time-to-market and reducing costs. Quality is also a decision driver when selecting a contract service provider, while affordability is the least important among the six surveyed decision drivers.[2] The concern about regulatory compliance and date integrity in offshore manufacturing facilities is now driving some offshore API manufacturing back to the U.S. and Europe, particularly for specialty APIs.[6] This trend means more opportunities for CDMOs/CMOs that focus on the U.S. and European markets.

BioVectra understands these concerns and is committed to the highest quality standards. At BioVectra, each project, regardless of size, is evaluated holistically with respect to the client's long-term development goal. Each solution is customized to meet clients' present needs, and also designed for smooth advancement to the next stage. The company is focused on forging strong partnerships elevated from custom-vendor level. For example, all of its drug development activities are conducted under partnership agreements in which BioVectra shares the cost and risk of development with clients. P

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**Stephen** received his master's in biochemistry from Memorial University of Newfoundland in 2003 and graduated with his master's in business administration from Saint Mary's University in 2004. Stephen joined BioVectra in 2004 as a Project Manager and worked in various business development roles within BioVectra leading to his current position in 2015.

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