ESTABLISHING SPECIALIZED CDMO CAPABILITIES FOR THE PRODUCTION OF ADVANCED THERAPIES

→ BY **OLIVER TECHNOW, SCOTT DONCASTER** AND **HEATHER DELAGE**, BIOVECTRA

Most pharmaceutical and biopharmaceutical companies are establishing closer relationships with a few select service providers that have unique combinations of capabilities and demonstrated performance.

To be successful, contract development and manufacturing organizations (CDMOs) must be forward thinking—constantly anticipating the future needs of potential customers and investing in state-of-the-art facilities, equipment and technologies. To attract those customers, CDMOs must also have a very strong track record of performance with respect to the quality of the products and services, their ability to meet project objectives and timelines, and their regulatory compliance history – all combined with advanced and specialized capabilities. A commitment to transparency, open communication, true collaboration and a genuine respect for the needs of each client's individual projects has also become essential for CDMOs that want to participate in strategic partnerships with their customers. BioVectra Inc. does all of this and more.

BIOVECTRA:

LEVERAGING OVER 45 YEARS OF EXPERIENCE

60,000 L FERMENTATION CAPACITY

13,000 ft² LOCATION EXPANSION

Industry leader in the field of metabolite microbial fermentations (small molecule, peptides, etc.) combined with core synthetic chemistry competencies for downstream chemical modification and purification of secondary metabolites produced by microbial fermentation.

Extensive experience with filamentous fungal and bacterial strains; native and recombinant bacteria; and salt water microbial organisms.

Drug development of challenging new entities and generic products, including particulate injectable formulations with highly potent and cytotoxic active ingredients, controlled release products, and APIs semi-synthesized from metabolites via highly challenging fermentation.

Fermentation and chemical processing suites equipped to handle potent substances with policies, physical containment measures, and analytical methods audited by customers and specialized consultants.

Specialized, innovative cGMP manufacturer of APIs, advanced intermediates, specialty bioprocessing reagents, enzymes, and biomolecules.

Manufacturing and development support services through every stage of drug development.

Expertise in synthetic organic chemistry, fermentation, custom MPEG production, and natural extraction, and producing both chemical and biologic molecules, including highly potent compounds

STRONG HISTORY OF PERFORMANCE

While outsourcing provides many benefits to drug manufacturers, including access to needed capacity and technical expertise, the ability to convert capital expenditures into operating expenses, and the opportunity to increase productivity and cost efficiency, it also carries a significant amount of risk. CDMOs that present minimal risk through demonstration of consistently high performance, combined with the needed technical expertise are most likely to be selected.

BioVectra has been providing a unique combination of synthetic organic chemistry and fermentation of chemical and biologic molecules – including highly potent compounds, downstream processing, methoxypolyethylene glycol (MPEG) production and conjugation chemistry services – for more than four decades to small and large pharmaceutical, biotechnology, generic, and early stage companies. R&D to commercial-scale quantities of cGMP raw materials, intermediates and active pharmaceutical ingredients are produced at three facilities on Prince Edward Island, Canada, all of which are regulatory audited by the FDA, Health Canada and the Japanese Ministry of Health.

The company has submitted 10 product filings, including ANDA, DMF, VMF and CMC section preparations for both the FDA and Health Canada. Through various partnerships, BioVectra has developed challenging new entities and generic products, including particulate injectable formulations with highly potent and cytotoxic active ingredients, controlled release products, and APIs semi-synthesized from metabolites via highly challenging fermentations. Its extensive capabilities in the handling, processing, and quantifying of APIs from natural sources have been applied to the isolation of domoic acid from mussels, adenosine deaminase from bovine sources, and taxanes from yew trees. BioVectra also offers cGMP bioprocessing reagents, such as dithiothreitol (DTT) and tris (2-carboxyethyl)phosphine hydrochloride (TCEP-HCl), and develops custom solutions for MPEG functionalization using proprietary, scalable chemistries.

SPECIALIZED YET DIVERSIFIED

Production of the advanced therapies under development today often requires a wide range of specialized capabilities. Many of today's drug candidates require both biologic and small-molecule production and purification capabilities, as well as expertise in pegylation and conjugation chemistry. Even so, most CDMOs have elected to focus either on biotechnology or small-molecule chemistry, and few can offer a combination of both.

Since its inception as a manufacturer of biological reagents, BioVectra has been evolving to meet its customers' needs. The addition of cGMP manufacturing capabilities for DTT and other reagents required the development of expertise in scaled chemical manufacturing, and the company continues to develop synthetic and analytical methods for customized bioprocessing reagents. During this period, the company

also developed expertise in the extraction, handling, and quantification of APIs (chemicals and proteins) from natural sources. By natural extension, BioVectra developed expertise in microbial fermentation for the production of metabolites, in particular using filamentous fungal and bacterial strains, native and recombinant bacteria, and salt water microbial organisms. Many of these products were highly potent, which led BioVectra to develop specialized facilities, equipment and procedures for the safe production and handling of potent compounds. Application of the company's core synthetic chemistry competencies for downstream chemical modification and purification of secondary metabolites was the next step in the company's evolution.

PRODUCTION OF THE **ADVANCED THERAPIES** UNDER DEVELOPMENT TODAY OFTEN REQUIRES A **WIDE RANGE OF SPECIALIZED CAPABILITIES**.

As a result, BioVectra has a unique combination of capabilities – it is in fact a highly diversified CDMO offering a range of very specialized technologies. With this technical profile, BioVectra can serve as a single development and manufacturing partner for pharmaceutical companies developing novel therapies that require expertise in the processing of both small and large molecules. In addition, these services are available at R&D to commercial scales, allowing customers to avoid the time and cost associated with technology transfer from one service provider to the next.

INVESTING FOR THE FUTURE

Innovation lies at the heart of the pharmaceutical industry, and CDMOs must keep pace with their customers. That requires the ability to anticipate future client needs and the willingness to invest in new capabilities. BioVectra has, throughout its history, worked closely with its customers, installing capacity and building expertise to meet their needs. More recently, the company has aggressively invested in capacity expansions around its core competencies of fermentation and downstream processing. Expenditures from 2014 through 2016 totaling more than $50 million include the following: acquisition of the former Sepracor API production facility located in Nova Scotia, Canada; installation of an additional 30,000L of fermentation capacity (for a total of 60,000L); installation of improved downstream purification equipment to support existing fermentation capacity with specialized capabilities in potent intermediate and API purification processing; investment in new preclinical fermentation and potent chemistry suites; and the addition of 13,000 square feet of laboratory, office, workstation, and meeting space for its growing workforce.

NEW LEADERSHIP TEAM FOCUSED ON GROWTH

In addition to these investments, BioVectra also recently brought Oliver Technow on board as President to guide the company through its next phase of development. With his extensive experience in commercial development and marketing, brand, and life cycle management for various global pharmaceutical companies, Mr. Technow has a unique perspective on the needs of CDMO customers. This market understanding, combined with the extensive knowledge of the company's long-serving business development and technical leaders, will help BioVectra expand its partnerships with existing customers and develop new collaborative relationships. P

→ ABOUT THE AUTHORS

Oliver Technow President, BioVectra

With more than 20 years of global pharmaceutical industry experience, Oliver Technow, President of BioVectra, has held numerous leadership positions in commercial development, marketing and brand management and life cycle management in Europe and North America, and was appointed President of BioVectra Inc. in December 10, 2015. He holds an industry master's degree from Frankfurt Chamber of Commerce, Frankfurt Germany.

LinkedIn www.linkedin.com/in/oliver-technow-b1b26a13?
Email otechnow@biovectra.com

Scott Doncaster Vice President, Manufacturing Technologies and Engineering, BioVectra

Since joining BioVectra in 1995, Scott Doncaster, Vice President, Manufacturing Technologies and Engineering has demonstrated his leadership supervising enzyme and natural products bioextraction process operations. In 2000, Doncaster was promoted to Operations Manager, to Director of Manufacturing in 2005 and to his current role in 2014. He holds a B.Sc. in biochemistry from Mount Allison University in New Brunswick, Canada.

LinkedIn www.linkedin.com/in/scott-doncaster-7177b813?
Email sdoncaster@biovectra.com

Heather Delage Vice President, Business Development, BioVectra

Heather Delage Vice President, Business Development for BioVectra has 25 years of experience in marketing management, project management, and business development in the pharmaceutical, biotechnology, and clinical diagnostic industries. She holds a B.B.A. with concentration in marketing from University of Prince Edward Island.

LinkedIn www.linkedin.com/in/heather-delage-1b5ba710
Email hdelage@biovectra.com

BioVectra

Pioneering Answers

Quality services and products

Specialized capabilities for your manufacturing, bioprocess reagents and drug development needs. Our collaborative and flexible approach combined with our customer focus, makes BioVectra your ideal partner.

For more information, call 866.883.2872 or visit www.biovectra.com

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