



>45  
Years of Experience in  
Custom API Manufacturing



BioVectra

Refreshing  
Adaptable CDMO

## Refreshingly Aligned

### Adaptable to Your Needs

BioVectra is a contract development and manufacturing organization (CDMO) that serves pharmaceutical and biotech companies with full-service cGMP outsourcing solutions for intermediates and active pharmaceutical ingredients (APIs). With 45 years of experience, we specialize in complex chemistries, including capabilities for high potent APIs and microbial/fungal fermentation.

### Flexibility of Four North American Facilities

BioVectra has three facilities based in P.E.I., Canada and a new facility in Nova Scotia, which adds further capacity for fermentation and small-scale complex chemistry. These four sites offer flexibility to customers seeking to outsource intermediates and APIs at all stages of development and commercialization in North America, combined with a highly experienced team and a track record supplying pilot to commercial-scale APIs.

Quality  
We work under one, mature  
quality system that is applied  
across all of our facilities.

Inspection history with:  
U.S. FDA  
HEALTH CANADA  
JAPANESE MINISTRY  
OF HEALTH

## Deep Experience Accessible To You

### Stable, Experienced CDMO Partner

BioVectra has applied its API development and manufacturing experience to structure a number of unique partnerships with our clients. Dedicated product operations, co-development programs, and program-specific capacity expansions have been undertaken successfully because of the deep and lasting relationships we form with our clients. Operating from a place of natural beauty in Eastern Canada, our long-tenured employees enjoy living and working in this place, and we have brought together a team of experts with diverse backgrounds in chemistry, biochemistry, biotechnology, polymer chemistry, chemical engineering, and formulation sciences. We have a unique ability to work together and apply this diverse knowledge, and solve our client's problems and challenges.

4  
North American Facilities

API FACILITY  
(FERMENTATION & SYNTHESIS)  
Charlottetown  
Prince Edward Island  
  
BIOCHEM FACILITY  
Charlottetown  
Prince Edward Island  
  
API FACILITY  
Charlottetown  
Prince Edward Island  
  
API FACILITY  
(FERMENTATION & SYNTHESIS)  
Windsor  
Nova Scotia

>10  
Commercial Filings  
ANDA, DMF, VMF & CMC

\$25 Million  
Capital Investments Across  
Four Sites Over 12 Months

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+ Drug Development Partnerships  
+ Complex Chemistry  
+ High Potent APIs  
+ Microbial Fermentation  
+ MPEG Reagents/Conjugation  
+ Four North American Facilities

[www.biovectra.com](http://www.biovectra.com)



# Complex API Synthesis

## Refreshingly Experienced

BioVectra has worked on hundreds of small molecule API projects at all stages of development. Our team has decades of experience taking processes from lab-scale to metric ton quantities. State-of-the-art equipment across our facilities allows us to provide scale-up and supply of critical API throughout the clinical life of the drug, and our commercial-scale capabilities further the opportunity for consistency, efficiency and risk mitigation through a single partner.

Up to 18,000 L

Lab-scale to large-scale commercial synthetic API manufacturing



64,000 L  
Fermentation capacity

# Microbial Fermentation Manufacturing Capabilities

## Refreshingly Scalable

Through investment and considerable project experience, BioVectra has become an industry leader in microbial fermentations of both small and large molecules, with one of the industry's most scalable operations. Due to market demand, we have invested in several expansions to increase capacity, including a new facility in Nova Scotia, Canada. We integrated our core synthetic chemistry to enable chemical modification and solvent-based purification of secondary metabolites produced by microbial fermentation.



- + Process Development
- + Analytical Services
- + Regulatory Support

<20 ng/m<sup>3</sup>  
Potent compound OEL levels

# High Potent APIs

## Refreshingly Specialized

BioVectra has made significant investments in equipment designed for process containment, which has enabled us to handle compounds with OEL levels of < 20 ng/m<sup>3</sup> (Band 4). We have chemical and fermentation processing suites equipped to handle potent substances. Our internal high potent staff training, environmental monitoring systems, and industrial hygiene methods have facilitated successful delivery in more than 10 HPAPI projects over the past decade, and it's an area where we plan to continue expanding our capabilities.



>10  
Years of Experience with High Potent API Projects



- FERMENTATION OF:
- + Small molecules
  - + Proteins, Enzymes
  - + Antibody Fragments
  - + Peptides

- WORKS WITH:
- + Filamentous Bacteria
  - + Marine based Bacteria
  - + Fungal fermentation
  - + E. Coli