



BioVectra has ensured
quality, value and service
for over 45 years.

CONTRACT MANUFACTURING

BioVectra operates from three FDA-inspected facilities in Prince Edward Island, Canada, with the capacity to produce commercial-scale active pharmaceutical ingredients. Its operations are currently expanding to a fourth plant in Nova Scotia, offering further capacity for fermentation and chemistry. Facilities are equipped to provide synthetic organic chemistry, natural extraction of bioactive compounds from both plant and animal-based biomass sources, PEGylation and conjugation chemistry, and fermentation of a variety of molecule types.

Your Manufacturing Partner

SCOPE OF CAPABILITIES

- Two pilot facilities equipped with reactors from 20L to 800L
- Commercial scale equipment: 3 x 4000L, 1 x 8000L & 1 x 18000L
- Depth of experience in complex multi-step synthetic chemistry
- Specialized in producing high-purity mPEGs
- Commercial fermentation and chemistry within a single facility
- Ability to handle highly potent compounds (<20 ng/m³)
- Range of purification capabilities and scales
- Ideally suited for 1-5 metric tonne volumes
- Five Class 100,000 production suites designed with mobile equipment

CUSTOM CHEMICAL MANUFACTURING:

BioVectra was founded on synthetic chemistry and it remains a core strength to this day. BioVectra has worked on over 100 chemical API projects in various stages of clinical development. With over 45 years' experience in the industry carrying processes from the bench to metric tonne scale, BioVectra is able to provide its customers with solutions today that will reduce risk in the future.

OTHER MANUFACTURING CAPABILITIES

- Microbial/Fungal Fermentation
- Complex Chemical Synthesis
- Biomass Extraction and Purification
- Custom mPEG Functionalization
- High Potency Chemical Processing
- Drug Development

We look forward to discussing your project:
866.883.2872 | info@biovectra.com



SERVICES TO COMPLEMENT GMP MANUFACTURING

Strong audit history with
FDA & Health Canada

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

24-hour operation,
7 days per week

Custom packaging and
labelling

biovectra.com



BioVectra is one of the largest fermenters of potent compounds in North America. We can accommodate pre-clinical to commercial projects and offer dual manufacturing capacity within Canada.

cGMP FERMENTATION

BioVectra has worked for the past 15 years with an extensive range of complex microorganisms in a cGMP commercial environment which has included filamentous fungi, bacteria, *Streptomyces* spp, yeast and *Actinomyces* spp.

To meet increased demand for our services, we are expanding our fermentation capacity from 25,000L to 50,000L with the addition of a second geographically distinct commercial site. We have also retained our core synthetic chemistry competencies to enable chemical modifications and solvent based purification of secondary metabolites produced by microbial fermentation.

Your Manufacturing Partner

SCOPE OF CAPABILITIES

- Dedicated processing areas
- Master cell banking
- Titer optimization
- Solvent handling for organic extractions
- Complex chemical processing
- Engineered broth filtration solutions
- Detailed fermentation process monitoring
- Downstream purification capabilities
- Full process containment (OEL <20ng/m³)
- Scaled process chromatography
- Full complement cGMP analytical testing

EXPERIENCE

- Since 2004 we have handled seven high potent projects (lowest OEL being <20ng/m³)
- Over 20 fermentation projects in the past seven years
- FDA pre-approved inspection for commercial fermentation
- Internal QA support for IND, CMC, and DMF submissions

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VESSELS

R&D:

Shake flask

3 x 20L

Pilot Suite:

1 x 130L

1 x 1,500L

Commercial Suite #1:

2 x 30L

1 x 500L

1 x 1,000L

1 x 10,000L

1 x 15,000L

Commercial Suite #2 (2016):

1 x 100L

1 x 3,000L

2 x 17,000L

A decorative background graphic consisting of a network of interconnected nodes and lines, with nodes in shades of blue and orange.

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