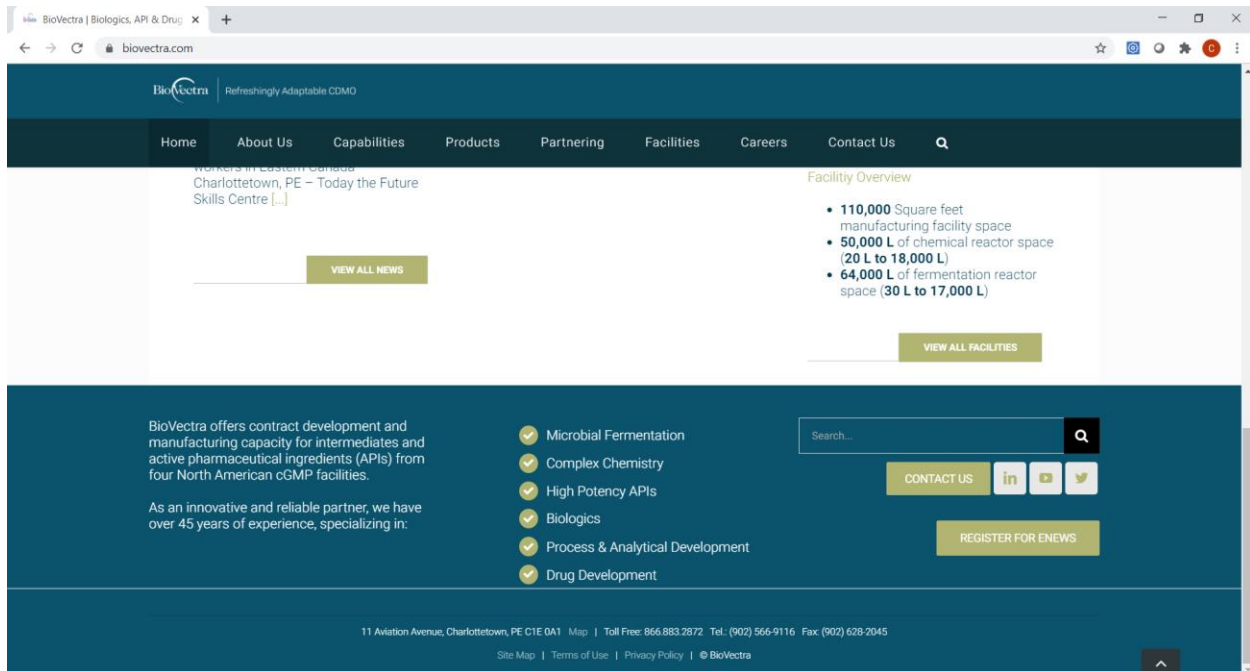


<https://www.biovectra.com/about-us/> Classes 40 and 42 January 26, 2021



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Canadian Biologics Contract Drug Manufacturing | biovectra.com/biologics/ | Toll Free: 866.883.2872

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Biologics Contract Drug Manufacturing

From Cell Line Development to BLA Filing

- Innovation
- Modern Manufacturing
- Unconstrained Business


Twenty years ago we were presented with a complex Microbial Fermentation project by a major pharmaceutical company who needed a high quality, cGMP North American supplier. Fourteen months and a capital expansion later, we entered into commercial manufacturing since then we have become an industry leader of both Small and Large Molecules, with scalable cGMP operations from 30L to 17,000L

This core competency has naturally led us into the Microbial Biopharmaceutical business, rooted in our modern Microbial Biologics facility in Windsor, Nova Scotia, Canada. This distinct facility is equipped to work with a range of biosafety level one (BSL-1) expression systems, including:

- Microbial Fermentation For APIs
- Complex Chemistry
- High Potency APIs (HPAPI)
- Biologics Manufacturing**
- Process & Analytical Development
- Drug Development
- Literature

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- E. Coli
- Pichia Pastoris
- Saccharomyces Cerevisiae

As a rare provider with competencies in both chemistry and biologics, we offer fast-moving development companies the opportunity to streamline their supply!

Types of Drug Substances

- Proteins
- Enzymes
- Antibody Fragments
- Peptides
- Attenuated Virus

Process Development for Complex Fermentation Processes and Difficult To Purify Molecules

- Analytical development for most Biologic release assays
- cGMP Manufacture for preclinical to commercial (Scale from 30L to 17,000L) and cGMP Cell Banking
- Post-production modifications (PEGylation, Conjugation, Liposomal Encapsulation)
- Support Services such as ICH Stability, Reference Standards, and

Canadian Biologics Contract Dr... x +

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Refreshingly Adaptable CDMO

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- Attenuated Virus Vaccines
- Support Services such as ICH Stability, Reference Standards, and Formulation Development

Process Development & Analytical Capabilities

cGMP Manufacturing



Please contact us to learn more about our Biologics capabilities.

CONTACT US

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Complex Chemistry Solutions | B... x +

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Complex Chemistry Solutions

BioVectra's chemical process development group is experienced. With over 30 years of know-how, we have assisted clients with small molecule projects from IND, through clinical trials and commercial supply (lab-scale to multi-metric ton quantities). Our team provides phase appropriate solutions; focusing on delivering clinical trial supplies, while addressing short-term scale-up requirements and long-term manufacturing options that address key Cost of Goods (COGs) targets.

We have worked on over 100 chemical API projects, including: complex multi-step synthesis, asymmetric chiral introductions, natural products, analogues and in-organics.

Support services include:

- Highly experienced staff with over 200 years of combined experience
- Route development
- Process development & optimization
- Chromatography – Biotage & reverse phase prep-HPLC
- High potency capabilities ($DP1's < 20 \text{ ng/m}^3$)
- Regulatory strategies & CMC support
 - Raw materials
 - Analytical controls
 - Impurity identification
 - Fate & purge
 - Establishing acceptable ranges for CPP's
 - Life-cycle management
- Process validation

Capabilities

- Microbial Fermentation For API's
- Complex Chemistry**
- High Potency APIs (HPAPI)
- Biologics Manufacturing
- Process & Analytical Development
- Drug Development
- Literature

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Microbial Fermentation For API's

BioVectra is an industry leader in microbial fermentation of both small and large molecules, with scalable cGMP operations from **30L to 17,000L**. In response to market demand we have invested in several expansions to double our capacity to **64,000L**, which is located across two geographically distinct locations providing commercial redundancy.

In addition to industry standard downstream processing techniques, BioVectra's core synthetic chemistry capabilities have been integrated into our fermentation service offerings, allowing for complex solvent-based purification processes. This is further extended by a core focus on natural product syntheses from secondary metabolites produced by microbial fermentation to

Types of Drug Products:

- ✓ Small molecules
- ✓ Proteins
- ✓ Enzymes
- ✓ Antibody fragments
- ✓ Peptides

Range of Microbes:

> Capabilities

> Microbial Fermentation For API's

> Complex Chemistry

> High Potency APIs (HPAPI)

> Biologics Manufacturing

> Process & Analytical Development

> Drug Development

extended by a core focus on natural product syntheses from secondary metabolites produced by microbial fermentation to generate highly complex intermediates and APIs.



Range of Microbes:

- ✓ Filamentous bacteria
- ✓ Marine based bacteria
- ✓ Fungal fermentation
- ✓ E. Coli

Downstream Processing:

- ✓ Centrifugations
- ✓ Lysis
- ✓ Purification
- ✓ UF/DF
- ✓ Synthetic chemistry

> Drug Development

> Literature



The screenshot shows a web browser window with the URL <https://www.biovectra.com/capabilities/chemical-process-analytical-development/>. The page features a dark teal header with the BioVectra logo and tagline "Refreshingly Adaptable CDMO". A navigation menu includes Home, About Us, Capabilities, Products, Partnering, Facilities, Careers, and Contact Us. The main content area is titled "Chemical Process & Development Services" and includes a descriptive paragraph, a list of services, and a sidebar menu.

Chemical Process & Development Services

BioVectra offers a fully integrated approach to the process development of chemical and biological active pharmaceutical ingredients (APIs). We combine scalable and adaptable development services with a proven history of scientific expertise to rapidly move APIs from development to commercial manufacturing.

Our process and analytical development services include:

- ✓ Process development and scale-up
- ✓ Tech transfer of new and existing processes
- ✓ Highly potent APIs and controlled substances
- ✓ Microbial fermentation
- ✓ cGMP analytical services
- ✓ Critical process parameter (CPPs) and critical quality attributes (CQAs) by Quality by Design (QbD)
- ✓ Clinical supply manufacturing
- ✓ Process improvements
- ✓ Complex chemistry
- ✓ Phase appropriate cGMP
- ✓ Production (cGMP and non-cGMP) at lab and pilot scale

Chemical API Process Development

Capabilities

- > Microbial Fermentation For APIs
- > Complex Chemistry
- > High Potency APIs (HPAPI)
- > Biologics Manufacturing
- > **Process & Analytical Development**
- > Drug Development
- > Literature

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