

Refreshingly Adaptable CDMO

Custom API Synthesis, High Potent APIs,
and cGMP Microbial Fermentation



Overview

- Process Development & cGMP CDMO for Pharma and Biotech companies
 1. Synthetic Chemistry – Multi-step synthesis, Natural Products, MPEGs, Inorganics, ADC related chemistries
 2. Fermentation – Small molecules, proteins
 3. Biochemical reagents – Custom and catalogue
- High Potency Containment
- Kilo Labs, Pilot Plant, Commercial Scales

**Strategic Partner from
R&D through Commercial**



Corporate



- 45 years experience
- 300 Employees
 - 15 Ph.D.
 - 29 Master's
- 110,000 Sq. Ft., 50 m³
- Over 10 commercial filings (ANDA, DMF, VMF, CMC)
- FDA, HC, PMDA Inspected & Approved

Management Team

Oliver Technow



President

Mark Wellman

Heather Delage

Scott Doncaster

Marc Sauer

Peter Phillips

George Rowat

Lester Wood

Valana Deighan



Vice President
Manufacturing

Vice President
Development

Vice President
Manufacturing
Technologies
& Engineering

Vice President
Research &
Development

Vice President
Quality
Assurance &
Regulatory
Affairs

Vice President
Finance &
Administration

Executive
Director
Human
Resources

General Counsel

Locations



Eastern Canada – PEI / NS

- Proximity to N.E United States
- 8 Nearby Universities
- Established Bioscience Community

Charlottetown and Windsor



Population:

- 145,000 (Summer months 500,000)



Island:

- 220 km long and 6-64 km wide

Charlottetown:

- “Birthplace of Canada”



Facilities



17 Hillstrom Av.

- R&D
- Fine chemical manufacturing



11 Aviation Av.

- API
- Fermentation
- Release labs



24 Ivey Lane

- Fermentation
- Chemical scale-up
- Hydrogenation suite



Dedicated API Facility

- Natural product extraction

Chemical Process & Analytical Development



- Phase Appropriate Development
- Analytical Method Development & Validation
- QbD (DoE Studies)
- Laboratories
 - Glassware to 50L
 - 400 MHz NMR Spectrometer
 - Biotage Purifications
 - Crystallization and Solid Form Development
 - High Potency Handling
 - HPLC, UPLC, GC, SEC and IC
 - UV, ELSD, RI, FID; MS; MS/MS
 - Process Hazard Analysis

cGMP Scale-up Facility

- 5 Suites
- Reactors (Modular)
 - 30L, 50L, 2x100L, 200L, 400L
 - 800L Fixed Reactor Train
 - 2 x 4,000L
 - -60 C to 140 C
 - Enclosed filters
 - Tray dryers
- Hydrogenations
- Class 100,000 capabilities



Pre-Clinical, IND, Phase I-III, Commercialization

High Potency Scale-up

- 2 Suites
- OEL ' s < 20ng/m³
- Entry and exit airlocks, Hepa filtered air
- Class 100,000 modular rooms
- Industrial hygiene monitoring program
- Reactors
 - 30L, 50L, 120L, 200L, 2 x 400L SS Portable
 - -60 C to 180 C
 - Enclosed filters
 - Biotage Chromatography
 - Custom Enclosed Fraction Collection System
- Isolator with built in filter dryer
(Up to 5 Kg capacity)



Purification Capabilities



- Biotage
 - 150L, 3 x 400L (5-40kg cartridges)
 - Normal phase, specialty and custom packed
- Reverse Phase HPLC
 - 3" column
- Ion Exchange
- Hydrophobic Ion
- Distillation
- Concentration WFE, UF/DF
- Lyophilization
- Crystallizations

Non-GMP Scale-up

- Intermediates
- Raw Materials
- Key Reagents
- Reactors
 - 200L, 2 x 400L, 800L
 - 2 x 2,000L, 3,000L, 4,000L
 - -25 to 120 C
- Enclosed Filters, Tray Dryers, Tumble Dryer



Dedicated Facilities

- Commercial Manufacturing Partnerships
- Reactors
 - 4,000L, 8,000L, 18,000L
 - Bulk Solvent Tank Farm
 - -20 to 140 C
- Specialized isolation and filtration equipment



**Strategic and Flexible Partner –
Growing with our Clients**

R&D BioTech Capabilities

Process Development

- Screening of medium components
- Design of experiments (DoE)
- Optimization of scale-up parameters from flask to fermenter scale

Tech Transfer Activities

- Cell Line importation permits
- Process confirmation (Upstream & Downstream) at lab scale
- Process transfer to production scale
- Supporting supply chain, analytical and production groups to setup new raw materials and preparation of QC and BPRs procedures



cGMP Fermentation



Range of Microbes

- Filamentous Bacteria
- Marine Based
- Fungal
- E. coli

Types of Drug Products

- Small Molecules
- APIs
- Peptides
- Antibodies

Facilities

- Pilot Suite
 - 1 x 130L
 - 1 x 1,500L
- Commercial Suite
 - 2 x 30L
 - 1 x 500L, 1 x 1,000L
 - 1 x 10,000L, 1 x 15,000L
- Expansion Suite
 - 1 x 100L
 - 1 x 3,000L
 - 2 x 17,000L

Downstream Purification of Complex Chemical & Biologic Molecules

Chromatography



- Normal-phase
- Reverse-phase
- Ion-exchange
- Hydrophobic interaction

Distillation



- Low pressure

Concentration



- Wiped film evaporation
- Ultrafiltration / diafiltration

Lyophilization



- Manifold
- Tray

Investments & Expansion



- \$34 M investments over 2015/16 for a significant expansion
- 4th facility was acquired to provide additional capacity for fermentation and small-scale complex chemistry (Windsor, Nova Scotia, total volume 64,000L)
- Enhanced downstream chemical modification and purification of potent intermediates and APIs
- 13,000 sq/ft expansion of our Charlottetown facility
- Continued support of process development for early stage API programs

Refreshingly Customer-Focused Offering

Expertise

Complex chemistry, high potent APIs, microbial fermentation, and MPEG Reagents/Conjugation

Adaptable

Flexible and scalable capacity aligned to the needs of our customers

Quality

One quality system applied to four facilities across North America
History with global regulatory agencies

Experience

45 years of custom manufacturing
>10 commercial filings over 10 years

Partnerships

Dedicated product operations, co-development programs, and program specific capacity expansions



Focusing on You



We are grateful for your time and the opportunity to make this presentation.

BioVectra looks forward to the opportunity to focus on you and meet your specific needs with Refreshingly Adaptable CDMO services.



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