

Drug Development

Canada

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Biovail Contract Research

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Profile 13831:11

Biovail Contract Research is an FDA-inspected Contract Research Organization (CRO) specializing in early clinical trials, and bioanalysis. Biovail conducts Phase I trials, Phase I/IIa trials, bioequivalence studies, and marketing trials involving healthy volunteers and special patient population groups, on a contract basis, for pharmaceutical, drug delivery, biotech, and nutraceutical companies. Biovail Contract Research is an independent CRO, and is a subsidiary of Biovail Corporation.

As a CRO specializing in early clinical trials, Biovail Contract Research has conducted more than 2,500 Phase I studies on more than 400 different chemical entities in all major therapeutic categories. This experience allows us to provide clients with critical input during the study design and planning stages, and helps ensure that their trial is considered top priority. Our large subject database has more than 72,000 healthy adult volunteers, and is one of the largest in the industry; this allows rapid study initiation. Our clinical facility has more than 200 beds, and our Phase I clinic houses 12 hospital beds and an ambulatory telemetry unit for intensive medical monitoring, allowing up to 7 studies to be run at our clinics at the same time. Our clinics are set up for mixed gender studies, since we have clinics with separate dormitories, washrooms and ECG rooms for males and females. Our clinics also allow for long institutionalized studies, up to 28 consecutive days, and for large studies comprising of up to 120 subjects in a single group.

Our pharmacokinetic group can provide clients with specific recommendations on study designs, and the type of studies required for NDA, NDS, ANDA, and ANDS filings, as well as provide pharmacokinetic analysis services.

Pre-clinical: Bioanalysis of drug and metabolites in plasma samples from animal studies.

Key Contacts

Mgmt: Dr. Paul Desjardins
Mktg: Tamar Aghamanoukian
R&D: Dr. Masood Bhatti
Licng:

Products / Services

- Contract Research / CRO
- Phase I First In Man
- Phase I BA/BE
- Drug Interaction
- Phase II Proof of Concept

Corporate Data

Established: 1975
Ownership: Subsidiary
Stock #:
Employees: 225
R&D: 225
Mfg. Facilities: n/a
Lab Facilities: Yes
Financial (\$Million)
2005 Revenue: n/a

BioVectra™ dcl

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Profile 13832:11

An Eastern Canadian based manufacturer of BioActive API's with a global customer base. BioVectra provides small to large scale custom manufacturing of active pharmaceutical ingredients (API's) and advanced intermediates (AI's) along with a complement of core products targeted toward bioprocessing. BioVectra operates out of three FDA-inspected facilities (April 2003 and June 2005) equipped to provide a range of contract services for our clients (highlighted below). BioVectra dcl's staff is knowledgeable in the requirements for commercialization of API's and has a Quality Management System that reflects those needs. We currently have five DMF's registered with the FDA.

BioVectra dcl specializes in:

- cGMP manufacturing from early development stage to commercial-scale for AI's & API's
- Plant bioactive extraction & purification
- Large-molecule animal extraction & purification, under strict BSE-Free controls
- Synthetic modification of bioextracted compounds
- Process-scale chromatography
- Purification of API's from complex biological matrices
- Specialty bioprocessing reagents: cGMP DTT, DTE, Animal-free IPTG, TCEP, EDAC and more
- Clinical Chemistry raw materials: Adenosine Deaminase, Urease, Cholesterol Esterase, Glutamate Dehydrogenase and more
- Custom bioconjugation and PEGylation
- PEG and MPEG reagent production

Key Contacts

Mgmt: Heather Stewart
Mktg: Stephen Ball
R&D: Dr. Gary Reid
Licng: Dale Zajicek

Products / Services

- cGMP Manufacture
- Contract Mfg / CMO
- Custom Synthesis
- Validation
- Pilot Plant
- Product Development
- Quality Assurance
- Fine Chemicals

Corporate Data

Established: 1970
Ownership: Private
Stock #:
Employees: 200
R&D: 25
Mfg. Facilities: Yes
Lab Facilities: Yes
Financial (\$Million)
2005 Revenue: 50.00