

2018 Full-Time Equivalent (FTE): Drug Product – Sterile Injectables

15 Dedicated Research and Business Intelligence Team Members

MARKET SEGMENTS

Preclinical Trials

Drug Substance

+ Small Molecule API

+ Biologics

Drug Product

+ Small Molecule

Sterile Injectables

Pharmaceutical Excipients

OEM Pharmaceutical Equipment

+ Drug Product

+ Biologics

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San Diego – San Francisco

Dallas – London – Frankfurt

Shanghai – Shenzhen



Supplier Business Story

POINT(S) OF CONTACT

Board-Level

CORPORATE PROFILE / BUSINESS STORY

We are a CDMO in the drug product sterile injectable outsourcing space offering manufacturing and fill-finish of small molecule sterile compounds. Our North American locations offer formulation development, manufacturing of sterile solutions, lyophilization services and aseptic fill finish. We are currently looking for projects from domestic and overseas innovators or generic pharma companies.



Ideal Supplier Business Offering

	RESPONSIBLE ROLE	PARAMETERS CATEGORY	PARAMETERS
1	Chief Executive Officer / President, General Manager	Project Definitions	Looking for projects in Phases I, II-a and II-b. Early stage clinical products – sterile small molecule injectable
2	Chief Scientific Officer, Plant Manager	Chemistry / Technical Barriers	No hormones or large molecules, non-HPAPI, non-lyophilized, intravenous small molecule injectable
3	Chief Executive Officer / President, General Manager	Project Type Prioritization / Focus (based on experience)	Plant Capabilities: Sterile manufacturing, sterile fill-finish, both clinical scale and commercial scale capabilities, multiple packaging capability – vials, ampules, flasks, bottles, bags
4	Chief Commercial Officer, Sales Director	Minimum Project Size (based on department) [Profitability is important for a small CDMO]	<ol style="list-style-type: none"> 1,000 clinical x1 batch with vial fill and aseptic process in 5mL type A glass: \$40,000 20,000 clinical x1 batch with generic ampule fill and aseptic process in 5mL ampule, \$60,000 5,000 orphan drug regional x1 batch with aseptic process, in single injection 5 mL pre-filled syringes: \$60,000
5	Chief Executive Officer / President, General Manager	Ideal Project Specifications (for consideration)	<ol style="list-style-type: none"> 100,000 regional x8 batch with vial fill and aseptic process in 3 mL type A glass: \$300,000 50,000 blockbuster region second source with aseptic process in single injection 5 mL prefilled syringes: \$500,000 500,000 generic ampule fill with aseptic process in 3 mL ampule: \$1,000,000



Research & Lead Generation by Phase

POINT(S) OF CONTACT

PARAMETERS CATEGORY

PARAMETERS

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Chief Commercial Officer, Sales Director

Geographic Target Area (Prospect) [With 50 states, this client expanded a sales territory]

56 companies in North America are working on 87 molecules that closely align with our capabilities.

PRE-CLINICAL	71
PHASE I	31
PHASE II	60
PHASE III	58
PENDING APPROVAL	2

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Chief Financial Officer, Compliance

Risk Assessment; Historical Success & Therapeutic Approval

COMPANY	R&D SPENDING (USD MILLION)	SALES (USD MILLION)	R&D INTENSITY (%)
Top 10 Biopharma	\$70,500	\$404,800	17.41
BioCryst	\$4,940	\$17,702	27.90
BMS	\$61	\$2	—
Marinus	\$22,005	—	—



Buyers' Molecule Specification & Compatibility

(3 OF 56 COMPANIES SHOWN)

POINT(S) OF CONTACT

COMPANY

PRODUCT

THERAPEUTIC CATEGORY

PHASE OF COMPANY INVOLVEMENT

ROUTE OF ADMINISTRATION

FAST TRACK

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Chief Marketing Officer

BioCryst Pharmaceuticals

Galidesivir

Infectious disease

Phase I

Intravenous

No

Bristol-Myers Squibb

BMS-986231

Cardiovascular

Phase II

Intravenous

No

Marinus Pharmaceuticals

Ganaxolone

Respiratory

Phase II

Intravenous

No



Leads Generated – 1,026 Leads from 56 Companies

(6 OF 1,026 SHOWN)

POINT(S) OF CONTACT

COMPANY

FIRST

LAST

CONTACT TITLE

PHONE NUMBER

EMAIL

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North American Competitors with Similar Capabilities, Equipment & Ability to Deliver on Specification

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POINT(S) OF CONTACT

Chief Marketing Officer

COMPANY

Albany Molecular Research Inc. (AMRI) / OSO
 Alcami
 Avid Bioservices
 Baxter BioPharma Solutions
 Catalent / Cook
 Emergent Biosolutions
 Grand River
 Jubilant
 Pfizer CentreOne
 Pharmascience
 Piramal / Coldstream
 Thermo Fisher / Patheon

LOCATION

New Mexico, USA
 North Carolina, USA
 California, USA
 Indiana, USA
 New Jersey, USA
 Maryland, USA
 Michigan, USA
 Washington, USA
 Michigan, USA
 Montreal, Canada
 Kentucky, USA
 Mississauga, Canada

THREAT LEVEL*

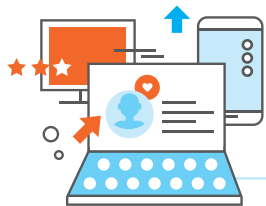
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*THREAT LEVELS KEY

★ **HIGH**
 Similar / same offering; direct competitor

↔ **MEDIUM**
 Compatible equipment; larger scale; indirect competitor

↗ **LOW**
 Larger scale equipment; aspirational competitor



Brand Awareness Through Strategic Content Subject Matter (FOCUSED ON BUYER NEEDS)

INJECTABLES

Facilitating Tech Transfer for Parenteral Products
 (Placed in *Pharma's Almanac Q1 March 8, 2017*)

A culture of quality and effective quality systems are essential to successful technology transfer, particularly for the production of complex products such as sterile injectables.

DELAMINATION

Pharmaceutical Packaging: Differentiation Equates to Brand Loyalty
 (Placed in *Pharma's Almanac Q4 October 1, 2016*)

SCHOTT, a parenteral packaging supplier, launched a new generation of pharmaceutical vials that keep the risk of delamination under control. "We optimized the hot-forming process in a way that the inner glass surface of the vials is more homogeneous and thus chemically very stable and less susceptible to delamination," explains Cassidy.

GLASS

Harnessing CDMO Expertise for Fill-Finish and Inspection of Sterile Pharmaceuticals
 (Placed in *Pharma's Almanac Q3 August 1, 2016*)

Sterile pharmaceutical drug development presents unique production challenges. As biopharmaceuticals continue to grow in popularity and biosimilars become more commonplace, research and development in the area of sterile drug production will only continue to evolve.

LOGISTICS/COLD CHAIN

Dissolving Boundaries in Worldwide Clinical Trial Logistics for Biological Samples and New Therapies
 (Placed in *Pharma's Almanac Q1 March 8, 2017*)

The challenges posed by the growing preference for in-home care became the platform for Marken's focus on patient centricity. Currently the company offers DTP services associated with over 100 active clinical trials that involve more than 1,200 investigator sites.