

2018 Full-Time Equivalent (FTE): Drug Substance — Biologics

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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Supplier Business Story

POINT(S) OF CONTACT

CORPORATE PROFILE / BUSINESS STORY

Board-Level

We are a CDMO in the drug substance large molecule biologics outsourcing space offering bio-manufacturing services. Our multiple northeast US locations offer both microbial and mammalian-based bio manufacturing. We are currently looking for projects from domestic and overseas biopharmaceutical companies with a specific focus on California.



Ideal Supplier Business Offering

	REQUESTER	PARAMETERS CATEGORY	Looking for projects in Phases II-a, II-b, III and commercial from biopharmaceutical outsourcing departments.		
1	Chief Executive Officer / President, General Manager	Project Definitions			
2	Chief Scientific Officer, Plant Manager	Chemistry / Technical Barriers	Through upstream and downstream process with an emphasis on our microbial cell line using a variety of our single-use and fixed stainless reactors.		
3	Chief Executive Officer / President, General Manager	Project Type Prioritization / Focus (based on experience)	Capabilities: Multiple host organisms, with cell culture capacity ranging from 50L to 10,000L. Full upstream and downstream capability with further drug product fill and finish aseptic capabilities. Customers who may need a CDMO partner with financial stability.		
4	Chief Commercial Officer, Sales Director	Minimum Project Size (based on department) [Profitability is important for a small CDMO]	 1. 12,000-liter batches of mammalian cell culture (2 single-use 6-pack GE Xcellerex): \$10 million 2. 20,000-liter batches of microbial fermentation: \$12 million 3. Robust cell line development: \$4 million 		
5	Chief Executive Officer / President, General Manager	Ideal Project Specifications (for consideration)	 4 batches of 12,000-liter mammalian cell line: \$40 million 4 batches of 20,000 liters of microbial cell line: \$48 million Access to company cell line: \$4 million. 		



Research & Lead Generation by Phase

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PARAMETERS CATEGORY **PARAMETERS**

Chief Commercial Officer, Sales Director Geographic Target Area (Prospect) [With 50 states, this client expanded a sales territory]

Specific focus on 279 customers in California that closely align with our capabilities The 279 companies with some physical presence in California

PHASE III 29 have a total of 149 products in the development pipeline with another 174 products marketed.

PENDING APPROVAL 11 MARKETED 174

36

26

PHASE I

PHASE II

Chief Scientific Officer, Plant Manager

Cell Line Microbial Cell Line - 38

Mammalian Cell Line - 70 Human Cell Line - 41

Chief Scientific Officer, Plant Manager

Therapeutic Category Oncology - 287

Immunology and Inflammation – 112

Hematology – 71

Cardiovascular - 40

Endocrine, Metabolic and Genetic Disorders - 58 Infectious Diseases - 57

Genitourinary Disorders – 28 Gastroenterology - 25

Ophthalmology - 32

Dermatology - 35

Other Therapeutic Categories - 48

Central Nervous System - 34

Chief Financial Officer, Compliance

Risk Assessment; Historical Success & Therapeutic Approval

	(USD M		
COMPANY	R&D SPENDING	SALES	R&D INTENSITY (%)
Top 10 Biopharma	\$70,500	\$404,800	17.41
Abbvie	\$4,226	\$25,638	16.48
Amgen	\$3,840	\$21,892	17.54
Genentech	\$1,060	\$4,749	22.32
Gilead	\$5,098	\$29,953	17.01



Buyers' Molecule Specification & Compatibility

POINT(S) OF CONTACT Chief

Chief Marketing	
Officer	

COMPANY	PRODUCT	THERAPEUTIC CATEGORY	PHASE OF COMPANY INVOLVEMENT	ROUTE OF ADMINISTRATION	CELL LINE
Amgen	Imlygic	Breast Cancer	Phase II	Intravenous	Mammalian
Genentech	Kadcyla	Metastatic Gastric Cancer	Phase I	Intravenous	Mammalian
Gilead	Andecaliximab	Oncology	Phase III	Intravenous	Human



Leads Generated – 978 Leads from 30 Companies (6 OF 978 SHOWN)

POINT(S) OF CONTACT

Chief Marketing Officer

COMPANY	FIRST	LAST	CONTACT TITLE	PHONE NUMBER	EMAIL
Amgen	Gudio	Palermo	Director, Contract Manufacturing	+1 805-447-1000	gpalermo@amgen.com
Amgen	Linda	Lia	Director, Biosimilars Operations	+1 206-265-7860	llai@amgen.com
Genentech	Tom	Wong	Principal Site Manager, Contract Manufacturing	+1 650-225-1000	twong@gene.com
Genentech	Camilo	Asuncion	Clinical Outsourcing Manager	+1 650-225-1000	casuncion@gene.com
Gilead	Mark	Wesson	Associate Director, Biologics Outsourcing	+1 650-574-3000	mark.wesson@gilead.com
Gilead	Yatin	Gokam	Director, Drug Product and Device, Biologics Development	+1 650-574-3000	yatin.gokum@gilead.com



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

POINT(S) OF CONTACT

(10)

Chief Marketing Officer

COMPANY	LOCATION	THREAT LEVEL*	
AbbVie CMO	Barceloneta, Puerto Rico	*	
Abzena	Pennsylvania, USA	\leftrightarrow	
Althea/Ajinomoto	California, USA	\leftrightarrow	
Catalent/Cook	Wisconsin, USA	\leftrightarrow	
Cepia Sanofi	Lyon, France	\leftrightarrow	
CMC Biologics/AGC	Washington, USA	\leftrightarrow	
Cyotovance	Oklahoma, USA	*	
Fuji Diosynth	North Carolina, USA	*	
GSK CMO	Maryland, USA	*	
KBI Biopharma	Colorado, USA	\leftrightarrow	
Lonza	New Hampshire, USA	7	
Novasep	Seneffe, Belgium	\leftrightarrow	
Pfizer Center One	Michigan, USA	7	
Rentschler	Laupheim, Germany	\leftrightarrow	
SAFC/Merck KGaA	Missouri, USA	\leftrightarrow	
Samsung Biologics	Incheon, Republic of Korea	7	
Sandoz	Kundl, Austria	7	
Therapure	Toronto, Canada	7	
Thermo Fisher/Patheon	New Jersey, USA	*	
WuXi Biologics	Pennsylvania, USA	*	

*THREAT LEVELS KEY

★ HIGH

Similar / same offering; direct competitor

→ MEDIUM

Compatible equipment; larger scale; indirect competitor

7 LOW

Larger scale equipment; aspirational competitor



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

MONOCLONAL ANTIBODIES

Achieving Continuous Downstream Bioprocessing

(Placed in Pharma's Almanac Q4 October 1, 2016)

Monoclonal antibodies (mAbs) and other therapeutic biologics represent the fastest growing sector of the entire pharmaceutical market with many pipeline candidates reaching late-stage development, including 53 mAbs in Phase III trials as of late 2015.

BIOSIMILAR DEVELOPMENT

Risk Minimization through Careful CDMO Selection

(Placed in Pharma's Almanac Q4 October 1, 2015)

Cost-cutting, downsizing, thinning pipelines, a lack of blockbusters, and the move to more biopharmaceutical — and in particular biosimilar — development, are leading many manufacturers to increase their reliance on contract development and manufacturing organizations (CDMOs).

MICROBIAL FERMENTATION

Establishing Specialized CDMO Capabilities for the Production of Advanced Therapies (Placed in Pharma's Almanac Q2 April 1, 2016)

By natural extension, we developed expertise in microbial fermentation for the production of metabolites, in particular using filamentous fungal and bacterial strains, native and recombinant bacteria, and salt \water microbial organisms.

ORPHAN THERAPIES

In-depth Process and Product Expertise – This is Key to CDMO Support of Orphan Drug and Breakthrough Therapy Development & Commercialization (Placed in Pharma's Almanac Q4 October 1, 2015)

As older blockbuster drugs lose patent protection and generic competition increases, many pharmaceutical companies are focusing discovery efforts on therapies with the potential to treat multiple niche populations. Increasingly, innovative small and emerging pharma firms are developing new drug candidates with orphan or breakthrough therapy status that are ultimately licensed or sold to large brand manufacturers.