

2018 Full-Time Equivalent (FTE): Pharmaceutical Excipients

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

Board-Level

CORPORATE PROFILE / BUSINESS STORY

We are one of the largest excipients manufacturers looking to expand into the effervescent tableting market in the USA. We are currently working on a line of excipients designed specifically for dissolvable tableting formulations and would like to understand market opportunities.



Ideal Supplier Business Offering

	RESPONSIBLE ROLE	PARAMETERS CATEGORY	PARAMETERS			
1	Chief Executive Officer / President, General Manager	Project Definitions	Looking for effervescent tableting dosage form projects in North America.			
2	Chief Scientific Officer, Plant Manager	Chemistry / Technical Barriers	Focused on slow and controlled API release, taste masking and moisture control in humid climates.			
3	Chief Executive Officer / President, General Manager	Project Type Prioritization / Focus (based on experience)	Difficult formulation shift to regional climate control; dealing with bi- and tri-layer tablets.			
4	Chief Commercial Officer, Sales Director	Minimum Project Size (based on department) [Profitability is important for a small CDMO]	 1. 10 tons of 200-grain lactose: \$20,000 2. Development of a new taste-blocking inhalation grade lactose excipient (including stability testing and toxicology study): \$2 million 3. Controlled release for a digestive OSD: \$1.5 million 			
5	Chief Executive Officer / President, General Manager	Ideal Project Specifications (for consideration)	 Moving a non-FDA product from Europe to North America with a portfolio of 10 molecules and reformulation capabilities (including stability testing and toxicology study): \$10 million 			
			2. 10 tons of inhalation grade lactose at 5 batches: \$250,000			
			3. 100 tons of inhalation grade lactose at 20 batches: \$2.3 million			



Research & Lead Generation by Phase

POINT(S) OF CONTACT

PARAMETERS CATEGORY

PARAMETERS

6 Chief Commercial Officer, Sales Director

Geographic Target Area (Prospect) [With 50 states, this client expanded a sales territory] Market for OSD effervescent tablets which are currently marketed in North America. The niche dosage form is the target market for their new line of excipients designed for effervescent tableting.

A total of 51 companies are manufacturers and marketers for 18 products marketed in USA.

Provided a SWOT analysis for 10 closest competitors, with detailed product profiling and opportunity recommendations for each competitor.

7 Chief Financial Officer, Compliance

Risk Assessment; Historical Success & Therapeutic Approval Snapshot of the SWOT analysis for Competitor 1:

Strength: Competitor has formed a partnership with a North American pharmaceutical firm to provide contract manufacturing, technical support, and formulation development services to prospective clients. Few excipient companies offer these packaged services alongside their core product offering.

Weakness: Competitor has a limited number of manufacturing and distribution sites worldwide, resulting in a limited scope of projects on which they can deliver.

Opportunity: Competitor's relative lack of novel offerings for innovative excipient products is an opportunity for our client to demonstrate the effectiveness of its alginates-based products. Clients looking for products designed for highly specialized dose forms or applications would be drawn to the potential that alginate polysaccharides show.

Threat: Competitor has a strong presence in Southeast Asia with significantly more regional and distribution office locations throughout the region, putting them in a commanding position to benefit more from that market as it continues to outpace growth in other, larger markets in western countries

PHASE OF COMPANY



Buyers' Molecule Specification & Compatibility— 18 Effervescent Tablets Of Interest (3 of 18 Products Shown)

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Chief Marketing Officer

COMPANY	PRODUCT	THERAPEUTIC CATEGORY	INVOLVEMENT	ROUTE OF ADMINISTRATION
Boehringer Ingelheim	Zantac	Gastroenterology	Marketed	Oral
Pfizer	Tramadol Hydrochloride	CNS	Marketed	Oral
Sandoz	Ranitidine Hydrochloride	Gastroenterology	Marketed	Oral

Leads Generated — 926 Leads from 51 Companies

(6 OF 926 SHOWN)

	POINT(S) OF CONTACT	COMPANY	FIRST	LAST	CONTACT TITLE	PHONE NUMBER	CHEMICAL / BIOLOGICAL CLASS
9	Chief Marketing Officer	Boehringer Ingelheim	Sabine	Noll	Head, Procurement Raw Materials	+49-6132-770	sabine.noll@boehringer-ingelheim.com
		Boehringer Ingelheim	Eduardo	Lioy	Global Head, Raw Materials & Outsourced API Sourcing	+49-6132-770	eduardo.lioy@boehringer-ingelheim.com
		Pfizer	Robert	Walton	API Project Leader/ Senior Principal Scientist	+44-1304-616161	robert.walton@pfizer.com
		Pfizer	Marc	Tesconi	Director, Formulation Design & Development	+1 860-441-4100	marc.tesconi@pfizer.com
		Sandoz	Ursula	Bauer	Global Head, Quality Assurance & Material Supply	+143-5338-200-0	ursula.bauer@sandoz.com
		Sandoz	Vinatzer	Dagmar	Global Head, Quality Assurance & Material Supply	+49-39203-71-0	dagmar.vinatzer@sandoz.com



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

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Chief Marketing Officer

LOCATION	THREAT LEVEL*	
Illinois, USA		
Miyazaki, Japan	\leftrightarrow	
Kentucky, USA	7	
Ballerup, Denmark	7	
Indiana, USA	*	
Borculo, Netherlands	*	
Grindsted, Denmark	7	
Darmstadt, Germany	\leftrightarrow	
San Priest, France	*	
Rosenberg, Germany	*	
County Kildare, Ireland	*	
Wasserburg, Germany	*	
Nihongi, Japan	\leftrightarrow	
Niigata, Japan	\leftrightarrow	
Delaware, USA	*	
	Illinois, USA Miyazaki, Japan Kentucky, USA Ballerup, Denmark Indiana, USA Borculo, Netherlands Grindsted, Denmark Darmstadt, Germany San Priest, France Rosenberg, Germany County Kildare, Ireland Wasserburg, Germany Nihongi, Japan	

*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)

SUCROSE

Quality by Design: Transforming 21st Century Pharmaceutical Manufacturing (Placed in Pharma's Almanac Q3 August 1, 2016)

Achieving QbD goals requires deep understanding of the product (including raw materials, excipients and intermediates) and the process (including process parameters and process performance attributes) and their impact on quality.

LACTOSE

Dry-Powder Inhalation Formulation: Balancing Performance and Manufacturability

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

For carrier formulations, the particle size distribution of the API and the percentage of fine lactose in a formulation are the main parameters that influence aerodynamic performance.

CONTROLLED RELEASE

Embracing Formulation Expertise to Extend Exclusivity & Improve the Patient Experience

(Placed in Pharma's Almanac Q3 August 1, 2016)

The most popular dosing change involves the development of modified release — including controlled or extended release (XR) and fixed-dose combination (FDC) — versions of the patented drug.

ENCAPSULATION

Particle Engineering for Improved Bioavailability in Oral Solid Dose Medications (Placed in Pharma's Almanac Q1 March 8, 2017)

Oral solid dose (OSD) form medications remain the industry juggernaut. Though biopharmaceuticals continue to grow and evolve, offering new and unique treatment options, small-molecule drugs maintain their dominance with OSD medications leading the charge.