Analysis of Contract Manufacturing Organizations Servicing the North American Market in the Manufacturing & Packaging of Prescription & Over-the-Counter Drugs

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Abstract

Abstract: Pharmaceutical Contract Manufacturing Organizations that serve the North American market are plentiful; however, determining which contract manufacturers provide the appropriate services for a specific drug type is difficult to determine. This document defines and provides a high level overview of the pharmaceutical industry, an overview of the pharmaceutical contract manufacturing industry, and details the capabilities of contract manufacturers focused on the non-sterile manufacturing of solid, semi-solid, and liquid dosage forms. The paper examines five companies in particular that are located in North America and service the market and analyzes the services that each company offers and how the companies are differentiated from each other.

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Limitations

The information that has been gathered and synthesized for this company analysis is limited based on the sources that were used, for example websites, and company brochures. Most of the information provided in these documents may be historical due to the confidentiality of the industry and thus may not be a good indication of the contract manufacturing organization and their strategic plan for the future.

Chapter I: Background on the Pharmaceutical Industry

The pharmaceutical industry as defined by the Census Bureau is "a combination of companies engaged in researching, developing, manufacturing, and marketing drugs and biologicals for human or veterinary use." Drugs and biologicals are intended for the use in the diagnosis, prevention and/or cure of sickness and disease. (Goods, 2010)

Industry Characteristics

The pharmaceutical industry is a globalized and diversified industry and the North American sector of the industry is enormous and competitive. Pharmaceuticals have contributed to the health and wellness of the human population; saving lives, increasing lifespans, and preventing or reducing suffering. (Goods, 2010) According to the 2007 economic census, there were an estimated 1552 companies in the US that were focused on developing, manufacturing, and marketing drugs and biological products. (Goods, 2010) This number continues to expand annually.

Product Sectors

The pharmaceutical industry can be segmented to account for the different types of drugs that are available on the market. (Goods, 2010) The different types of product sectors are:

- Originator chemical drugs
- Generics
- Over-the-counter drugs
- APIs and excipients
- Biologicals and biosimilar's.

The key characteristics of the product sectors help to differentiate each of the sectors respectively. Originator chemically synthesized drugs are first to market drugs that are developed as a result of years of research and development (R&D). These drugs can take as long as 20 years until they are market-ready. After the drugs are identified, they then have to be tested in numerous trials including both human and animal clinical trials, prior to being approved by the US FDA for consumption by consumers. The originator drug relies on patents and other forms of IP to bring the product to market and maintain market share. At the moment in the pharmaceutical industry, the cost of bringing a drug to market in the US has been estimated to cost between $500,000,000 to an excess of $2 billion depending on the therapeutic area. Furthermore, the likelihood of bringing a drug to market is narrow, as only 1 in 1,000 compounds that enter preclinical testing make it to human clinical trials and 1 out of 5 drugs tested on humans is approved. (Goods, 2010)

The next segment of drugs is generic drugs. Generics are developed to mimic the originator chemically synthesize drugs as they contain the same active ingredient and remain identical in dosage form and route of administration. Generic drugs typically undercut the sell price of the originator chemically synthesized drug. There are two types of generics; commodity generics, which are manufactured by more than one company and compete mainly on price and branded generics, which are marketed by drug companies. Branded generics are higher in cost than commodity generics but less costly than the originator chemically synthesized drug. (Goods, 2010)

The next segment is of over-the-counter drugs (OTC). OTC's are distinguished from originator and generic drugs because you do not need prescriptions to purchase these drugs. OTC drugs are used for self-medication and it is estimated that there are 100,000 OTC drugs marketed and sold across the US. There are a number of drugs at the moment in which companies are switching from prescription to OTC in order to try and increase use of their product, which is a process regulated by the FDA. (Goods, 2010)

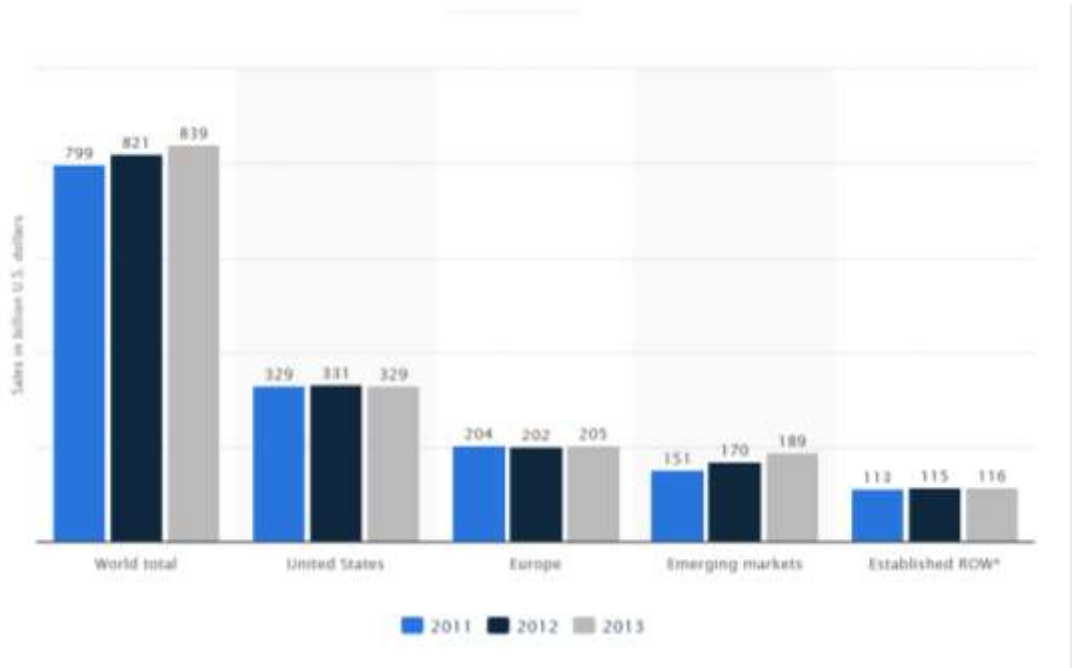
Active pharmaceutical ingredients (APIs) and excipients are the raw materials that are used to make a drug. Active pharmaceutical ingredients are the ingredients that make the drugs effective, whereas excipients give the medication its structure and form. Excipients can also be responsible for some claims made by drug companies such as prolonged disintegration of drugs or protecting the product stability. (Goods, 2010)

Biologicals are often referred to as biotech drugs or large molecular weight drugs or biopharmaceuticals. Biologicals differ from chemically synthesize drugs because they are derived from living material. As a result biologicals are larger, more complex, and harder to characterize. Typically, biologics take the form of vaccines or injected drugs. (Goods, 2010)

Market Size

The global pharmaceutical market is encroaching on one trillion USD and the region that is contributing more than 40 percent of the revenues is the pharmaceutical market in North America. (Unknown) As depicted below if Figure 1, the world total in 2013 was $839 Billion USD, with $329 Billion USD being sold in the United States.

Figure 1: Global pharmaceutical sales from 2011 to 2013, by region (in billion U.S. dollars)



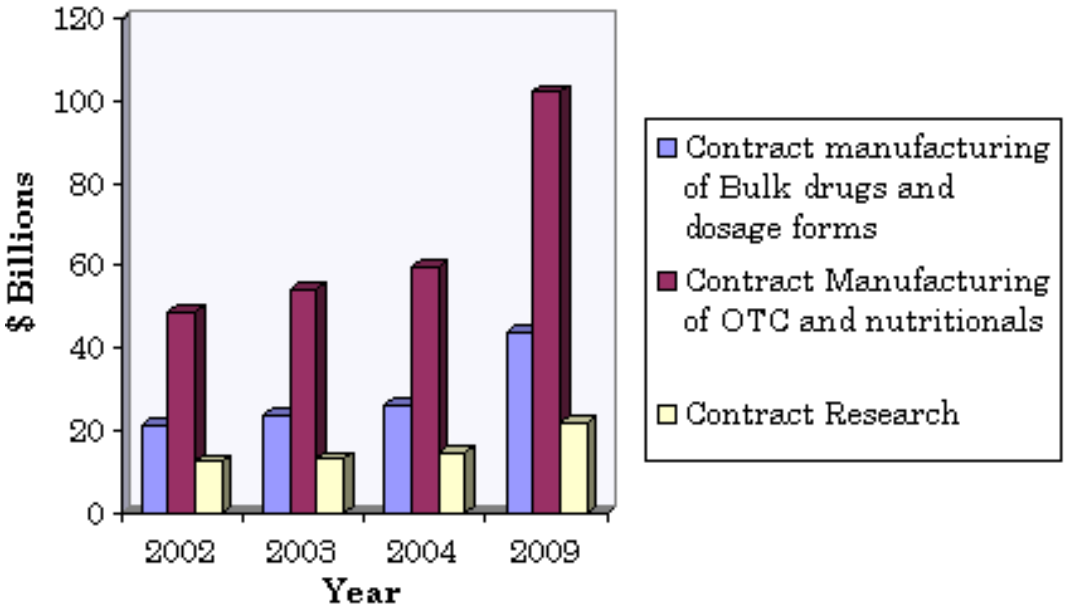
Source: (Statistica)

Chapter II: Background on the Pharmaceutical Contract Manufacturing Industry

The global market for pharmaceutical contract manufacturing represents one of the fastest growing markets and it is expected to continue to grow in the near future. According to Pharma Leader Series, the worldwide pharmaceutical contract manufacturing organisation (CMO) market will earn revenues of $71 billion in 2018. (VisionGain, 2014)

In 2011, U.S. pharmaceutical companies outsourced 30% and maintained 70% of their manufacturing in- house. Industry executives anticipate that the future will result in contract manufacturing becoming 70% of pharmaceuticals companies outsourcing strategy, specifically as costs continue to rise. (Chaodong Han, 2012) As the cost of manufacturing increases due to global economic constraints, it has exerted extensive pressure on pharmaceutical manufacturers to reduce the cost of products. Contract manufacturing, as a strategic option, offers pharmaceutical companies certain benefits such as cost reduction in the event that the manufacturing facility is fully functioning, as well as improved product quality, and a reduction in time to market. Figure 2 below illustrates the dollar value of outsourcing between 2002-2004 and 2009, which aligns with the Pharma Leaders Series statement that the worldwide pharmaceutical contract manufacturing organisation (CMO) market will earn revenues of $71 billion in 2018.

Figure 2: World-Wide Revenue of Contract Manufacturing and Contract Research Organizations, 2002-2004 and 2009 ($ Billions)



Source: (World-Wide Revenue of Contract Manufacturing and Contract Research Organizations, 2005)

Market Segments

According to Allied Market Research, (Research) the global market for pharmaceutical contract manufacturing is segmented into two different categories: type of contract manufacturing and geography. This market segmentation will provide the basis for how companies are analyzed in further detail in the Company Analysis section below. Contract Manufacturers will be broken initially into the below segments for market by drug type and geography:

Market by Drug Type

- Active Pharmaceutical Ingredients (API) / Bulk drug

- Final Dosage Form (FDF) - (** These FDF's could require sterile or non-sterile manufacturing, depending upon the product.)
    - Solid dosage form
    - Semi-solid dosage form
    - Liquid dosage form
- Advanced drug delivery products
- OTC medicines and Nutritional products
- Packaging

Secondly, contract manufacturers will be segmented by geographic region as listed below. (Research)

Market by Geography

- North America
- Europe
- Asia-Pacific
- LAMEA

Manufacturing Conditions

As stated above, there are two main environmental conditions within which to manufacture in the pharmaceutical industry; a sterile environment and a non-sterile environment. The main difference between non-sterile and sterile manufacturing pertains to how the drug will be administered rather than how it is made.

Sterile Dosage Forms

Sterile dosage forms are an important class of pharmaceutical product and they can be classified into three broad categories: 1) Conventional small volume injectables; 2) Conventional large volume injectables; and 3) Modified release injectables. (Research) Sterile products are preparations intended to be administered parenterally, which means through injection rather than an oral route such as a pill or cough syrup. There is a requirement for the absence of microorganisms under sterile manufacturing conditions.

Non Sterile Dosage Forms

Non-sterile manufacturing, although it sounds as though it is not a clean environment, is a technique that has been used for creating drugs for hundreds of years. It requires medication to be prepared in solid form, liquid form, or semi-solid form. Although it is considered to be non-sterile, the manufacturing is still performed in closely regulated environments with extremely strict rules and guidelines monitored by the FDA.

For the purposes of this paper, the analysis will focus on non-sterile solid, liquid, and semi-solid dosage forms. Solid dosage forms come in the form of capsules or tablets and come in various shapes and sizes and strengths and also could have one or more active ingredients. Semi-solid dosage forms normally take the form of creams, gels, or ointments as they contain a number of active ingredients that are uniformly dispersed into a base. Liquid dose preparations, for oral use, can come in the form of solution, syrups, and suspensions and also could have one or more active ingredients.

Chapter III: Analysis of Contract Manufacturers listed as servicing North America

Objective of Analysis:

Currently, there is not a strong understanding of what CMO's are located in North America and what services they provide to industry. Thus, this report will benchmark the services of manufacturing businesses that directly compete on the basis of offering non-sterile solid, liquid, and semi-solid dosage forms, specifically for the North American market. It will be essential that the companies of focus will be offering similar services in solid, liquid, and semi-solid dose manufacturing for both the over-the-counter (OTC) and prescription (Rx) drugs, which will allow for a direct comparison of service offering. The objective of this study is to do a company analysis of contract manufacturers for the pharmaceutical market in North America specifically focused on manufacturers and packagers of solid, liquid, and semi-solid dosage forms of prescription (Rx) and over-the-counter (OTC) products.

It will be very advantageous to understand the complexities and variability of the service offering of the companies in this sector. The research question that will be answered is: How do the service offering and capabilities of North American based contract manufacturing organizations compare to each other?

Gather Competitive Information

In order to perform the analysis, secondary sources of information were used to gather the competitive information. Contract Pharma (Pharma) is a directory that provides a listing of organizations that market services to the North American market. The company information was downloaded and used to then develop a competitive industry analysis. Articles, websites, and marketing reports offered to the general public were used to collect relevant data on each company, which allowed for the services offered to be located. Companies websites did a very poor job of designing and publishing information, special offers, service features, and benefits. All companies used some imagery to convey their services such as drug forms, equipment, and maps to show where the facilities were located. Most of the advertisements were in color but there was very little effort put towards advertising campaigns that communicated why each company was innovative or detailing any distinguishing factor. Sales brochures were also helpful when analyzing service information, along with databases, which listed the original source of the companies.

Once all of the competitive information was analyzed it was synthesized using an Excel platform. The service offerings were identified, followed by location, sales, and numbers of employees when available. Lists of all of the featured services were identified and a table was prepared to show which companies were offering what services. Factors that were undistinguishable were quality, on-time delivery, and price per unit as that information was not freely provided.

Analyze Competitive Information

Once the data was located for 349 Contract Manufacturing Organizations servicing North America, the data was collected and synthesized from each company's website. As a result of the 349 companies that were analyzed, the results were as follows:

Table 1: Breakdown of Contract Manufacturers in North America

Service Type	**Number of Contract Manufacturing Companies**
Sterile Only Products	68
Non-Sterile Only Products	51
Sterile & Non-Sterile Products	51
Other (Equipment, APIs, Biologics)	178
Total	**349**

In order to understand each of the areas further an analysis was done on the sterile and non-sterile product areas.

Table 2: Sterile Product Breakdown

Dosage Form Manufactured	**Number of Contract Manufacturing Companies**	**Percentage Breakdown**
Liquid, Solid, Semi-Solid	33	28%
Liquid Dose Only	31	26%
Solid Dose Only	28	24%
Liquid & Semi-Solid Dose Only	17	14%

Liquid & Solid Dose Only	7	6%
Solid & Semi-Solid Dose Only	2	2%
Semi-Solid Dose Only	1	1%
Total	**119**	

Table 3: Non-Sterile Product Breakdown

Dosage Form Manufactured	Number of Contract Manufacturing Companies	Percentage Breakdown
Liquid Dose Only	25	24%
Solid Dose Only	23	22%
Liquid, Solid, & Semi-Solid Dose Only	16	16%
Liquid & Semi-Solid Dose Only	17	17%
Liquid & Solid Dose Only	15	15%
Solid & Semi-Solid Dose Only	4	4%
Semi-Solid Dose Only	2	2%
Total	**102**	

As a result of the analysis, 16 companies were identified as manufacturing all three dosage forms (liquid, solid, and semi-solid) in a non-sterile manufacturing environment.

Chapter IV: Overview of Companies

These 16 companies, listed in Table 4, were then analyzed further to understand the capabilities of each individual firm, which are overviewed in Table 5 below. The

information has been gathered from company websites. Each of the organizations are also summarized below.

Table 4: List of Companies with All Three Dosage Forms

Companies	
Abbvie Contract Manufacturing	MEDA Manufacturing GmbH
Aenova	Mission Pharmacal
Alliance Contract Pharma LLC	Pegasus Laboratories
APL	Pharmatics
Attix Corp	Pierre Fabre Medicament
Dechra Pharma Services	Sterling Pharmaceutical Services
Legacy Pharmaceuticals International	Takeda
Lyne Laboratories	Trillium Health Care

Table 5: Capabilities of Companies Servicing North America with All Three Dosage Forms

Competitors	Location	EMEA	Health Canada	FDA	Non Sterile Metered Dose Pumps	Non Sterile Syringes	Non Sterile Rectal/Vaginal Applicators	Non Sterile Extrusions	Non Sterile Tablets	Non Sterile Capsules	Non Sterile Powders	Non Sterile Pellets	Non Sterile Suppositories	Non Sterile Creams	Non Sterile Emulsions	Non Sterile Gels	Non Sterile Lotions	Non Sterile Ointments	Non Sterile Solutions	Non Sterile Suspensions	PKG Blisters	PKG Bottles	PKG Sachets	PKG Syringe	PKG Vial
Abbvie Contract Manufacturing	1 sites EU, US, Mexico	●	●	●					●	●	●			●						●	●	●	●	●	
Aenova	Europe & North America	●	●	●		●	●	●	●	●	●	●	●		●	●				●					
Alliance Contract Pharma LLC	US			●					●	●	●	●				●									
APL	Sweden	●		●						●			●	●		●	●	●							
Attix Corp	China			●					●	●	●			●			●	●	●						
Dechra Pharma Services	UK & Netherlands	●		●					●	●	●			●		●		●	●	●	●	●	●		
Legacy Pharmaceuticals International	Switzerland	●		●					●		●			●		●		●			●	●			●
Lyne Laboratories	Brockton, MA			●						●	●					●	●	●	●	●		●			
MEDA Manufacturing GmbH	Sweden	●		●	●				●	●	●			●	●	●		●	●	●	●	●	●		
Mission Pharmacal	San Antonio, TX			●					●		●			●				●	●	●	●	●			
Pegasus Laboratories	Pensacola, Florida			●					●	●				●			●	●	●			●		●	
Pharmatics	North York, Ontario			●					●	●	●			●				●			●	●			
Pierre Fabre Medicament	USA, Europe, Japan, Brazil	●		●					●	●				●			●	●	●						
Sterling Pharmaceutical Services	Dupo, IL			●					●	●				●	●				●	●					
Takeda	Zurich, Switzerland	●		●					●	●			●	●				●	●			●			●
Trillium Health Care	Brockville, Ontario		●	●					●	●	●		●	●	●	●	●	●	●	●	●	●			

*Information has been researched and gathered from company websites

Abbvie Contract Manufacturing:

Website: www.abbviecontractmfg.com

Founded: 1989

Employees: Unknown

Location of Facilities: Global

Abbvie Contract Manufacturing is a multinational operational with a multitude of service offerings, including drug product manufacturing with solid, liquid, and semi-solid capabilities in addition to biologics, potent products, fermentation, prefilled syringes, hot melt extrusion, and APIs. AbbVie benefits from its knowledge as a drug developer to offer CMO services to companies on a global basis. One interesting fact is that while AbbVie has CMO capability, it also is a drug producer and as such may appear to have a conflict of interest when it comes to manufacturing its competitor's product and gaining the intel of formulations and processes.

Aenova Group

Website: www.aenova-group.com

Founded: Unknown

Employees: >4,500

Location of Facilities: Europe and the USA (29 sites)

The Aenova Group is a leading, world-wide contract manufacturer that manufactures for pharmaceuticals, medical devices, supplements, and cosmetics. The capabilities are ever growing with the ability currently to manufacture tablets, soft gel capsules, hard capsules, hormones, cytotoxics, effervescent products, suppositories, powders, semi-solids, and liquids. In addition, Aenova has the ability to take on antibiotics, and injectables.

Aenova supports its clients with full turnkey capabilities, as well as development support. The flexibility and product knowledge allows for a one-stop shop for a lot of clients requirements.

Alliance Contract Pharma LLC

Website: www.alcoph.com

Founded: 2008 (with 70 years facility experience)

Employees: Unknown

Location of Facilities: Pennsylvania, USA

Alliance Contract Pharma LLC also has a number of years of experience in the pharmaceutical industry. The company has facilities in the US and has the capability of manufacturing/packaging all three non-sterile dosage forms - solids, liquids, and semi-solid - as well as offering other manufacturing capabilities such as liquid-filled capsules, powder-filled capsules, over-encapsulation, vial filling, and potent handling capabilities. Alliance Contract Pharma also offers full turnkey solutions. Furthermore, they provide

laboratory services incorporating raw material testing, release testing, method development, qualification, validation, and on-site stability storage and testing.

APL

Website: www.apl.se

Founded: 1970

Employees: 520

Location of Facilities: 4 facilities in Sweden

APL is a Swedish organization that was founded approximately thirty years ago. The company focuses on providing contract manufacturing, as well as clinical trial and development work. The equipment that APL has in-house can function for both small-scale and large-scale manufacturing. APL has the capability to do oral liquids, capsules, suppositories, lotions, creams, as well as sterile capabilities for parenterals and eye ointments and solutions. Although APL is located in Sweden, the company manufactures for organizations globally.

Attix Corp

Website: www.attixpharmaceuticals.com

Founded: 2000

Employees: Unknown

Location of Facilities: China

Attix was founded in Canada by Dr. Liu, who was a well-known chemist. As the pharmaceutical industry continued to grow, a need was acknowledged in China and facilities were opened overseas. Attix manufactures bulk ingredients for the pharmaceutical, nutraceutical, biotech, cosmetic, chemical, and food & feed industries. In addition to manufacturing bulk ingredients, Attix also manufactures Custom Formulations and tablets, capsules, softgels, sterile injectables, gels, creams, lotions, ointments, and powders among other things.

Dechra Pharma Services

Website: www.dechramanufacturing.com

Founded: 1948

Employees: >300

Location of Facilities: UK & Netherlands

Dechra Pharma Services has been manufacturing since 1948. Dechra operates in two European facilities in the UK and the Netherlands. Not only do they manufacture the three dosage forms of liquids, semi-solids, and solids, Dechra has the ability to manufacture sterile powders. Additional services that they provide are formulation development, analytical methods development, validation, and stability studies. Dechra are licensed to manufacture, import, and assemble pharmaceuticals for both human and

veterinary use. Dechra has FDA approval for solid oral dose production and has both controlled drugs and precursor licenses.

Legacy Pharmaceuticals International

Website: www.legacypharmaceuticals.com

Founded: 2007 (Site has been operational since 1947)

Employees: 150

Location of Facilities: Switzerland

Legacy has the capability to manufacture and package sterile liquids, powders and semi-solids, in addition to non-sterile solids, semi-solids, and liquids. Legacy services Europe and the Middle East mainly; however, distributes to more the 70 countries worldwide. The focused service offering is on OTC's, generics, niche and specialty pharmaceutical products, and cosmetics products.

As a separate offering to manufacturing, Legacy also offers support services for acquisitions and as a result has been the successful recipient of the manufacturing business.

Lyne Laboratories

Website: www.lyne.com

Founded: 1965

Employees: >80

Location of Facilities: Massachusetts, USA

Lyne Laboratories is located in the USA and has FDA approval. Lyne has a focus on the development of ANDA's. Lyne has manufacturing capability and packaging lines and in addition offers development services as an add-on. Lyne has the capability to manufacture liquid, semi-solid, and solid dosage forms as well as the ability to handle controlled substances and products with a high alcohol content. Lyne has the manufacturing ability to manufacture 100 L batches up to 10,000 L batches and the tanks are equipped to handle both heating and cooling processes. Furthermore, Lyne has the ability to package all three dosage forms, in addition the ability to offer their clients the differentiation factor of unit dose packaging of oral liquids in unit dose cups.

MEDA Manufacturing GmbH

Website: www.meda-manufacturing.com

Founded: Unknown

Employees: Unknown

Location of Facilities: Europe (Sweden and France)

MEDA is located in Sweden and has been around for a number of years. MEDA manufactures all three dosage forms solids, semi-solids, and liquids, as well as having other offerings. MEDA manufactures and packages at two sites in Europe and are GMP compliant as well as has approval from the US FDA European and Japanese authorities. MEDA is in a similar situation as other big pharma as it has a pharmaceutical division as well. As a result, some companies may not want to provide formulas to them in an effort to mitigate knowledge-sharing risk.

Mission Pharmacal

Website: www.missionpharmacal.com

Founded: 1946

Employees: Unknown

Location of Facilities: Texas and Pennsylvania, USA

Mission Pharmacal manufactures and packages solid dose powders and tablets, liquids and semi-solids. Mission has been manufacturing for more than 65 years and is based in Texas. Mission Pharmacal manufactures both prescription and over-the-counter products and has a specific focus on the therapeutic areas of womens health, urology, pediatric, and dermatology. Coupled with the R&D capabilities of Mission and in addition to manufacturing and packaging, Mission Pharmacal has partnered with Alamo Pharma

Services and BioComp Pharma to provide add-on services to its clients, including distribution internationally and commercialization.

Pegasus Laboratories

Website: www.pegasuslabs.com

Founded: 1986

Employees: >80

Location of Facilities: Florida, USA

US based Pegasus is a seamless operation, from development through commercialization, for a variety of dosage forms in specialized packaging configurations of its clients choice. Pegasus manufactures both human and animal health products and is involved in development of drugs along with manufacturing and packaging of solid, liquid, and semi-solid dosage forms. One benefit that Pegasus offers in the development and manufacturing of product internally, which can provide its clients with a smooth transition from development through scale-up to commercialization.

Pharmetics

Website: www.pharmetics.com

Founded: 1956

Employees: >600

Location of Facilities: Canada (Laval, QC & Burlington, ONT)

Pharmetics has been manufacturing since 1956 and is located in Canada with two facilities in Ontario and Quebec. Pharmetics manufactures OTC and natural products including vitamins, herbals, dietary supplements, analgesics, GI products, cough, cold, and allergy and sports nutrition products. The primary focus is on the private label marketplace, as well as contract manufacturing for medicines. Pharmetics has the ability to manufacture and package all three dosage forms and employs more than 600 people. Finally, Pharmetics is in accordance with both FDA and Health Canada.

Pierre Fabre Medicament

Website: www.pierre-fabre.com

Founded: Unknown

Employees: Unknown

Location of Facilities: USA, Europe, Japan, Brazil

There is very little information available about Pierre Fabre CMO as the website is undergoing development. Pierre Fabre does manufacture solid, liquid, and semi-solid products for the pharmaceutical, cosmetics, food supplements, and medical equipment sectors. The facilities have many approvals, including FDA, which allows for sale of products in the United States.

Sterling Pharmaceutical Services

Website: www.sterlingpharma.com

Founded: 2005

Employees: Unknown

Location of Facilities: Dupo, Illinois

Sterling Pharmaceutical Services is located in the United States and has been manufacturing for a number of years. Not only does Sterling focus on formulation development, it also provides contract manufacturing services within the United States. Capabilities include the ability to manufacture and package capsules, tablets, solutions, suspensions, emulsions, and creams for NDAs, ANDAs, OTCs, and nutritional products in conjunction with having the ability to manufacture sterile ophthalmic products.

Takeda Contract Manufacturing

Website: www.tpi.takeda.com

Founded: Unknown

Employees: Unknown

Location of Facilities: Global sites with CMO sites in Europe and South America

Takeda Contract Manufacturing has a global presence and manufactures for more than 50 organizations. Takeda provides services for clinical development, product launch,

formulation, process optimization, as well as manufacturing and packaging of solids, semi-solids, non-sterile liquids, and sterile products. Takeda has a similar conflict of interest as other large pharmaceutical giants that also provide contract manufacturing services; however, Takeda also has a large number of resources and knowledge to put towards the successful production of product.

Trillium Health Care Products

Website: www.trilliumhcp.com

Founded: 1993

Employees: >200

Location of Facilities: Ontario, Canada

Trillium Health Care Products is a facility that has been manufacturing product for more than 50 years; however, began focusing on contract manufacturing in 1993. Trillium has the capability to manufacture OTC and Prescription Products for the North American market and currently manufactures and packages solid, semi-solid, and liquid dose products. Trillium is FDA and Health Canada approved and has the ability to manufacture controlled substances and precursors.

Chapter V: Analysis of Lyne Laboratories, Mission Pharmacal, Pegasus Laboratories, Stirling Pharmaceutical Services, & Trillium Health Care Products

Positioning and competitors when marketing to pharmaceutical companies is imperative to a contract manufactures position in the market. Special emphasis on company's experience, quality standards, regulatory approvals i.e. FDA and Health Canada, and regulatory track record are imperative to the ongoing success in the industry. Pharmaceutical companies should understand the offering of the contract manufacturer and choose the one best suited to manufacture and/or package their product.

The pharmaceutical industry is very diverse and has multiple dosage forms and applications. As a result, I have chosen to focus this study on the non-sterile manufacturing conditions and specifically on contract manufacturing organizations that have the capability to manufacture and package solid, semi-solid, and liquid dosage forms. The detail above highlights 16 companies that are servicing the North American market with respect to non-sterile solids, liquids, and semi-solid dosage forms. Companies that could be a target focus for these organizations are pharmaceutical and biotechnology companies that are marketing prescription and OTC products for the Canadian and American markets. There are hundreds of companies that have products in these three dosage form areas and to know specifically which CMO's are most aligned is important. Based on the 16 companies above, all organizations are active in all three dosage forms. This provides an advantage to pharmaceutical companies that have more

than one product or dosage form on the market that can be outsourced, as the pharma company can form a strategic partnership with a particular contractor manufacturing organization. This partnership increases the stability that the pharma company has within the contract organizations manufacturing and packaging operations.

I have decided to analyze five companies in particular Lyne Laboratories, Mission Pharmacal, Pegasus Laboratories, Sterling Pharmaceutical Services, and Trillium Health Care Products. While all of the organizations, as previously mentioned, are active in all three dosage forms, these companies are located within North America. Due to the fact that the above mentioned companies have a presence in North America and serve the North American market it leads me to believe that they are more closely related and provide a similar service offering compared to the large multinational contract manufacturing organizations such as Abbvie. Furthermore, the fact that these five organizations are based in North America and provide competitive services to the industry leads me to believe that they will be competing for the same business. The larger organizations most likely are manufacturing very high-volume products and shipping to multiple locations around the world, whereas these five companies could potentially be serving mid-tier as well as large pharmaceutical organizations, yet slightly lower volumes.

These five organizations are slightly differentiated. Each of the companies provide services in solid, semi-solid, and liquid dosage areas; however, the companies market one

or two differentiating services, in addition to the three dosage forms, in an attempt to separate from the competition. There are very few distinctions between the organizations and as such, these five companies appear to be a strategic group, which is a set of firms that are competing the same way, in the same space and are very weekly differentiated.

Lyne Laboratories

Lyne Laboratories has FDA approval; however, it is unknown as to whether or not Lyne services the Canadian market. In addition to the capability of manufacturing and packaging all three dosage forms, Lyne differentiates itself on its ability to develop and manufacture ANDAs. ANDAs are generic drug forms and the FDA has recently implemented a charge called GDUFA fees for facilities that are manufacturing generic drugs of approximately $262,000 USD annually. This means that any facility manufacturing an ANDA product for the American market has to pay this fee. As a result, only the larger producers of ANDAs can provide a business case to support this market. As a result, by paying the GDUFA fees it allows a company to gain market share in the generic market. In addition, Lyne provides development services for ANDAs. This is also a key differentiating factor in the generic market, as some companies have the ability to market and sell generics, but do not want to develop the drugs. Consequently, Lyne is providing an opportunity for a company to focus on its strength of marketing rather than the development aspect.

Finally, Lyne offers unit dose packaging of oral liquids in unit dose cups. This is a unique dosage form that not all companies offer. Unit dose or single dose is a packaging form that is becoming more attractive to the industry due to the fact that it is aiding in the elimination of drug misuse, as it eliminates the opportunity to extract the wrong amount of medicine from the package.

Mission Pharmacal

Mission Pharmacal claims to succeed in specific therapeutic areas and offers a distribution and commercialization service, which is a differentiation from a traditional CMO. Mission has a specific focus on the therapeutic areas of womens health, urology, pediatrics, and dermatology. By claiming that these specific therapeutic areas are a focus, it provides drug companies with the confidence that Mission excels in these therapeutic areas. Coupled with the therapeutic focus, Mission has R&D capabilities. R&D capabilities are a benefit to pharma companies because it allows for innovation. Innovation is an ongoing focus of the pharmaceutical world due to the fact that there is always a goal to achieve additional market share. Thus, a differentiating factor pertaining to innovation of a formula or a differentiating factor pertaining to how a drug is packaged is always attractive to industry. The ability for a company to offer that service to its clients is essential to the growth of brands.

Finally, Mission Pharmacal has partnered with Alamo Pharma Services and BioComp Pharma to provide add-on services to its clients including distribution internationally and

commercialization. Thus, for virtual organizations this may be an extremely attractive offering because it reduces the head count internally, keeping costs down.

Pegasus Laboratories

Pegasus differentiates itself through its ability to manufacture both human and animal health products, as well as providing development services to its clients.

There are several large pharmaceutical companies in the industry that have products in both the human and animal health sectors. Therefore, a CMO that has the capability to manufacture both human and animal health products provides a company with a one stop shop for its manufacturing needs. This is a benefit because it is costly to manage a CMO properly, thus the more an organization can reduce the complexity of its manufacturing network, the more efficient an organization can be in aligning the working relationship as well as the integration of key systems, such as inventory counting and financial payment methods.

Sterling Pharmaceutical Services

Sterling focuses on formulation development for a greater breadth of products than the other CMOs, such as ANDAs, NDA's, OTCs and nutritional products, in combination with having the ability to manufacture sterile ophthalmic products. Development services, as previously stated, are a benefit to pharmaceutical organizations because

development can be done externally, which reduces headcount. Furthermore, line extensions can be developed at the CMO for products that are in the CMOs portfolio. This is a benefit because the CMO is so intimately involved in the manufacturing of the product, there may be quick changes that help to reduce costs or differentiate from a formula standpoint.

Additionally, to have the ability to manufacture sterile ophthalmic products is a different service offering. The capability to manufacture a sterile product requires many more constraints to ensure that the facility is free of any microorganisms. By providing this service, it allows Sterling to compete in a different market sector (sterile ophthalmics).

Trillium Health Care Products

Trillium Health Care Products has the ability to manufacture prescription and OTC products and in addition has the ability to manufacture controlled substances and precursors. The authority to handle controlled substances and precursors is important for some raw materials required to make both OTC and prescription products. As a result, this is a differentiator that Trillium may have over some of its competitors that enables the site to manufacture and package products that other CMOs cannot.

Based on the service offerings, it appears that there are differentiating factors that each company markets in addition to its reputation in the industry. Each of the five

organizations appears to have discovered a minutely differentiated offering that has allowed for a niche marketing claim in a very narrowly differentiated market.

Chapter VI: Conclusion

The contract manufacturing industry for the pharmaceutical sector is one that is continuing to grow. It is anticipated that the contract manufacturing market will be greater than US $71 billion in 2018. As the market is so large and continuing to grow, there are opportunities as a contract manufacturer to specialize in a specific offering.

As a result of this work, the contribution will allow for a greater understanding of contract manufacturers that provide a similar service offering in North America. It is imperative for each contract manufacturing organization to survive; it needs to be able to find a niche in order to differentiate itself. Based on the research that has been completed, there appears to be a multitude of organization serving the North American market (approximately 350 companies). Of the 350 companies that are providing manufacturing services, there are 119 companies that have sterile manufacturing capability and 102 companies that are focused in the non-sterile manufacturing space. Furthermore, only 16 companies provide manufacturing and packaging services in solid, liquid, and semi-solid dosage forms. Within the 16 companies are a strategic group of five organizations that are competing for the same business but are very weakly differentiated, serving the North American market. While each of the five organizations have attempted to differentiate themselves through an additional unique service offering,

whether it be development, a specific therapeutic area focus, or a product type such as an ANDA, Rx, or OTC product, the organizations are weakly differentiated. As such, it is imperative to each company to deliver a quality product on time to ensure that the customer base can be maintained. Furthermore, each of the five organizations should be seeking a way to strategically separate itself from the competition, as they are so weakly defined at the moment.

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