ILLINOIS INSTITUTE OF TECHNOLOGY

# Comparative Industrial Operations Analysis

## Final Project Report

IPRO 312
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# 1. Introduction

IPRO 312 for Spring 2007 was initially intended to research rapid response manufacturing of casters for *Colson Associates*; however, as objectives of the company shifted course, IPRO 312 was left without a target of research. A new idea of pharmaceuticals arose as a topic of study. The teammates were determined to hunt for information pertaining to problems in the pharmaceutical field, but this determination was cut short by the realization that it is a very secure, secretive, and private business. The teammates of this IPRO were not discouraged by this obstacle and kept pressing for information. The advisor, Prof. Maurer, brought in speakers from the field and helped the class change its direction into what it is today: Comparative Industrial Operations Analysis.

In order to find out more information about pharmaceuticals, the team decided to focus their efforts on comparative industries such as food/beverages, cosmetics, FDA regulated and non-FDA regulated drugs which experience similar manufacturing problems to pharmaceuticals in general.

In our competitive and entrepreneurial economy, start-up companies emerge every day with the hope of creating a niche market in which to offer a product that they believe is either an improved version of an already existing product or an innovation that has not yet been marketed. Of all the hurdles that businesses must overcome, the manufacturing of the product can be the most costly and rigorous in dealing with regulation and liability.

Furthermore, after researching the four categories, our IPRO realized a common objective that became the new main focus of this IPRO:

- Investigate problems faced in introducing a product in the pharmaceutical (with and without FDA approval), food/beverage, and cosmetic industries and then compare the results.

The next step for the group was to understand how the four types of companies operated. After the class was divided into four sub-teams, everyone was responsible for researching and presenting their findings to the other teams. Once we had an understanding of what other information we critically needed, our advisor set up factory tours so that we could experience manufacturing operations first hand.

On March 26th the team visited Vienna Beef Factory in Chicago, Illinois. The goal of the visit was to learn more about manufacturing processes in the food category and how regulatory bodies affected their processes. This trip also allowed us to ask questions to professionals in the field.

On April 13th IPRO 312 visited Concept Labs and Goose Island Brewery which both are also located in Chicago, Illinois. Concept Labs provided information on non-FDA approved products while Goose Island showed teams that they undergo very little

regulation due to the nature of their product. Both tours provided much insight on problems in manufacturing and the oversight of regulatory bodies and the lack thereof in certain processes.

## 2. Objective / Goals

The visits to the factories and research throughout the course of the semester warranted some changes to the overall goal of the IPRO. The following presents a few areas of concentration of the newly targeted project:

- Identify entrance barriers to industries (cost, patents, trade, monopolies)
- Determine regulatory bodies including authority and levels of enforcement
- Investigate manufacturing practices used
- Identify quality control, assurance problems, and possible solutions
- Develop a systematic method to compare industries

To accomplish these goals the next actions were:

- Divide the IPRO into four sub-teams with the assignments of FDA and non-FDA approved drugs, food/beverages, and cosmetics.
- Research each category.
- Provide feedback to the other sub-teams.
- Collaborate to determine commonalities and differences.

## 3. Team Organization

Since our first class meeting, we all understood the importance of organizing as a team. By organizing into sub-teams, we would allow ourselves to accomplish a massive amount of project research in an effective amount of time. From the very beginning, the class was broken down into the four following groups:

**FDA**
Keith Olsen
Scott Larson
Jeff Schejbal

**Non-FDA**
Hosung Chun
Michael Hagan
Hong-Kwon Kim

**Food/Beverage**
Robert Logisz
Edward Parry
Dominic Walters

**Cosmetics**
Elizabeth Bilitz
Priscilla Simmons
Anthony Ziskovsky

Each teammate was required to contribute in the research and mid-term class presentations. We also appointed Elizabeth to take minutes at each meeting and for Dominic to hold the position as liaison to the IPRO office to ensure all documents and deliverables were uploaded and turned in on time. Scott Larson fed information from the IPRO office emails to the other members in the class. By dividing the crucial tasks to a few team leaders, we ensured that our deadlines were met and communications were followed through.

## 4. Research Methodology

In order to gain a full understanding of exactly what we needed to research, we defined a research methodology appropriate to the manufacturing business.In task orientated sequential terms, the research of the project was conducted in the following way:

1. Identify specific products for each category
2. Research current manufacturing processes for each product
3. Develop a clear outline of current manufacturing processes
4. Research issues that affect quality
5. Identify current testing inefficiencies and governing regulatory bodies over the processes
6. Brainstorm potential options regardless of cost
7. Narrow options to realistic solutions
8. Create check sheet to improve processes

Our tentative time plan from our Project Plan is as follows:

| ***Week*** | ***Task*** | |
|---|---|---|
| 1 | IPRO introduction | |
| 2 | Brainstorming | |
| 3 | Brainstorming | |
| 4 | Task 1 | COMPLETE |
| 5 | Task 2 | |
| 6 | Task 2 | COMPLETE |

| *Week* | *Task* | |
|---|---|---|
| 7 | Task 3 | |
| 8 | Task 3 | COMPLETE |
| 9 | Task 4+5 | |
| 10 | Task 4+5 | COMPLETE |
| 11 | Task 6 | COMPLETE |
| 12 | Task 7 | |
| 13 | Task 7 | COMPLETE |
| 14 | Task 8 | COMPLETE |
| 15 | | |
| 16 | | |

These tasks were all completed; however the timeline was altered a bit due to obstacles encountered.

## 5. Obstacles

The following is a list of obstacles encountered while completing the tasks planned for the project:

- Uncooperative industries
- Communication constraints with limitations in weekly meetings and informal communication
- Drawing conclusions based on limited information and inferring industrial habits
- Comparing significantly different industries on a balanced scale
- Working within narrow timetable and significant amount of

To overcome the first obstacle, the team found round-about ways to link together similar processes of the uncooperative industries. The most difficult to find information about was the FDA approved pharmaceutical businesses primarily because of their fierce competition to create new and effective drugs on the market. The business of producing pharmaceuticals is a billion dollar industry so their secrecy was clearly acknowledged. The round-about ways discovered were going to similar batch-manufacturing companies such as the food/beverages, supplements (non-FDA approved), and cosmetic industries.

The Spring IPRO 312 was scheduled to only meet on Monday evenings. This provided many communication constraints on the team; however, the class resorted to informal communication through email and small sub-team meetings to overcome the obstacle.

Finding dollar amounts on the costs of manufacturing and the problems and obstacles companies face was extremely difficult. Most companies do not like to advertise their difficulties, profits, expenses, and encounters with regulatory

bodies such as the USDA and FDA. Pulling information from online resources, our meeting with Stephanie Colletti, and the factory tours were the most effective in uncovering the well-kept data.

Though IPRO 312 visited both a food (Vienna) and beverage (Goose Island Brewery) company with the thoughts of similar industry, we quickly discovered that our ideals of each were skewed. Vienna undergoes heavy regulation in their beef products due to its nature and life expectancy; however, Goose Island has little regulatory processes on their beer due to its nature of lacking sufficient ways to "go bad." Given two very different processes, we were still able to draw parallels to the main focuses of the project.

One semester is a very short time span to completely research a project such as comparative industrial operations analysis. Our IPRO would have liked to visit many more factories in the Chicago area and investigate their issues in their processes. After nearly three months of research we compiled a hefty amount of data which needed to be organized into commonalities. We accomplished this by utilizing the established sub-teams who focused on the same objectives for the different sub-categories of businesses.

## 6. Results

**FDA / Pharmaceutical Industry**

The FDA is a scientific, regulatory and public health agency under the United States Department of Health and Human Services whose mission is to ensure the safety and efficacy of the products it regulates. Product categories are:

Food (except meat and poultry; includes nutritional supplements)
Drugs (prescription, OTC)
Medical Devices (pacemakers, eye contacts, hearing aids, etc.)
Biologics (vaccines, blood products)
Animal Feed and Drugs
Cosmetics (labeling only)
Radiation-Emitting Devices (cell phones, lasers, microwaves, medical imaging)
Combinations of the above

**What authority do these agencies have and how do they enforce the rules?**

The FDA derives ALL of its authority from various acts of congress, the most prominent act being the Federal Food, Drug and Cosmetic Act of 1938.

State Departments of Public Health power comes from state congress

The FDA has an Office of Criminal Investigations (OCI) and also works closely with the DOJ

There are several enforcement strategies:

Working with the manufacturer to correct the problem(s) voluntarily
Inspections
Warning letters
Product recalls
Seizure of goods
Fines
Prosecution/Imprisonment

**What are the costs associated with compliance?**

Non-compliance can cause illness, disablement or death.

It is best to answer this question by looking at what non-compliance can cost. Some recent examples include:

FDA`s most serious enforcement activities are having unprecedented success. A noteworthy string of record-breaking penalties against medical product manufacturers have resulted from FDA enforcement actions and Federal investigations that involved FDA in the last two years, including two major actions this month. These include:
- $879 million settlement for conspiracy to commit violations of the Prescription Drug Marketing Act--TAP Pharmaceuticals (October 2001)
- $500 million for failure to comply with Good Manufacturing Practices--Schering Plough (May 2002)
- $355 million settlement for health care fraud--AstraZeneca (June 2003)
- $92.4 million for failing to report malfunctions of a medical device to the FDA--Guidant (June 2003)
- $33.1 million in fines and forfeitures for submitting false information to the FDA--Aventis Pharmaceuticals, Inc. (October 2001)
- $30 million for failure to comply with Good Manufacturing Practices--Wyeth Ayerst (October 2000)
- $4.7 million in restitution for resale of pharmaceuticals--Northland Provider (August 2001)

## Cosmetic Industry

### Regulatory Governing Bodies

The Food, Drug, and Cosmetic Act (FD&C Act) defines cosmetics by their intended use, as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance" [FD&C Act, sec. 201(i)]. Among the products included in this definition are skin

moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, toothpastes, and deodorants, as well as any material intended for use as a component of a cosmetic product.

**How Much Authority**

FDA does not have a premarket approval system for cosmetic products or ingredients, with the important exception of color additives.

**Enforcement (self or government)**

FDA maintains the Voluntary Cosmetic Registration Program, or VCRP, for cosmetic establishments and formulations [21 CFR 710 and 720]. As its name indicates, this program is voluntary.

Factories are checked occasionally, and if complaints are filed with FDA

**Cost Associated with industry**

Manufacture close to ¼ of retail selling price. Must work with retailers, buy back old product, give kickbacks, work with bureaucracy.

Good Manufacturing Practices followed?

However, no regulations set forth specific GMP requirements for cosmetics.

Many companies follow for increased prestige or efficiency

**Latest Money Saving/Efficiency Methods**

Large batch production the most efficient, Oversees plants are important, highly automated only good for very large orders. Using Brokers to contract raw materials sometimes more efficient.

**Quality Issues and cost associated**

Must maintain quality in consistency, batch and raw material testing done, consistency tests are done on sight, but analytical tests are either done at dedicated 3rd party`s or Inhouse operations

**NON-FDA / Supplements Industry**

**Regulation**

Primarily includes nutritional supplements along with dietary supplements and various holistic supplements. FDA Approves them like foods not Drugs.

Establishes accurate labeling

Requires approval for only new dietary ingredients

Can only make claims that have been approved by significant scientific agreement or authoritative statements by bodies such as National Academy of Sciences

- Can not make claims as alternatives drugs
  - Cures cancer
  - Treats arthritis
- All Claims must include - "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

**GMP**

It follows similar GMP's as other food industries.

No regulation by FDA are only suggested compliance.

No premarket approval except for new dietary ingredients

Firms are responsible in determining if supplement is safe and effective

**Money Saving/Efficiency Methods**

6Sigma is an activity to improve product quality. Whole staff has a mind to increases the quality of their products.

Collaborative Forecasting Planning and Replenishment (CFPR) allows correct demand forecasting; it helps make less expired products and improve product safety.

Lean system leads no inventory. It is highly related on CFPR. It permits the company save logistic cost.

**Costs**

Sales have been increasing 5 times in past years

- $13 billion, according to the Nutrition Business Journal.
- prescription drugs-approximately $85 billion

FDA seeking to reign in violations

- 1000 companies
- 20000 products
- 100 Million Consumers

## Food and Confectionery Industry

### Regulatory Governing Bodies

The main regulatory body for the food and confectionery industry is the FDA. Another federal agency involved with the production of food is the US Department of Agriculture Food Safety and Inspection Services.

### How Much Authority

Because products in the food and confectionery industry are ingested, the FDA has quite a bit of say concerning the ingredients and manufacture of ingestible goods. Fortunately, the raw materials for food are non-toxic, unlike several of the raw materials found in drugs or supplements, which are often toxic in their original form or in massive quantities. If a company uses a known, non-harmful product, it is categorized as "Generally Recognized as Safe," or GRAS. If all the products used in the manufacture of a food or candy are GRAS, then the scrutiny by the FDA will be significantly less severe. More on GRAS ingredients:

http://www.fda.gov/Fdac/features/2004/204_gras.html

If a company is using ingredients that are GRAS, then the major issues then occur if there is a problem with the final product, such as tainted ingredients that result in food poisoning.

### Enforcement (Self vs. Government)

Although the food industry mainly sees interaction with the FDA only when something goes awry, the industry investigations could be extensive. For example, when mad cow disease began to appear in the US in late 2003, the FDA began to impose stricter government regulations on the beef industry. Margaret Webb Pressler of The Washington Post wrote an article in early 2004 concerning the fine balance between creating the safest food supply possible and making the food industry an efficient business. In this article, Pressler states that "despite years of criticism, it was only after the BSE incident that the government declared, and the industry agreed, that downer cattle - cows too sick or injured to walk - would be eliminated from the food supply. "That sentence shows that in the food industry, self enforcement and government enforcement often go had in hand, where the a recommendation by the federal governing bodies will be echoed by the industry who doesn't want to have the stigma of tainted product. Sometimes, however, the industry will proceed without any prompting by the agencies, particularly when the technological advances or upgrades can improve the bottom line. For example, in

the beef industry, new RFID tags allow the beef to be tracked literally from the stockyard to the supermarket. Because the competition in this industry is so stiff and a recall of mass quantities of food could be devastating to a corporation's reputation and future, it is often essential to use technology to track product. Because of the industry's ability to adapt, the food industry differs from the pharmaceutical industries, whose standards are set and are usually stationary because changes in standards would require vast inspections from the regulatory agencies. The cosmetics industry, however, is less interested in tainted ingredients, because they are not ingested and they have a bigger opportunity for new companies and products.

**Cost Associated with Industry**

| Expenditures | 1980 | 1990 | 1995 | 1999 |
|---|---|---|---|---|
| Labor | 81.5 | 154 | 196.6 | 241.5 |
| Packaging | 21 | 36.5 | 48.2 | 50.9 |
| Rail and truck transportation | 13 | 19.8 | 22.3 | 25.2 |
| Fuels and electricity | 9 | 15.2 | 18.6 | 22 |
| Pretax corporate profits | 9.9 | 13.2 | 19.5 | 29.2 |
| Advertisiting | 7.3 | 17.1 | 19.8 | 24.8 |
| Depreciation | 7.8 | 16.3 | 18.9 | 23 |
| Net interest | 3.4 | 13.5 | 11.6 | 14.4 |
| Net rent | 6.8 | 13.9 | 19.8 | 25.3 |
| Repairs | 3.6 | 6.2 | 7.9 | 9.6 |

| Expenditures 2000 Billion dollars | |
|---|---|
| Labor | 252.9 |
| Packaging | 53.5 |
| Rail and truck transportation | 26.4 |
| Fuels and electricity | 23.1 |
| Pretax corporate profits | 31.1 |
| Advertising | 26.1 |
| Depreciation | 24.2 |
| Net interest | 16.9 |
| Net rent | 26.7 |
| Repairs | 10.1 |
| Business taxes | 23.5 |
| Total marketing bill | 537.8 |
| Farm value | 123.3 |

| | |
|---|---|
| Consumer expenditures | 661.1 |

Source: USDA`s Economic Research Service.
Figure 2

Labor Took Biggest Chunk of Food Dollar in 2000

Farm value 19.0cents

| | Cents |
|---|---|
| Marketing Bill | |
| Labor | 38 |
| Packaging | 8 |
| Transportation | 4 |
| Energy | 3.5 |
| Profits | 4.5 |
| | |
| Advertising | 4 |
| Depreciation | 3.5 |
| Rent | 4 |
| Interest | 2.5 |
| Repairs | 1.5 |
| Business | 3 |
| Other | 4 |

Source: USDA`s Economic Research Service
Good Manufacturing Practices Followed?

In the food industry, the manufacturing practices vary, depending on the size of the operation. Obviously, the larger companies, such as Nestle, Chef Boyardee, Stouffers, etc. must rely on rapid manufacturing practices in order to satisfy their supply needs, but more regional and local manufactures can use more traditional manufacturing methods. While these may save money in the long run, this prevents growth of the industry and flexibility in the operation. For example, if a local manufacturer suddenly receives a large order, they may not be able to produce it without extending their operation by hiring additional workers (which costs money) or by paying their current workers overtime (which also costs money). A larger company, however, would be better adept at adjusting to such inflations in the market by using automated technology, which could be adjusted in the cast of large orders.

## Latest Money Saving/Efficiency Methods

As mentioned in the previous section, the best money savings and efficiency methods come from the automation manufacturing and distribution of the products. The cost of the raw ingredients, such as sugar, flour, cocoa, etc. is fixed by the market and cannot be adjusted by the manufacturer. Therefore, the best opportunity to maximize profits is to automate as many processes as possible. Energy has also become a major issue, both in terms of quantity and quality. Either purchasing more efficient equipment or using current equipment more efficiently will garner benefits.

## Quality Issues and Cost Associated

Estimated annual costs due to selected food borne pathogens: Year 2000
Numbers: 1 Pathogen Estimated annual food borne illnesses, 2 Costs,3 Cases Hospitalizations Deaths, 4 billions of dollars:
Campylobacter spp 1,963,141 10,539 99 1.2
Salmonella5 1,341,873 15,608 553 2.4
E. coli O157 62,458 1,843 52 0.7
E. coli, non-O157 STEC 31,229 921 26 0.3
Listeria monocytogenes 2,493 2,298 499 2.3
Total 3,401,194 31,209 1,229 6.9

# 7. Conclusions and Recommendations

**Accomplishments**

- Met with significant industrial leaders and scheduled them to present to the team
- Toured Concept Laboratories, Goose Island Brewery and Vienna Beef
- Gathered extensive information on regulation, costs, manufacturing practices
- Established a formal way to compare industries

**Future work**

- Expand research to different manufacturing industries
- Gather more data on profit margins, industry revenues, and start-up costs
- Obtain precise quality control and assurance statistics from pharmaceutical companies
- Introduce cost saving, quality control ideas to industrial representatives and gain greater feedback

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