Geniale: On the Verge of Losing a Multi-Million Peso Market

It was a beautiful sunny Sunday in Manila. While everyone was spending time with their families, Robert Mendez was at the office. "I just can't let this company fall. We all worked hard for our reputation and I can't let this single mistake destroy our lives and our source of living," he thought. He walked toward the cabinet that contained the results of the analyses and browsed through them. He was convinced that his company, Geniale had taken all the necessary precautions, followed every standard operating procedure (SOP), and adhered to the provisions of the current good manufacturing practices (GMP). "We have been selling these products for how many years? Why now?" he said to himself as he shook his head. "This is a mistake! I've got to do something!" Sitio Minla, a small community situated in Northern Luzon, claimed that the company had supplied its local store with herbal supplements that were contaminated with heavy metals such as lead. The hearing on the allegations against Geniale at Quezon City Regional Trial Court would be held in two weeks and as the company's senior analyst and chief pharmacist, Mendez would have to address the charges.

As he was pondering over the situation, the phone rang. "Yes boss. I know we are facing challenges but rest assure, I will be doing something to address this," Mendez said in a nervous voice. The company was in the midst of negotiations for a partnership with ABG Incorporated, a multinational company, and these developments could throw a monkey wrench into their plans for expansion with the company.

Later that day, Mendez had a meeting with senior leadership.

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"Where did the complaint come from?" the company's president asked with a look of disappointment.

"Sir, the report came about when a group of students did research on lead contamination in herbal supplements; it was Big Ace (a competitor) that funded the research. One of the products tested was Sugardep, our supplement for high blood pressure, diabetes, and kidney disease," Mendez replied.

"And why was Sitio Minla involved in this?" the CEO asked.

"The constituents in the sitio[i] initiated the complaint sir, after the findings of the research came out in a journal article," the marketing officer said.

"But it can't be our product! We've been supplying them with Sugardep for 10 years now and there has not been a single complaint," the CEO exclaimed.

"Sir, in our initial investigation we found out that a match company by the name of Bearer was constructed within the vicinity about three years ago," the marketing officer said with a curious face. "Isn't it true that that no one was allowed to construct an establishment in that particular area since it is so close to a water source?"

"That's not our concern! Our problem is how to clear our company's name. We have to conduct our investigation before Robert goes to court," the CEO said in a powerful voice, leaving everyone in the room uneasy.

"Robert, I know it's not proper to think negatively about others, but could this be a part of Big Ace's plan of destroying the reputation of our company since they are also interested in having a partnership with the company we are targeting?" the marketing officer asked. "Maybe, this is a desperate move! Maybe they have learned that ABG Incorporated preferred us than them."

Mendez, who was sitting next to the CEO, inhaled deeply and after catching his breath, stood up, and left the room quietly. His anxious aura had now become apparent to everyone he met as he walked through the hallway to his office. Some of his workmates were already starting to get worried. As he quietly walked along the corridor, he tried to recall every aspect of the quality control measures he and his team implemented in the production of Sugardep. He was trying to assess if there were some failures in carrying out the SOPs. As the man in-charge of ensuring the quality of the company's manufactured products, he was the one most responsible for validating results of assay procedures[ii] to support the quality of these products. As far as he could recall, workers were following the appropriate procedures. However, he was also aware that aside from him, there were also former employees at Big Ace who intimately knew the product due to a past alliance for the creation of Sugardep.

"Could this just be a competitive move?" he thought. "Did the quality control system of the company fail to ensure safety of our manufactured products? Is this issue part of a demolition job by Big Ace to stop our partnership with ABG Incorporated for our dream expansion? There is really something wrong with this whole scenario."

i A sitio in the Philippines is a territorial enclave that forms part of a barangay. A barangay is the smallest administrative division in the Philippines and is the native Filipino term for a village, district, or ward.
ii Testing methods for determining the purity of drug products.

The World Class Manufacturer: Geniale

Founded in the early 1980s, Geniale was considered one of the leading local medium-sized companies engaged in the manufacture, importation, and distribution of pharmaceutical products. The company was focused on its commitment to create quality health products for the enhancement of life. Up to the present time, it continuously provided the public with high quality, yet affordable pharmaceutical products.

Geniale aimed to become an exclusive distributor of high quality herbal products in Asia as well as markets outside the region. The company invested in research and development, production and manufacturing equipment, and expansion of its distribution and marketing services. It also worked hard to ensure that it met global standards.

Not an ordinary pharmaceutical company, Geniale had always been known as a company with a good heart. It distributed herbal products to small communities in the Philippines at low prices with the aim of providing health care to those who could not afford synthetic medicines. One of these communities was Sitio Minla. This small community was very poor, and many of its residents suffered from common lifestyle diseases such as hypertension, diabetes, and kidney disease. Geniale had been supplying the community with Sugardep, a product known to treat these conditions, for 10 years.

The Competitor: Big Ace

Established approximately 20 years ago, Big Ace Corporation, was a local pharmaceutical company vying to become the number one producer of herbal products in the Philippines. A strong competitor of Geniale, the company had first class facilities that were clean, orderly, and in top condition. It also employed top caliber professionals who were experts in the fields of research and quality control.

Market expansion had always been Big Ace's primary goal. It had established links to companies all over Asia and was prepared for entry into the United States. ABG Incorporated, the leading pharmaceutical company in North America, was its target partner for the expansion. The company's preference, however, was Geniale since it had long been regarded as the most stable herbal supplement company in the Philippines.

Big Ace also invested in student research. In one of the studies it funded, lead contamination was found in herbal supplements marketed in the Philippines. The researchers, however, excluded Big Ace's popular herbal supplement, Gozin from the study. Lead contamination can lead to developmental disabilities in children and weight loss, loss of appetite, abdominal pain, sluggishness, and fatigue in adults. In the study, the students disclosed the names of the products tested and their respective manufacturers. An article about the lead contamination, naming Geniale and Sugardep was written a month later. That is how the information trickled down to the residents of Sitio Minla. The community was outraged; some residents sued.

The Forgotten Alliance

Geniale and Big Ace had formed an alliance for R&D 15 years ago. The manufacturers joined forces to create a one-of-a-kind herbal supplement that would combat hypertension, diabetes, and kidney disease. Everything went smoothly for the first three months of the project until one day, Mendez discovered that Big Ace was making alterations to the companies' original agreement on exclusivity

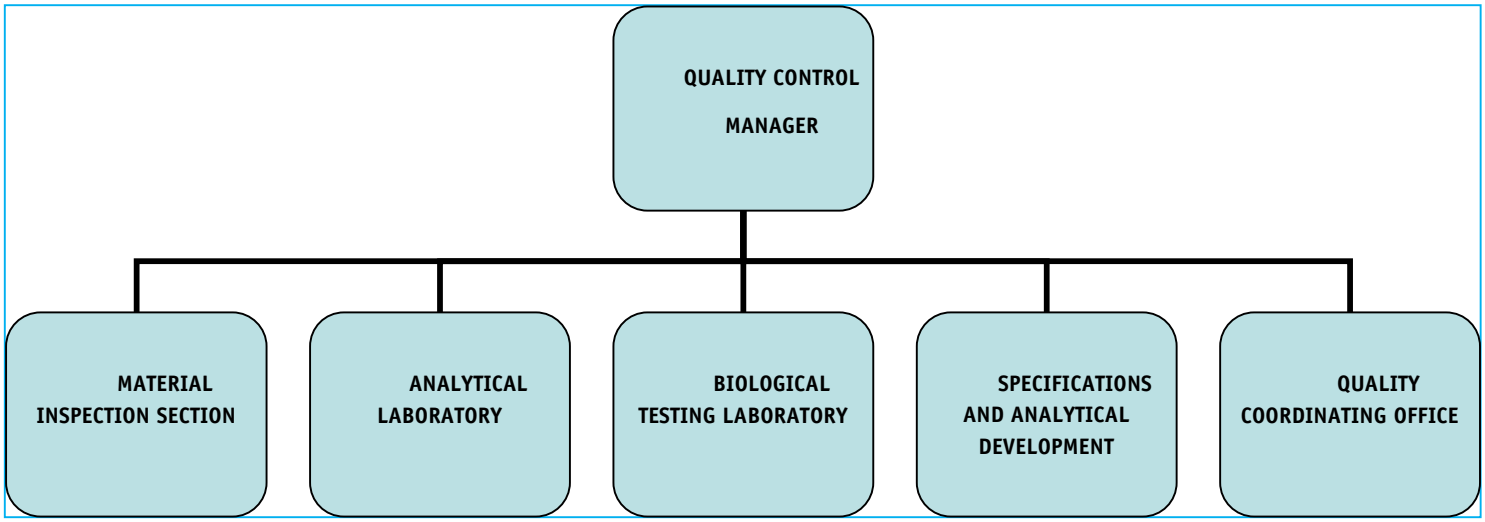
rights. Mendez, who was then Geniale's pharmacist confronted his counterpart at Big Ace. Not happy, the executives of Geniale decided to sue Big Ace. The court ruled in Geniale's favor, granting it exclusive rights to produce its product, Sugardep. The dispute embittered the once friendly organizations. Since then, Big Ace did everything to overtake Geniale as the most popular herbal supplement company in the Philippines. Because it was once a part of the Sugardep project, some of its quality control personnel knew every aspect of the product and all its limitations.

Quality: The Big Deal

People expect quality and safety of the products they find on the market. Quality control is the process concerned with sampling, specifications, and testing. The sum of all activities and responsibilities required to ensure that all medicine that reaches the patient is safe, effective, and acceptable is quality assurance.[1] To ensure smooth operation, each pharmaceutical company has a quality control organizational chart; each subdivision of the chart is assigned a scope of work and responsibilities (see **Exhibit 1**).

Exhibit 1

A Quality Control Organizational Chart



Source: Lerma, Norma and Marina Osi. "Drug and Cosmetic Quality Control with Instrumentation." 1996. Open Library. Accessed 6 Oct. 2015. <https://openlibrary.org/books/OL23835713M/Drug_and_cosmetic_quality_control_with_instrumentation>.

As part of the quality control of products, standards and specifications are indicated. These are reflected in the master formula record and batch reproduction records. Guidelines for the formula, raw material specifications, SOPs, finished product specifications, packaging material standards, and testing materials are written in these documents. These documents are used as the basis for assessing quality characteristics and determining if a product is accepted or rejected.

Quality is everybody's business. It is built into the company's processes and procedures. A quality control system is established to ensure that a safe, pure, and effective product is made and delivered to the end user. In a quality control system, laboratory managers should assume professional, organizational, educational, and administrative responsibility. They should be engaged in and responsible for the day-to-day management of the laboratory. They are responsible for ensuring that

there are enough adequately trained and experienced personnel to supervise and conduct the laboratory work. The laboratory managers should also ensure the continued competency of the laboratory personnel by documenting their in-service training, reviewing their performance, and verifying their skills. If the quality control system fails to meet performance specifications, laboratory managers should ensure that test results are not reported until corrective actions have been taken and that they are accurate and reliable. Furthermore, they should also take responsibility for taking remedial action.[2]

Confidentiality of records is an important aspect of a quality control system. In the company's SOPs, workers should document the arrangements to be made to ensure that individual records are maintained with the highest regard for individual privacy and confidentiality. Only authorized personnel should have an access to these records.[3]

The "Natural" Trend

Filipinos buy supplements for trimming down, keeping the body fit, and alleviating common ailments. The increased global consciousness surrounding health and body image makes supplements attractive to consumers. Moreover, the common notion that "natural" supplements are free of side effects and are safer than synthetic drugs has further increased sales of these products. Herbal medicines are prepared from materials of herbal origin which are often obtained from varied geographical and/or commercial sources.[4] Herbal medicines can be considered more or less potent than synthetic drugs because they contain several active ingredients that are chemically similar and work synergistically to contribute to, or detract from, the therapeutic effect of each individual ingredient.[5]

The use of herbal medicines is popular both in developed and developing countries. In a Turkish study it was found that in developing countries like the Philippines, the use of complementary and alternative medicines (CAM) is popular due to their efficacy and economic availability. Many countries do not have regulations for CAM. The absence of these regulations greatly influences the efficacy, quality, and reliability of these products in addition to awareness of their effects in the general population. As a result, about one third of the surveyed population thought that herbal medicines were more natural and thus harmless.[6]

In the Philippines, herbal medicines, just like synthetic ones, are governed by law to ensure that only quality products are made available to consumers. Republic Act No. 8432 or the Traditional and Alternative Medicine Act of 1997 provides the guidelines for the manufacture, sale, and distribution of traditional and alternative medicines. Under Republic Act 9711, also known as Food and Drug Administration (FDA) Act of 2009, as well as provisions of Republic Act 9502, also known as the Universally Accessible Cheaper and Quality Medicines Act of 2008, establishments involved in the manufacture, importation, exportation, sale, offer for sale, and distribution of herbal products are required to be licensed with the Republic of the Philippines Food and Drug Administration. Furthermore, all herbal products must be registered before they can be marketed, distributed, or sold.[7]

Due to the inherent complexity of naturally grown medicinal plants and the often variable nature of cultivated ones, there is often contamination in herbal medicines. Consequently, GMP in the manufacture of herbal medicines is an essential tool to assure quality.[8] With the increasing demand for herbal medicines and the awareness that much control should be exercised with these products, the World Health Organization (WHO) developed guidelines for herbal medicine manufacturing practices. These guidelines cover almost all areas of manufacturing from the sanitation and hygiene of the workers to the qualification and validation of equipment and the qualifications of the personnel involved in the

production and testing of herbal products. A person who is tasked to give the seal of assurance in terms of the quality and safety of these products should have adequate training in the fields of pharmaceutical technology, taxonomic botany, phytochemistry, pharmacognosy, hygiene, microbiology, and related subjects.[9]

Challenges in monitoring the safety of herbal medicines are often the most important concern of manufacturers. Because regulations vary from country to country, quality assurance and control measures, such as quality specification and standards, GMPs, labeling, and licensing schemes for manufacturing and importation should be developed at the national level. A high incidence of undesirable effects may be brought about by weak regulation and quality control and are the result of adulteration with undeclared potent substances and/or contamination with potentially hazardous substances.[10.]

Blame it on Lead

Lead is the most common heavy metal contaminant found in nature. It can be found in paints, dust, soil, drinking water, air, folk medicines, cosmetics, and children's jewelry and toys. It is often generated as a byproduct of oil, coal, smelters, and automobile exhaust.[11]

Pre-school children and fetuses are usually the most vulnerable population relevant to lead exposure. This increased vulnerability can be attributed to several factors such as 1) the developing nervous system of the fetus or neonate that is more susceptible to the neurological effects of lead; 2) the tendency of children to play in dirt or to place their hands and other objects in the mouths; 3) the greater efficiency of lead absorption in the gastrointestinal tracts in children, and 4) nutritional deficiencies such as low levels of iron and calcium. Studies have established a relationship between exposure to lead and a variety of adverse effects in children. These effects include impaired academic performance and deficits in motor skills, decreased hemoglobin levels, elevated hearing threshold, and decreased levels of Vitamin D.[12] Likewise, adults suspected of lead toxicity may exhibit fatigue/irritability, impaired concentration, hearing loss, and peripheral neuropathy.[13] Geniale's potential herbal product contamination is magnified by the fact that consumers do not merely limit their intake of these products to once a day. A twice or thrice daily dose may exceed the allowable limit for these products.

The Conflict

Geniale is eager to defend itself against the allegations. Sugardep is a strong market contender. If Geniale loses this battle it will lose millions in addition to the public' trust. Mendez is determined to defend himself and the company. Residents of Sitio Milna are questioning Geniale's manufacturing processes and its adherence to the guidelines specified by WHO. Mendez knows he has to do something. This calls for a drastic and immediate action, but alas, which route to take.

Endnotes

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