



Empty Bubbles: The Case of the Missing Tablets

Gazing at the daintily-framed photograph of her curly-haired twin granddaughters, Leticia Rodriguez was deep in thought. She had a faint smile across her lips as she sipped a tall glass of cold lemongrass-infused tea. She just finished reading an endearing e-mail from her only child, Norjon. He was based in Cagayan de Oro City, Philippines for the last three years, busy managing a veterinary supply startup. He was trying to talk her into taking a one- or two-week vacation next month with the family on Camiguin Island in celebration of the twin's fifth birthday. He outlined how they would take her around the famous spots in the so-called "Island Born of Fire," from Ardent Hot Springs to Katibawasan Falls on to the Catarman Church Ruins and the Sunken Cemetery to Sto. Nino Cold Spring and the Giant Clam Sanctuary. Rodriguez could barely remember the last time she went on a trip that wasn't business-related.

Rodriguez had recently joined Neo Viva Inc., a newly established but very aggressive local nutritional supplement company. She was recruited as vice president of quality assurance because of her more than 45 years of experience. Her duties included ensuring that the company followed the good manufacturing practice (GMP) lifestyle (**Exhibit 1**). The GMP Lifestyle integrates the principles of GMP into a company's strategic plan and everyday operations. It starts with setting standards of performance and training everybody (from top management to support staff) to follow the standards. These standards are then reinforced and audited to make certain that they are met. At the heart of the GMP lifestyle is the commitment to practice it.

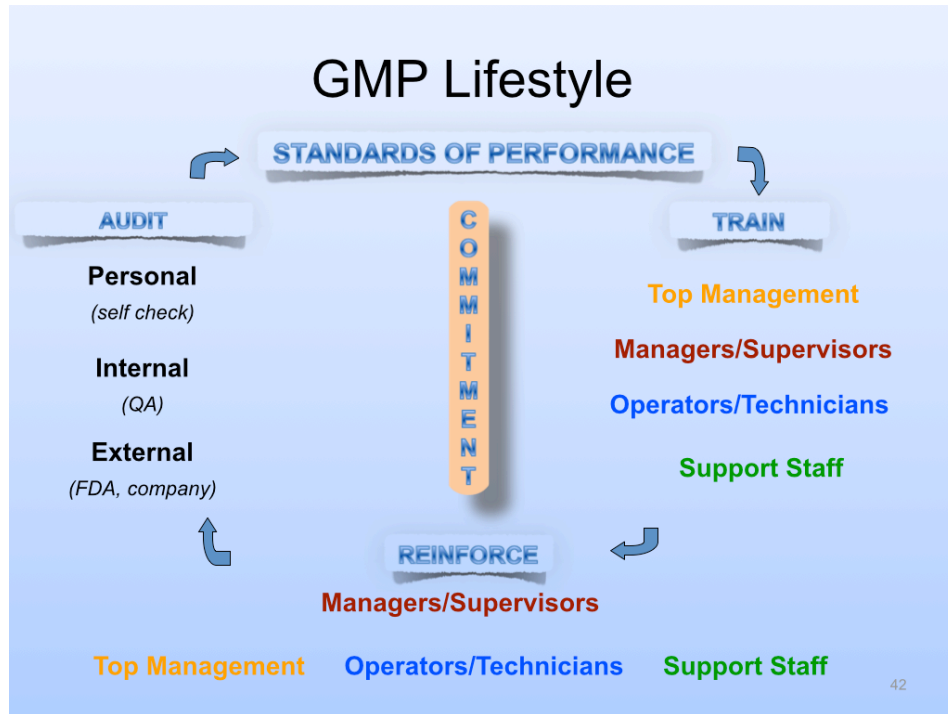


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Exhibit 1

Good Manufacturing Practice Lifestyle



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Rodriguez was handed a customer complaint about empty bubbles on a blister pack of Amazevit, Neo Viva's top selling product. Amazevit was a multivitamin tablet formulated with the popular herbs, ampalaya and malunggay. Ampalaya or bitter melon was an alternative remedy for diabetes and hypertension and was considered a blood tonic while malunggay or moringa was believed to strengthen the immune system. Amazevit was a product that had caught the fancy of consumers because it was endorsed by celebrities.

Should they just recall the product? It appeared to be the easiest thing to do. Rodriguez believed the complaint did not warrant an immediate and total market recall as the defect did not pose danger to the consumer. She also knew that a market recall could alarm consumers and attract the attention of competitors. There was no guarantee that it would lead to an instant solution and might uncover other problems. Were the requirements of GMP being complied with? Was the company really practicing the GMP lifestyle? She had to help the owners of the company decide on a course of action that would not jeopardize the popularity of Amazevit and the renewal of the company's license to operate (LTO), which was set to expire in less than three months.

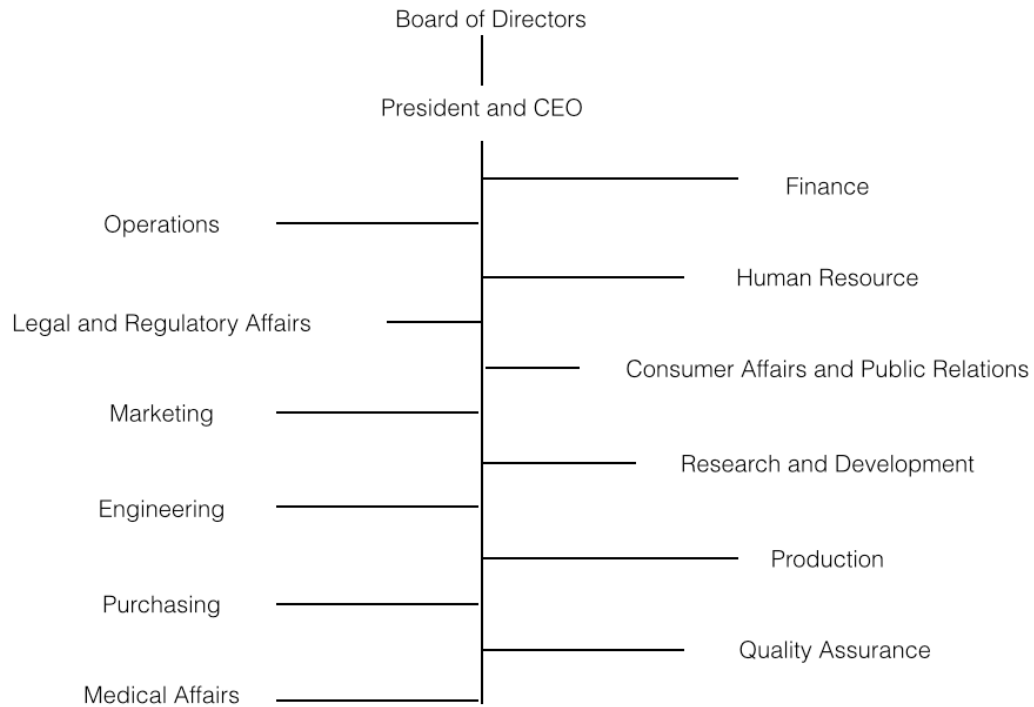
Breathing Life into Neo Viva

Owned by the Bautista family, Neo Viva Inc. began operations in 2013 in Silang, Cavite. The family had long been in the business of organic farming, wanted to diversify, and recognized nutritional supplements as a market opportunity. They wanted to create products that would use the medicinal herbs that they had grown for more than 10 years.

The Bautistas carefully planned the organizational chart of their company with the main objective of keeping full control of operations. This was, after all, a family-owned company. The president and CEO was Mateo Bautista Sr. He along with his wife and children made up most of the company's board of directors. The remaining seats were assigned to very close and loyal business associates. **Exhibit 2** shows Neo Viva's Organizational Chart.

Exhibit 2

Organizational Chart of Neo Viva



Source: Created by the author of the case.

In their first year in business they saw a whirlwind of activity in terms of constructing the company's facility and getting the LTO from the Republic of the Philippines Food and Drug Administration (FDA). The Bautistas envisioned a facility that was both compliant to GMP and environmentally sound. Compliance to GMP was essential to being granted an LTO as a nutritional supplement company. Nature-lovers, the Bautistas were conscious of elements that could affect the environment. They wanted a facility that would efficiently use natural resources and renewable energy sources.

GMP was a system that ensured that products were consistently produced and controlled to meet quality standards. Its objective was to minimize, if not eliminate, bad products. Areas covered by GMP included production, equipment, training, and personal hygiene. These requirements were expressed as the 10 commandments of GMP (**Exhibit 3**).

Exhibit 3

The Ten Commandments of GMP

1. Thou shalt write procedures.
2. Thou shalt follow thy written procedures.
3. Thou shalt document thy work.
4. Thou shalt validate.
5. Thou shalt design, build, and use proper facilities and equipment.
6. Thou shalt maintain thy facilities and equipment.
7. Thou shalt be competent as a result of education, training, and experience.
8. Thou shalt be clean.
9. Thou shalt control for quality.
10. Thou shalt audit for compliance.

Source: Created by the author of the case.

Something is Missing

Dolly Tolosa was a 28-year-old advertising account executive. She lived alone in a studio unit on the 15th floor of Sunrise Condominiums. She regularly watched telenovelas after dinner as a way of de-stressing. The celebrity endorsers of Amazevit were the lead actors of the telenovela that she was currently watching. They were Tolosa's favorite celebrity couple and had influenced her to try Amazevit.

Come payday, Tolosa was elated that she had extra money to buy a blister pack of Amazevit from the neighborhood pharmacy. She had to hurry home, so she did not bother to check the merchandise. It was only when she got home that she noticed that three of the 20 blisters were empty (**Exhibit 4** shows what a blister pack looks like). It was getting late so she decided she would return the product the next day.

Exhibit 4

Blister Pack



Source: Photo taken by the author of the case.

A blister pack is a type of packaging wherein a small product (like a tablet or capsule) is sealed between a transparent plastic dome and a laminated paperboard backing. It is a unit dose packaging for pharmaceuticals.

The packaging lends adequate barrier protection against the environment, makes tampering evident, and provides for convenience in carrying the product and ease in dispensing medication by pressing the product out with the thumb.

Early in the morning, Tolosa stopped by the pharmacy to return the whole pack and to ask for her usual brand made by another local manufacturer in exchange for the defective Amazevit. The pharmacy assistant was a new graduate from Cebu and appeared rattled when Tolosa started complaining about the product. Tolosa would be late for work if the situation was not resolved soon, and thought it best to just talk to the store manager. The pharmacy assistant was only too relieved to call her manager to handle the situation.

Glancing through the glass office window, the pharmacy owner, Bien Gutierrez, promptly set aside his inventory logbook after he saw the anxious looks of the customer and his assistant. After curtly directing the assistant to attend to another customer, he pleasantly greeted Tolosa and asked how he could help her. Tolosa then quickly proceeded to retell her complaint about the empty blisters on the Amazevit pack.

Gutierrez inspected the pack and located the three empty but intact blisters. He made a mental note to check the remaining Amazevit packs and informed Tolosa that he planned to contact the distributor of the product to relay the customer complaint. He provided her with the substitute product from the other local manufacturer and threw in a promotional umbrella. As Tolosa thanked him, Gutierrez offered to hail a cab for her so she would not be late for work.

Once inside, he retrieved the stock of Amazevit and inspected it. He found two defective packs out of three in the same box Tolosa's pack came from. The box originally contained five packs. He opened the next five boxes and again found defective packs. He called the distributor.

Next in Line

The distributor listened intently as Gutierrez spoke. He assessed that the problem did not lie with him, but with the manufacturer. So he passed the complaint on to Neo Viva.

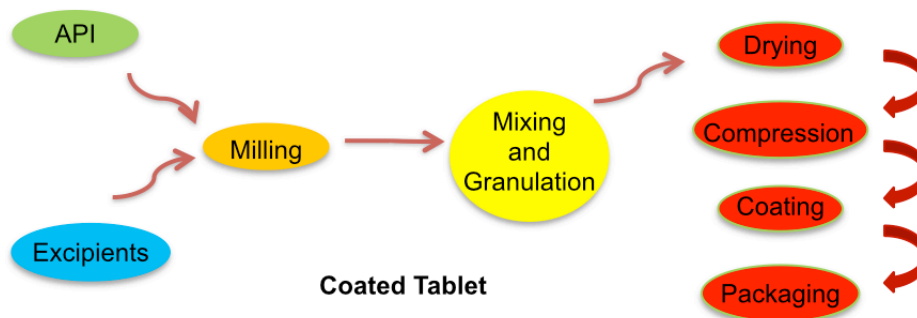
Ethel Bulatao, the product complaints coordinator for Neo Viva, contacted Guitierrez to get the details of Tolosa’s complaint and asked him to fill out a customer complaint form.

Bulatao submitted the complaint form to Rodriguez, who then scheduled a meeting with legal counsel and the managers of quality assurance, production, regulatory affairs, consumer affairs, and production. During the meeting, the batch production record (BPR) of the Amazevit batch in question was reviewed. A typical process for manufacturing coated tablets (a solid drug delivery system) is shown in **Exhibit 5**.

Exhibit 5

Manufacture of Solid Drug Delivery Systems

- complex multi-stage process
 - starting materials change their physical characteristics a number of times before the final dosage form is produced



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Source: Created by the author of the case.

Floyd Ladignon, the production manager, pointed out that there were no unusual events during the manufacture of the Amazevit batch in question, that everything was religiously followed as outlined in the BPR, and the initials of the production operators and quality control analysts were clearly visible in the document. Likewise, packaging records did not show any power interruption or machine breakdown during the packaging operation. “So what could be the root cause of the problem?” Rodriguez thought.

Halfway into the meeting, Agnes Pulumbarit, the company’s legal counsel, glanced at her smartphone and started to appear impatient, gently tapping on the wooden conference table. She read the complaint and tried hard to understand the ongoing flurry of technical discussions. Pulumbarit waited for what she thought was the last technical analysis of the documents and clarified if there was anything that the customer demanded from the Neo Viva.

The consumer affairs manager, Clinton Quibin expressed his opinion that whatever demand the consumer may have sought was not indicated in the complaint and may already have been addressed by the pharmacy owner. Pulumbarit then concluded that the problem was already resolved for the consumer, but Neo Viva would either have to recall the rest of the products bearing the same batch number as the Amazevit in question or provide public notice that the company would gladly replace or refund any defective blister pack. Ladignon, thought the second option was unacceptable and could even damage the product's image.

Quibin suggested a visit to Tolosa and Gutierrez to reassure them that Neo Viva Inc. was committed to producing quality products and that the welfare of the public was foremost in their list of priorities. As a sign of goodwill from the company, they signaled they were willing to give Gutierrez and Tolosa complimentary premium promotional items and a box or two of Amazevit.

Decisions, Decisions, Decisions

Half-stirred from her pensive silence, Rodriguez carefully pondered the steps on how to best explain to the owners and the board of directors the courses of action that they would have to decide on within the next two days. Her almost half a century of experience in the industry told her that manufacturing and distributing inferior quality products would result in loss of credibility, especially for the manufacturer. An incident like this, although not life-threatening, would cast doubt on the quality of any product or service from Neo Viva. The FDA would also learn of the complaints and could use them as the basis for an investigation.

In three months' time, Neo Viva would renew its LTO and would be subject for inspection by the FDA. Needless to say, the management of Neo Viva had to choose the best option to control the situation and keep the company on track. Will there be enough time to complete an investigation of the incident? What would be the impact of product recall? Should they attempt to repackage Amazevit?

In the middle of a particularly sweltering summer day, the air-conditioning unit in Rodriguez's elegant office seemed to be unsympathetic. Between sips of her ice-cold lemongrass-infused tea, she took long deep breathes and let out equally long quiet sighs.