Quality - A Prerequisite

Case study
Reference no 411-038-1

This case was written by Dr. Upinder Dhar, Ms. Veena Chavan, Ms. Prema Mahale, Mr. Aditya Sontakke. It is intended to be used as the basis for class discussion rather than to illustrate either effective or ineffective handling of a management situation. The case was made possible by the corporation of an organization that wants to remain anonymous.

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The Case*

Background

Salvi Parenteral Limited (SPL) located at Navi Mumbai in the State of Maharashtra in India was a research-based, international pharmaceutical company that provided a wide range of quality products and services, at reasonable prices. The company focused on quality and customer satisfaction, and strived to grow on the principles of passion, performance and partnership. The core product range was quite wide and included oral solids, small volume parenterals and sterile powder formulations for antibiotics, anti-emetic, anesthetic, anti-malarial, analgesic, vitamin and multivitamins and veterinary products. The raw material was procured mainly from local suppliers and which was not available within the country was procured from China. The company manufactured 6.5 million Vials/Ampoules per month. Established in 1997 by A.H. Khemka, Ashwin Khemka and Somesh Khemka, under the technical direction of Mahendra Kalwankar, the company had grown manifold and aspired to be a respected research-based company. With its diverse product portfolio, and success in India it was rapidly expanding in the world's emerging and developed markets.

The company had state-of-the-art WHO GMP approved manufacturing facility at Navi Mumbai. Intensive technological development was augmented for various injectables, sterile powder and suspensions under various processes such as compounding of batch, aseptic filtration, aseptic filling, sealing, visual checking, packing, and dispatch. A special emphasis was put on research activities at Salvi. A team of scientists worked continuously for new product development and technical advancement activities. In 2005 the company started a subsidiary called Tenesen Laboratories in the vicinity of the production plant to take care of the Research & Development activities for Salvi. It was purposely put, so that the production and research teams could continuously work in collaboration. It helped the company with the patent drafting and filing, regulatory support for APIs and formulations and finding various techniques for reducing the cost of the products. This would help end-user to draw benefit.

Young professionals, pharmacists and scientists were hired from time to time, as the company believed in the power of youth and dynamism. The scientists at the Research and Development department provided continuous guidance to the production team to

comply with all the technical requirements of manufacturing. There were separate teams for quality assurance (QA) and quality control (QC) to achieve quality throughout the production process. These teams ensured that the core value of the company, of providing the highest standards of quality, is protected. To avoid contamination, employees working at the plant used to change their clothes and enter the plant in the specially designed clothes to suit the requirements and the ambience of the plant. The floor in the plant was painted with epoxy paint which had excellent anticorrosion properties, and was water as well as oil resistant. The Company claimed that its major strengths were manufacturing capability, focus on technology and quality and In-house research activity and believed that these strengths gave them an edge in the market, since very few companies had this combination of competencies.

Salvi was a regular supplier to the hospitals of the armed forces in India, government agencies, private hospitals, NGOs, other types of organizations and Individuals across the country. The company also had its own marketing operations in India and had over 1000 distributors all over India. Establishing itself in India was not Salvi's goal. It had extended its reach globally by making its active presence in countries like Russia, Ukraine, Uzbekistan, Turkmenistan, Fiji, Vietnam, Sri Lanka, Nepal, Malaysia, Thailand, Nigeria and Peru, to name a few. It had also got its plant approved by the registration authorities of Congo, Sudan and Sri Lanka and was making its presence felt in the world market by leveraging its manufacturing capacity, quality products and international alliances.

The total turnover of the company was $ 25 million in the financial years 2008-09. International business contributed about 30 percent of the company's revenue and it was set to grow to more than 50 percent by 2011. This included the sales of Salvi's own brands and the revenue generated from the contract manufacturing services that the company provided to its overseas clients Salvi offered the CRAMS (Contract Research and Manufacturing Services) model for the overall growth of its business. The company had been investing in research and manufacturing facilities, to comply with the global standards and to meet the ever-growing international requirements of quality. It also offered Contract Manufacturing facility to the clients who were based in India and outside India, in the regulated and semi-regulated markets from all over the world.

The company had to face rough weather in 2007, when one of its products Broadcef came under scrutiny. It was administered on 10 patients in a local hospital managed by the Government of Maharashtra and two patients died after two days. The incident was highlighted by the print and electronic media blaming the company for supplying the contaminated medicine to the hospital. It was claimed by the hospital authorities that the patients had died after they were given the injection. Food and Drug Administration (FDA) ceased all the vials of the medicine available in the hospital. The particular batch of the product, which was under shadow, had 27000 units. FDA collected samples of the medicine from the hospital as well as SPL for testing it in lab. The testing procedure required 14 days and it meant keeping the credibility of the company at stake.

SPL also took various steps to cope with the situation. It communicated to its distributors not to distribute the remaining vials of the medicine of that particular batch till test results were declared by FDA. The management of SPL was under tremendous pressure, as the incident could not only lead to the financial or production loss but also the goodwill of the company was at stake. It was for the first time in the history of the company that it had to face such kind of a situation. There was a risk of getting blacklisted by government which could have lead to the closure of the company. In the meantime SPL also tested its samples and found them contamination free and non toxic. It investigated internal processes particularly production and quality control and found them in order as per international standards. After completing the investigation, FDA declared that there was no problem in the medicine and certified that the medicine was absolutely safe for use.

The postmortem reports of the bodies of the patients revealed that, the deaths had taken place due to a bacterial infection and not due to the medicine, Broadcef. Based on this, Government declared through a public notice that the medicine supplied by SPL was absolutely safe for administration on the patients. Interestingly, after the whole episode, SPL was not only able to sell all the vials of the particular batch of Broadcef but its overall sales turnover increased, which boosted its confidence. The goodwill of the company in the market, had helped it to retain the confidence of its customers. This also endorsed their confidence in their expertise in manufacturing pharmaceutical products and to provide the best possible solutions to esteemed customers. Their focus on research, technological innovation & up gradation and in-house and out-bound training

programmes continued. The company started planning for expansion nationally as well as internationally. SPL had targeted the growth in exports by 100 percent and was planning to expand its horizon to Latin America and Africa. It was also planning to enter into the regulated market of the US and Europe with more than 100 overseas product registrations.

Questions:

1. Discuss the strengths of SPL.
2. “QUALITY A PREREQUISITE” comment on the statement
3. In your opinion what helped SPL in overcoming the crisis.
4. Do you think SPL could draw any leverage from the incident? Discuss
5. Comment on the strategy of SPL to manufacture and market a wide range of products.