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Quality Control and Inventory Management Practices at Pharmaceuticals Industries in Bangladesh - A Case Study on Central Pharmaceuticals Ltd.

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If we go back ten years from now, no industry other than Pharmaceuticals have such profound impact on the country's economy in terms of economic return and overall wellbeing of its citizens. After the declaration of Drug Control Ordinance – 1982, the development of this sector has accelerated and now it is the second largest sector after agriculture that contributes to the revenue generation of the Bangladesh Government. The billion worth Pharmaceutical industry export drug items to 120 destinations from 83 countries boosting the country's export earnings. This is a descriptive research that studies and evaluates the two most important aspects of any industry which are inventory and quality management capability in respect to the Pharmaceuticals sector. The main aim of this paper was to give the readers the practical exposure regarding the quality control and inventory management practices of a local pharmaceutical company. The write-up will provide up to date knowledge about different laws and regulations such as the CGMP guidelines of the World Health organization as well as the National Drug policy and Drug Control Ordinance – 1982 that a company should follow if it wishes to produce here and abroad. The study revealed that it is essential for businesses to take a holistic outlook for managing inventory and quality since both the aspects are part of the series of activities known as the supply chain. Keeping track of unused inventory and key inventory metrics, designing flexible factory layout, constant information sharing and record keeping are some of the recommendations. All in all it provides an insight to the pharmaceutical world of Bangladesh.

1. Introduction

If we go back ten years from now, no industry other than Pharmaceuticals have such profound impact on the country's economy in terms of economic return and overall well being of its citizens. Even in our wildest dream we could not think of countries like USA or Russia and Australia will be consuming medicines manufactured at home. It is indeed a tremendous achievement for the country. Not only that, the sector has achieved international competitiveness and upheld the country's image all over the world. The pharmaceuticals sector is the second largest sector after agriculture that contributes to the revenue generation of the Bangladesh Government. The sector has growth potentials both in local and export market. The research studies and evaluates the two most important aspects of any industry which are inventory and quality management capability in respect to Central pharmaceuticals ltd.

Like all other assets, inventory represents a costly investment to the firm. Many studies have been conducted so far regarding the establishment of effective distribution networks and production systems to cut down companies overall cost. But, in this current globalized

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business environment with more competition and highly diverse markets in which new product and product features are continually introduced, the cost of inventory has been rising due to rapid product obsolescence.

Therefore, effective inventory management strategies have greater impact and scope and so is an obvious candidate for cost reduction. Almost all activities in the organization are directly or indirectly affected by the management of inventory and quality. Similarly, Quality management has been a much talked issue and continues to be the pressing concern of all kind of industries However, no industry influences human life as greatly as the pharmacy since they directly deal with peoples' life and death. So quality plays even a greater role here.

The first section of the study gives illustrative description of the state of the pharmaceutical industries of Bangladesh including the strengths, weaknesses and underlying threats. Next it describes the inventory and quality management practices of the Central Pharmaceuticals limited followed by the recommendations to be considered by the company according to the Good Manufacturing practices Of WHO.

1.1 Pharmaceutical Industry of Bangladesh

The local pharmaceutical manufacturers cater to about 97% of the internal demand. Pharmaceutical industry mulls to export drug items to all 120 destinations from the existing 83 countries by the next few years to give a big boost to the country's export earnings.

Two organizations, one government (Directorate of Drug Administration) and one semi government (Pharmacy Council of Bangladesh), control pharmacy practice in Bangladesh. The Bangladesh Pharmaceutical Society is affiliated with international organizations International Pharmaceutical Federation and Commonwealth Pharmaceutical Association.

1.2 Objective of the Study

The main aim of the report was to give the readers the practical exposure regarding the quality control and inventory management practices of a local pharmaceutical company. The report will provide up to date knowledge about the different laws and regulations such as the CGMP guidelines of the World Health organization as well as the National Drug policy and Drug Control Ordinance – 1982 that a company should follow if it wishes to produce here and abroad. All in all it provides an insight to the pharmaceutical world of Bangladesh.

1.3 Rationale of the Study

Many studies have been conducted regarding the financial aspects of sectors such as readymade garments and services such as the telecom industry. There is a need to study the pharmaceutical industry which is currently one of the fastest growing sectors that generates a chunk of country's revenue and employment. It's with this pressing concern the topic *Quality control and inventory management practices at Central Pharmaceutical has been chosen.* The study is unique since it gives a comprehensive outlook of the inventory and quality management of a local company.

1.4 Scope of the Study

This is a descriptive research that studies the inventory management and quality control practices at a local Pharmaceutical company .Inventory management practices is a comprehensive topic and for the purpose of analysis only the most basic types of inventory i.e. raw materials work-in-process and finished goods are considered for the study. The report will provide up to date knowledge about the different laws and regulations such as the CGMP guidelines of the World Health Organization (WHO) as well as the National Drug policy and Drug Control Ordinance – 1982 that a company should follow if it wishes to produce here and abroad. All in all, it provides an insight to the pharmaceutical world of Bangladesh.

2. Literature Review

Quality control and Inventory Management - Managing quality means managing every aspects of a business and requires the establishment of an efficient quality management system. For a Pharmaceutical company, quality is actually the foremost concern and requires delicate handling. To be able to establish manufacturing facility at home and to market their products requires compliance of the guidelines entitled WHO Good practices for national pharmaceutical control laboratories Quality has been conceptualized by many quality experts in their research starting from W.E. Deming to Walter Shewart. Walter Shewart (1920) developed control charts and came up with the term Quality assurance. W. Edward Deming developed courses during World War II to teach statistical quality techniques to engineers and executives of companies that were military suppliers. Joseph Juran(1954) followed Deming and focused on strategic quality planning while Armand V. Feigenbaum (1951) introduced the concept of total quality control and continuous quality improvement and Philip Crosby (1979, 1984) emphasized that costs of poor quality far outweigh cost of preventing poor quality defined absolutes of quality management—conformance to requirements, prevention, and “zero defects”. Kaoru Ishikawa (1960) Promoted use of quality circles and developed “fishbone” diagram and emphasized the importance of internal customer. Most of the modern day researches on quality of pharmaceutical industries were conducted by the WHO body with the motive of implementing standard procedures for manufacturing medicine worldwide. In simple words, medicines and drugs produced at any corner of the world should include the same components and in the same amount. (Annex 3 of the WHO Technical Report Series, No. 902, 2002(*Quality assurance of pharmaceuticals. A compendium of guidelines and related materials, Vol. 2, 2nd updated edition. Good manufacturing practices and inspection*. Geneva, World Health Organization, 2007). According to the study conducted by Kevin Burgess, Prakash Singh and others (Supply chain management: a structured literature review and implications for future research,2006) the inventory management is needed as being a portion of supply chain network to guard the manufacturing program towards any types of disturbance. Moreover, it also prevents the system from working out of stock, components and products. From the original work by Harris (1913) on Economic Order Quantity (EOQ), Love (1979), Silver, Pyke and Petterson (1998), Muckstadt (2004), Sherbrooke (2004) and Hopp and Spearman (2008) are a few references which approach the vast theme of inventory control. Lonardoetal (2008) has presented a method for the determination of the desired levels of spare parts inventories, minimizing only the storage costs subject to constraints of minimum service level and assuming a normal distribution for demand. Many case studies on the applications of models and techniques for inventory control in real companies have been conducted during the last decade emphasizing the differences between the

theoretical and the practical understanding of inventory control systems. Examples of this type of study can be found in Cohenetal (1990), Botter and Fortuin (2000), Strijbosch, Heuts and Schoot (2000), Trimpetal (2004), Levén and Segerstedt (2004), Wanke (2005), Porras and Dekker (2008), Wagner and Lindemann (2008), Syntetos, Keyes and Babai (2009) and Silva (2009).

However there is a dearth of literature that looks on to these aspects in a holistic way especially in case of a pharmaceutical industry and also few studies have been conducted till now on the perspective of Bangladesh.

3. Methodology

Methodology applied to carry out the study include desk research and review of important and related statistics, interview with key entrepreneurs and senior officials of the concerned companies, government officials involved in the industry, policy makers and trade representatives and other stakeholders. Secondary data has been collected from different sources like government gazette notification, newspapers articles and journals, expert publications, annual reports of the sector association and leading companies, documents of Directorate of Drug Administration (DDA), Export Promotion Bureau (EPB), Bangladesh Bank, National Board of Revenue, Bureau of Statistics, relevant Import and Export Policies of the government, Chambers and Associates etc. Discussions and meetings held with relevant and concerned persons that include researchers, quality experts, sector specialists, individual entrepreneurs, CEOs, etc. Analysis have been conducted by comparing the quality control practices of CPL with that of the procedure of current good manufacturing guidelines of WHO. This is an evaluation of the company's quality position as how to it can maintain the standard conditions, procedures, system and implementation according to the harmonized system of WHO.

4. Findings and Analysis

4.1 Company Portfolio: Central Pharmaceuticals Ltd.

Good health is vital to all of us and finding sustainable solutions to the health care are the challenges of all the pharmaceutical companies. That's why Central Pharmaceuticals Ltd. is committed to be a participant in health care and to help change millions of lives for the better health through providing access to safe, effective and affordable medicines and related health care services to the people who need them. CPL has a moderate portfolio: currently 16 portfolios which consist of 58 medicines that prevent treat and cure diseases across a significant range of therapeutic areas. The principal activities of the Company throughout the year continued to be manufacturing and marketing of quality medicine. The Company was incorporated in 13 November, 1980 as a 'Private' Company limited by shares and registered with the Registrar of Joint Stock Companies & Firms of Bangladesh under the Companies Act, 1913 vide Registration No.C-8514(353). On 20 December, 2010 the Company registered itself as a Public Limited Company under the Companies Act 1994.The registered and corporate office of the Company is located at Ibrahim Chamber (6^{th} Floor), 95 Motijheel C/A, Dhaka-1000 and its factory is situated in its own premises at 2A/1, South-West Darus Salam Road, Mirpur-1, Dhaka-1216. Central Pharmaceuticals Ltd. (CPL) is producing and marketing finished formulation products for general Peoples, Hospitals, Clinic, Govt. Organizations, NGO's, Corporations & other Non-govt. Organizations.

4.2 Practices at Central Pharmaceuticals Limited

An inventory system provides the organizational structure and the operating policies for maintaining and controlling goods to be stocked. The system is responsible for ordering and receipt of goods; timing the order placement and keeping track of what has been ordered, how much, and from whom.

Inventory management system has two main concerns. One relates to the level of customer service, and at the right goods, in the sufficient quantities, in the right place, and at the right time. The other relates to the cost of ordering and carrying inventories. As an export oriented manufacturing company, CPL places a great importance in valuation and management of inventories.

Inventory is the stock of any item or resources used in an organization. An inventory system is the set of policies and control that monitors and controls the level of inventory and determines what levels should be maintained, when stock should be replenished, and how large the orders should be.

4.2.1 Inventory Management Why it is Important:

Like all other assets, inventory represents a costly investment to the firm. In order for this investment to be worthwhile there must be some advantages in making it. These reasons vary with the types of inventory carried.

Types of inventory: There are various types of inventory. Some of them are given below, Such as:

Raw materials: The raw materials inventory contain items that are purchased by the firm from others and are converted into finished goods through the manufacturing (production) process. Having an available stock of raw materials make production schedule easier, avoid price changes and hedge against supply shortages.

Work-in-process: The work- in-process inventory consists of items, currently being used in the production process. They are normally partially or semi-finished goods that are used at various stages of production of multi-stage production process.

Finished goods: Finished goods represent final or completed products, which are available for sale. The inventory of such goods consists of items that have been produced but are yet to be sold. These are kept to stabilize the production process and to provide immediate service for the end consumers.

Packing materials: The packing materials contains of materials related to goods, which are used for the purpose of packing materials. Mainly packing materials are used for the purpose of covering the final products and to give an attractive look.

Laboratory and promotional materials: Laboratory and promotional material refers to the goods or materials used for the purpose of laboratory and promotional activities.

Physician Sample: These are materials generally made for the physicians as new products always need to be physician approved and tested for defects or side effects.

Purposes of inventory keeping: The Central Pharmaceutical Limited keeps a supply of inventory for the following reasons:

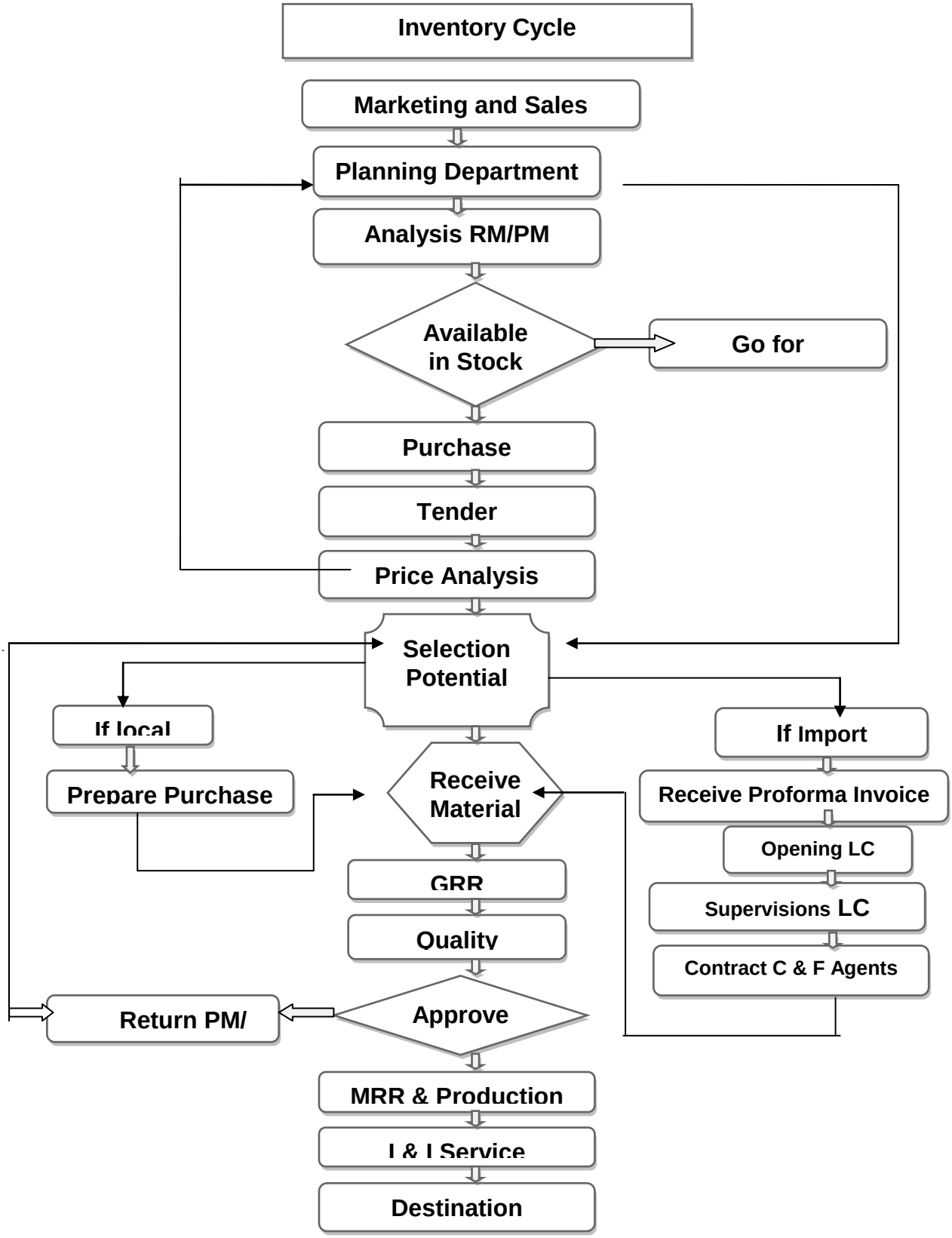
- To maintain independence of operations.
- To meet variations in product demand.
- To allow flexibility in production scheduling.
- To provide a safeguard for variation in raw material delivery time.
- To take advantage of economic purchase-order size.

Key functions: The key functions of the Central Pharmaceutical Limited's inventory management systems are:

- To ensure material is available.
- Receipts, custody, and issues of materials.
- To record the record of all stock movements.
- Coordinate with management, maintenance, production, marketing, and finance departments and other departments in the company for meeting their requirement for materials and spares.
- Assist in devising management reports.

4.2.2 CPL Inventory Cycle

Figure 1:The Inventory Cycle of CPL



Source: CPL Website: www.centralphl.com

These are the stages of the cycle:

Look for Sources of raw & packing materials - The sources are classified into two categories: Local purchase and Import purchase. If there is a need for packaging material for production then purchase department can purchase the material locally. For local purchase, the concerned department seeks for appropriate materials and si is contingent on the quality and rate of the material, lead time, and previous record of the supplier.

The procedures of the local purchase are given below:

Step 1: Processing purchase order: The procedure begins with need recognition. The respective department identifies its need, gets approval of the department Head and with the approval, an authorized person sends purchase requisition to purchase department to initiate the purchase. In case of property, plant and equipment acquisition, before sending purchase requisition, a budget has to be prepared by the user department. If the departmental head or higher authorities, whichever is required, approve the proposed budget, a purchase requisition is sent to purchase department, and in case of raw or packing material, the planning department determines the quantity and timing of raw materials. This department informs the purchase department when to buy materials.
When purchase department gets the requisition, it calls for quotation or tender. After receiving the quotation or tender, supplier has been selected. The supplier may be local or international. If the terms and conditions are in favor of both the parties, an order for the purchase is than issued by the purchase department. In case of raw or packing material, the purchase order is issued by the factory. A purchase register is maintained by the purchase department in which it maintains all the information relating to a consignment.

Step 2: Receiving material, goods and services: Generally the goods and services are received by the user department who has issued the purchase requisition or in some cases by the authorized department. Materials are received by Quality Assurance Department (QAD) in the factory.

Step 3: Factory sends MRR (Material Receiving Report): After receiving materials, goods and services an MRR is issued for materials and other than materials a GRR is issued by receiving department to purchase department. In the mean time the invoice or bill is received by the purchase department. Before using the products by user department that is at the time of delivery, it has been inspected by the inspection or QAD, by user department or by authorized department. QAD examines the materials on a sample testing basis and provides a certificate. Generally:

- QAD inspects standardized items like raw material, packing materials etc.
- User department inspects non standardized items like services, stationeries, etc.
- Inspection department inspects machineries, plants etc.

Step 4: Voucher Entry: After checking purchase order and MRR, respective person enters this information in to journal vouchers, where suppliers name, description of product, approved amount are recorded. Every journal voucher stapled with photocopy of bill and original bill are send for payment. The necessary documents that are mandatory for payments include: Original bill, Photocopy of bill and Vat challan.

4.3 CPL Inventory Management and Quality Provisions

Inventory management is a sub area of the total supply chain management as it has been mentioned in the literature review for this reason CPL concentrates on the followings chain:

4.3.1 Forecasting/ Planning

The starting point for the management of inventory is forecasting customer demand. Based on the statistics of the accumulated sales in the past 2 years CPL decides on the types and the amount of products that will be manufactured in the following year. The amount of ingredients or raw materials required to be imported is then estimated and a Block list (A formal document to the Ministry of Health) is sent and permission for import is sought. The process is a lengthy one and takes 6 months. Shipment takes another 3-6 months. Therefore it takes a minimum 9 months to start the production process.

4.3.2 Purchasing / Procurement: Import Practices

Packing materials used in the local pharmaceutical industries include aluminum foil (blister & strip), Alu alu foil, rubber stripper, flip-off seal, printing materials, plastic cap, injectible, tear-off seal, tube, PVC, PVDC, level, bottle (white & color), plastic container, paper carton, printing materials, packets, etc. Almost every packing material is locally available except aluminum foil, alualu foil, PVC, PVDC, color bottles, etc which are imported from countries like Korea, Dubai, India, China and so on. It is expected that a number of packaging industries will appear in near future as backward and forward linkages to support pharmaceutical sector. Following documents should be submitted to obtain permission for import of pharmaceutical Products in Bangladesh:

- Copy of approved "Block list" of Directorate of Drug Administration (DDA)
- Copy of Import License from Chief Controller of Export and Import.
- Import Relevant other papers for Block list
- Approval for new products (in case of Formulations)
- Certificate of country of origin
- Copy of indent quoting source and price of goods (six copies)
- Filled-in & stamped letter of credit application (full-set of documents Bank prescribed)
- IMP form of Bangladesh Bank
- Insurance coverage acceptable to the bank
- Free Sales Certificate or No Objection Certificate from the two countries including the country of origin (in case of Formulation)

Before import, a sample needs to be sent to the laboratory for testing quality. Once the sample is found acceptable, then it will be sent to the DDA office for inclusion in the Block list. After getting delivery of the products at the factory of the manufacturer another testing will be done. Following documents, attested and certified by the Directorate of Drug Administration, should be produced to the Customs Authority for clearing the imported goods from the port:

- Certificate of analysis
- Copy of Invoice
- Copy of certificate of origin
- Copy of bill of lading/ airway bill Form-9 (an undertaking according to the World Wide Drug Rules)

4.3.3 Logistics

Pharmaceuticals are predominately a tech based operation process and in many stages human touch is absent to have flawless process. Pre-formulation studies are conducted to check bio-chemical action of ingredients.

Trials and stability study are carried out to assess efficiency and reproducibility of formulation (process validation).

4.3.4 Operations and Factory Layout

Currently CPL plant consists of a general purpose manufacturing building, a dedicated cephalosporin manufacturing building, and a specialized manufacturing building for the production of lyophilized products, insulin and amino acids in addition to several floors dedicated to the production of solid dosage forms- tablets and capsules. A newly built liquid and semisolid manufacturing building is also in operation at this site. The site also houses a warehouse for raw, packaging and finished goods. To meet the increasing domestic demand, another warehouse is currently under construction with three times the capacity of the existing one. Manufacturing and packaging operations are carried out according to the validated methods through systematically qualified machines with full documentation at all stages of operations. The production sites follow the GMP guidelines for environmental requirements of the manufacturing and packaging area, as well as comply with the EHS requirements.

Highly sophisticated HVAC systems are used to condition, monitor and supply clean air to the working zone according to the manufacturing zone concept, capture and control any dust, vapour, gas or fume generated, as well as treat re-circulated and/or exhausted air. Temperature and moisture level are maintained at the desired level through this system. Design of the room and air-conditioning systems ensure the prevention of contamination and the protection of the work environment.

There are different environmental zones maintained within the manufacturing area.
Purified water and water for injection plant and distribution systems are designed to maintain the water quality according to the relevant requirements and state-of-the-art engineering design which include e.g. 24 hours run circulation loops, smooth interior surfaces, adequate materials, and minimum flow rates. At the plant the following activities are carried out

- Pharmaceutical Manufacturing – processing and packaging of pharmaceuticals to supply to the local market. Approved suppliers supply the active substances used in manufacturing. Most of the auxiliaries used for production are bought from approved third parties.
- Logistics, Warehousing – Storing of raw and packaging materials to meet the requirements of production and also storing and dispatch of finished products as per concept of Good Storage Practice of pharmaceuticals.
- Engineering/Industrial Engineering – In line with pharmaceutical production, health safety and environmental protection, infrastructure maintenance, machinery and other maintenance. Effluent treatment and safe disposal of pharmaceutical waste.
- Quality Assurance/Quality Control – Quality Control of pharmaceuticals, raw and packaging materials, reagents and chemicals, plant and personnel hygiene, method and process validation, and overall quality assurance of pharmaceuticals.

- Research & Development – Formulation development and adaptation for scale up production with process validation, method validation in collaboration with QA/QC. Stability study and shelf life determination of pharmaceutical products. Reformulation/improvement of existing formulations in line with new/advanced technology.
- Plant HR/Administration – Support different units of the plant for HR related issues, general services, general logistics and administrative issues.
- CPL vows to minimize waste and hence enhance quality by keeping a narrow margin of a 2.5% waste in each stages of production. Training programs take place on a regular basis according to written plan. Personnel at all levels undergo general cGMP and Technical Training to perform their job satisfactorily.

4.3.5 Inventory Control System:

An inventory system controls the level of inventory by determining how much to order and when to order. There are two basic types of inventory systems: i) Continuous system where an order for the same constant amount is placed whenever the inventory on hand decreases to a certain level, whereas ii) in Periodic system, an order is placed for a variable amount after specific interval.CPL does not follow either of the systems exclusively. However ,The API and excipients of the those product that had a stable demand on the last two years are actually managed through Continuous system whereas newly enacted products' raw materials and additives are actually purchased on demand and are managed through a rough system of Periodic inventory control.

4.3.6 Warehousing

The warehouse of CPL is an enclosed building and protects the stored goods from environmental influences. They are secured against fire by the design of the buildings and technical facilities. The fire brigade facility has access to enable appropriate fire fighting. The warehouse is equipped with four different storage conditions; a) $2^{o}C – 8^{o}C$, b) $8^{o}C – 15^{o}C$, c) $15^{o}C$ $-25^{o}C$, and d) ambient condition. There are controlled rooms with HVAC for specific materials and the conditions are monitored to confirm compliance with the requirements. Also there is retention sample room. The materials are stored in the warehouse by pallet racking. The status of materials and products is controlled by colored status sticker.CPL follows a ware housing process that they call Yellow Green and Red system, where yellow represents the newly arrived raw materials that requires to be checked through the multiple check points of the quality department. Green represents the materials that has been already checked and ready to be shelved. The shelved life varies from components to components so accordingly are refrigerated or kept at different temperatures. Red represents those materials that are going to be used immediately for the production stage .The Yellow; Green and Red materials are kept separately and require a specific factory lay out to facilitate the work flow.

4.3.7 Distribution and Transportation

CPL has a team of efficient closely knitted distributing channel that makes its product available to the selected market outlets and hence to the final consumers. Back-up services are there at retailers' level. Expired unsold products are refunded at a certain percentage. Loss damages are also compensated depending on the quantity of medicine.

4.4 Quality Control Practices

Table 1: Findings compared with the WHO Good practices for national pharmaceutical control laboratories

Criteria	Present	Absent	Needs Improvement	Remarks
Drug registration, Standard Operating Procedure (SOP) based on WHO recommended GMP guidelines for manufacture of each product as well as for each manufacturing unit process.	√			Regd.No.B-01511
Management and infrastructure :Personnel- Registered Pharmacist and quality experts, Machinery ,testing equipments, warehouse, flexible workflow process	√		√	
regular in-service training programmes	√			Need customization
Quality control laboratories, Quality (safe)packaging, design	√		√	At present there is only one of such facility needs at least two more according to their production output
Segregation of herbal and chemical drugs	√			Separate production facility exist for Herbal and chemical drugs
Quality workshop		√		
Rational Use of Drugs (RUD)		√		Rational Use of Drugs (RUD) should be ensured by conducting surveys on the systems of prescribing, dispensing and patient compliance.
Monitoring and reporting of adverse reactions of drug (ADR)	√			Based on market report
International certification ISO - 9001, ISO - 9002, WHO & UNICEF		√		In the process

According to the Drug Rules 1946, every manufacturer of pharmaceutical products must have a standard laboratory with all required quality control facilities. Like others, the local pharmaceutical companies follow Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) besides Good Manufacturing Practice (GMP). Presently, CPL has attained a certain standard level of quality that allows them to produce 71 products. They have well designed QC department with adequate equipment and staff that includes Quality Administration Manager, Quality Control Managers, Assistant Managers (Project Development & Quality Control), etc. However there is a need to hire experts and consulting services on quality control management improvement that are representative of the western organizations.

The company is yet to receive any quality certification from outside though is in the process of doing so. There is an absence of a formal RUD system or the rational use of drugs that is should be ensured by conducting surveys on the systems of prescribing, dispensing and patient compliance. CPL conducts regular study to monitor the acceptance of its products to the consumers.

5. Conclusion

5.1 Quality Management

Compare to the number of years in the business CPL fares well on most criteria but the following strategies will enhance the quality of the company; such as:

- Undertake Quality control polices- the laboratory management's commitment to good professional practice and quality of testing, calibration, validation and verification, the operational and functional activities pertaining to quality, so that the extent and the limits of the responsibilities are clearly defined, maintenance and verification of instruments and equipment; and finally the testing of samples with descriptions of the methods and equipment used.
- The activities of the laboratory should be systematically and periodically audited (internally and, where appropriate, by external audits or inspections) to verify compliance with the requirements of the quality management system and to apply corrective and preventive actions, if necessary. The audits should be carried out by trained and qualified personnel, who are independent of the activity to be audited. The quality manager is responsible for planning and organizing internal audits addressing all elements of the quality management system. Such audits should be recorded, together with details of any corrective and preventive action taken.
- The management review of quality issues should be regularly undertaken (at least annually), including reports on internal and external audits or inspections and any follow-up required to correct any deficiencies the outcome of investigations carried out as a result of complaints received, doubtful or aberrant results reported in collaborative trials and/or proficiency tests; and corrective actions applied and preventive actions introduced as a result of these investigations.

5.2 Inventory Management

The most successful retail, warehouse, and supply chain management are those that are fully aware of the state of their stocked inventory at any time and have a regulated system that allows them to easily index and monitor the coming and going of product within that inventory.CPL seemed to have managed it well. Still a novice in the industry its inventory

control is sufficient to cater its demand. However the following steps will smoothen the process:

Maximize Profit**:** The ultimate aim of any business is to maximize the company's profit. Many times, the items in the inventory may sit for long periods of time due to lack of demand. This is not only a wasted expense; it also takes up precious room in the warehouse or supply room that could be filled with a faster selling item which would draw more profit. The inventory management strategy should include some form of tracking system to identify quick selling products, as well as those with the highest profit margin. Such systems will report what items are required to be maintained at high levels within the inventory to meet demand and maximize profit.

Software Systems: The inventory management strategy would be deficient without a software system that will help keeping track of every item that comes in and out of the warehouse. This means that, when inventory checks are fulfilled one can identify errors, thefts, losses, and any other discrepancies much more readily. It will also assist the company in ordering process, since the electronic tracking will give information on exact quantities of inventory without having to run out and count everything by hand. When the responsible employee sees that the stock of a particular item is low, a reorder can be made. However this decision involves cost and should be taken only after deciding for the cost benefit analysis.

Labelling and Identification**:** One final execution of an effective inventory management strategy is to make sure that all items are properly labelled. Incorrect or incomplete labelling can lead to several problems, including wrong identification, misplacement when restocking the inventory, loss of the item, or inability to find it for shipment or shelving later.

Revamp the organizational structure: To implement more-streamlined inventory practices, many companies have adopted a new organizational structure which is as follows: The merchandising department handles product selection, sourcing, and development and works with the creative department on promotions. The inventory control group is primarily responsible for overseeing the prior season's category and item history, working with the merchants on assortment planning, managing the inventory, forecasting, reordering, receipt planning, post-mortem evaluation of item performance, and vendor communication and compliance. Merchandising may still place initial purchase orders, but in most cases inventory control will pick up relationships with vendors and do the necessary reordering and stock balancing**.**

Tracking key inventory metrics: An industrial engineering axiom states that what isn't measured cannot be improved. From an inventory perspective, the metrics include:
Initial customer order fill rate: How much of the product had been ordered in each time period?

Gross margin return on investment (GMROI) Gross Margin Return on Inventory (GMROI) is a "turn and earn" metric that measures inventory performance based on both margin and inventory turnover. In essence, GMROI answers the question, "For every dollar carried in inventory, how much is earned in gross profit?" GMROI can be calculated at the organization level and, if the proper data is collected at the item level, all the way down to an individual item.

GMROI Formulas

$$GMROI = \frac{\$gross\ profit}{\$sales} \times \frac{\$sales}{\$average\ inventory\ at\ cost}$$

Age of inventory: The shelf life for all the API, packaging materials and excipients should be determined to know the duration in which they can be stored to its best condition.

Measures of overstock: Overstock inventory usually are sold at a discount rate in secondary market.

Inventory reorder point- The level of inventory at which a new order is placed.

*Safety stock r*equired during peak period.

Order cycle time- The time required for receipt of orders.

Carrying cost-The cost of holding an item in the inventory. This information comes in handy when decision needs to be taken in rash and leads to more effective storage and warehousing strategy.

There are several ways in which the company can simplify its system of product inventory management, and choosing the methods and procedures that suit its ability to adhere to the guidelines that are set forth. First of all, the most popular products should be most easily accessible, since these will be accessed most frequently. Next, the company should map out the space it has and look at the size of items in its stock, as well as the quantities kept. The company should look through sales records to find items hasn't sold in months, depending on what the product is, how large a quantity you required in stock, and the number of other items for which need more storage space is required, the best course of action is to simply write it off.

A complete and comprehensive discussion of the issues in inventory management is beyond the scope of this study. The coverage of the study is limited to only the most basic types of inventory. Also in theory, there are two basic types of inventory control system both of which require the correct forecasting of demand which in reality is very difficult due to the lack of information and market survey.

Finally the pharmaceuticals inventory management and quality control process is a cycle of complex actions that require highest security standards and constant information sharing. Keeping full control over the system and having insight into even the smallest components determines the ultimate quality and efficiency of the total management. The drug's road from its manufacturer to the patient is easy only in theory. It requires continuous observation and monitoring even the smallest movement of goods, accelerating their circulation and increasing the precision of activities. Legislation requires drug distributors to use state-of-the-art packaging and transportation technologies to eliminate human errors from the logistics processes. Unfortunately, the human factor is in fact the weakest link in the entire process. Therefore constant training of the concerned employees on all the procedures and keeping them updated is obligatory to survive in the market. After all as they all say that they directly deal with peoples' lives.

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