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Review Article

Delivery of Quality Pharmaceutical Products - The Ultimate Need of Corporate & Consumers

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ABSTRACT

Health care quality is strictly perceived as the fitment for intended use by patients. In fact the responsibility of drug manufacturer to ensure quality starts from product discovery and ends when the bioavailability of medicines are confirmed by patient. Pharmaceutical business operation is the only segment where quality of products plays an ultimate role in its success. The basic reason behind this quality centered approach due to any quality failure of products shall cause irreparable loss to company in terms of revenue and goodwill.

The exploratory study has been conducted to comprehend the quality need of various stakeholders of pharmaceutical business. The review indicates the severity of implication of manufacturing and distribution of pharmaceutical products categorized as Not of Quality Standards (NSQ).

The impact of decay in quality standards shall have direct or indirect blow on business in one hand whereas in other hand the patients won't be able to get the quality medicines on time. Quality of life saving drugs is the need of all pharmaceutical stakeholders including corporate and consumers.

Key words: Health care, Pharmaceutical, QMS, GMP, GCP, GDP.

INTRODUCTION

The pharmaceutical products have specific quality criteria duly endorsed by drug regulatory agencies through pharmacopoeia monograph otherwise through special approval of specification. The drug manufacturer owes the responsibility of appropriate drug design sustainable throughout product life cycle and their delivery to patient on time [6] Pharmaceutical business operation is deemed to be highly regulated segment because of its mass consumers and potential of hazards of quality failure. The regulatory agencies inspect the quality system of manufacturer as well as draw samples from retailers in market.

Quality System constitutes a fundamental component of pharmaceutical operation. The main quality attributes of pharmaceutical product includes following parameters:

a. Assay of active ingredient
b. Bioavailability of product
c. Dissolution pattern
d. Disintegration time
e. Impurity and degradation
f. Microbial contaminants

The study shows that United States of Food and Drug Administration (FDA) take a leading role in protecting consumers' interest through regularly updated webpage. [10] The FDA webpage holds the most updated Drug Safety Communications from FDA as well as other useful links for different messages, letters, information for

healthcare professional sheets, and public advisories issued priory etc.

The pharmaceutical industry as a rule operates at a high level of quality assurance system by complying with current Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP). Manufacturers achieve their pharmaceutical quality objectives during the production of their products and testing to assure quality prior to their release for distribution, however such release system is not prevalent during distribution stages. [4]

During the course of development and release of a commercial pharmaceutical product, an essential critical part of Chemistry, Manufacturing and Controls (CMC) is to establish the safety, identity, strength, quality and purity of product. [11]

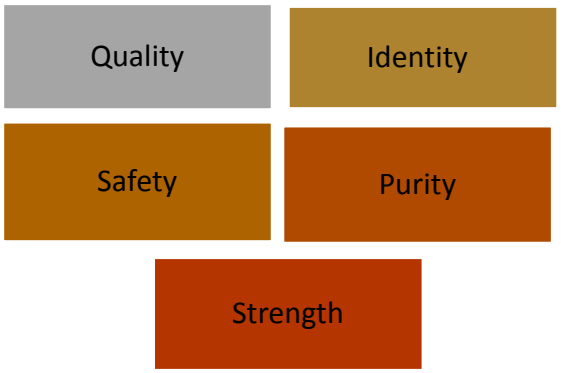

Figure-1, Essential Requirement of Pharmaceutical Products

Quality failures may be occur during any stage of product life cycle, but prominently noticed during following operations:

a. Manufacturing
b. Warehousing, storage and handling
c. Transportation
d. Distribution
e. Retailer's handling
f. Dispensing
g. Prescription and medication

The manifestations of above failures erupt in the form of customer complaints, product recalls and regulatory actions. [8]

MATERIALS AND METHODS

This review paper is based on exploratory study on pharmaceutical guidance papers issued by regulatory agencies and industrial practices, wherein the data are collected from literatures and drug regulatory guidance, issued by WHO, MHRA, USFDA etc. The materials from internet search engines have been reviewed and the pertinent information has been derived according to exclusion principle. The irrelevant information has been omitted as per consent of both authors.

DISCUSSION

The pharmaceutical manufacturers are concerned about conformance of quality parameters of their products. Each batch of medicinal product is tested by quality control unit of manufacturer. The non compliance to the specification leads to the rejection of product batch. In case any of the out of specification of batch is not caught by the manufacture's quality unit, there are fare chances that regulatory agency shall catch the non conforming batches and shall initiate action against the firm. There are numerous examples of product recalls due to pharmaceutical products of not quality standards (NSQ). The symptoms of unhealthy quality system of pharmaceutical manufacturers are listed as under:

a. Adverse Drug Reporting
b. Frequent market complaint
c. Voluntary and forced recall
d. Market returned good
e. Regulatory action

Drug regulatory agency from United Kingdom namely MHRA has taken a lead in protecting health of healthcare consumers. [9] Consumers can report a suspected problem ('adverse incident') with a pharmaceutical products if,

a. a medicine originates side effects
b. someone's injured or almost injured either because its ambiguous labeling or instructions
c. a medicine lacks effect
d. a medicine is of low quality
e. a medicine is fake or counterfeit

If there is on the path of decline in quality standards during a pharmaceutical operation, there is loss of company's

business that impacts all stakeholders. Various stakeholders of pharmaceutical business are listed as under:

a. Society
b. Investors
c. Government
d. Distributors
e. Medical practitioners
f. Patients

When a company shuts down its pharmaceutical business due to some quality issue, there is impact on all stakeholders like investors and customers. Hence utmost attention is given to maintain the quality of pharmaceutical products to avoid dire consequences of non compliance of regulatory terms. The quality is essential part of pharmaceutical business and is regularly reviewed through internal and external inspection system.

In general complaints against deficient products are reported as - substandard quality or not of standard quality and reported by at least one of following:

a. Patients
b. Doctors
c. Regulators
d. Handlers

The basic reason behind this quality centered approach of pharmaceutical business is fatal impact of potential quality failure shall cause irreparable loss to company.

i. Pharmaceutical business operation- A Global Scenario

The global business of medicines engrosses a varied set of international transactions, legitimate markets and salient economies, and public or private sector stakeholders. Companies operating in developed nations have in past conquered pharmaceutical production and export of medicines. However, now there is a reduction in turnover of export from the developed world to the developing world. Multinational companies appear to be establishing manufacturing facility in developing economies to serve regional market demand. There is substantial growth in active pharmaceutical ingredients production within developing countries including India, South Korea and China. These countries have successfully built significantly strong pharmaceutical supply chains extending from fine chemicals to finished pharmaceutical product. [12] Asian countries such as India are expanding pharmaceutical production for both domestic use and export to developed western nations.

ii. Manufacturing vs. Distribution business operation- A Quality Outlook

The pharmaceutical trade is on the pathway of unprecedented growth and expansion. This faces multiple challenges during business operations. Since there is a structured framework to handle quality system during pharmaceutical manufacturing, the quality is somewhat taken care within plant premises. Distribution operation doesn't operate strictly as per standard operating procedure and the flexibility to follow often creates quality issue.

iii. Quality System during manufacturing operation - A Business Perspective

The market share for pharmaceutical generics, which are exported by Indian pharmaceutical manufacturer to the several countries, shows increasing trend – with India home to some of the largest generics companies.

There are instances when quality systems were not adequately followed by drug manufacturer and quality issues were noticed by regulatory agencies. This resulted initiation of stringent against the respective firms. Ranbaxy, one of the leading pharmaceutical company of India had suffered due to weak quality system. This firm spearheaded India's pharmaceutical industry and had captured significantly larger business of United States of America. In view of non compliance to quality system, Ranbaxy was slapped with warning letter by United States Food and Drug Administration (USFDA). Warning letter followed by application of import ban was a setback to the Ranbaxy

and the company could not cross this stumbling block.

iv. Delivery error at retailer shop – Consequence of wrong interpretation of prescription

Medicine transcription error is a specific type of medication error and is due to data entry error that is commonly made by the human operators at retailers shop. Although such errors are rare, improvements in pharmacy distribution systems are still important because retailers deliver high volumes of medicines. [2] Even a low error in reading prescription can render into a large number of errors.

CONCLISION

The quality system is diligently followed during pharmaceutical manufacturing, through well structured and documented 'Standard Operating Practices (SOP)'. The manufacturing control system is inspected periodically by quality assurance professionals. Similar use of 'Standard Operating Practices (SOP)' is recommended for a medicinal supply operation that can ensure the quality of products, which an industry intends to maintain throughout the numerous steps in the distribution process. The retailing shops play a pivotal role in delivery of quality products. Training and awareness about quality amongst personnel deployed in various subunit operations are important tools to overcome quality issue.

Any failure in linkages between manufacturing, distribution and dispensing of medicines shall be detrimental for manufactures goodwill. Substandard quality of products is liable to spoil the business of a pharmaceutical organization, whereas patients shall be deprived of good quality of medicines, which is essential requirement of mankind. Therefore, Quality is the need of corporate, manufacturer and customers, as an essential element of pharmaceutical business.

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