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Original Article

Quality risk management during pharmaceutical 'good distribution practices' – A plausible solution

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ABSTRACT

Quality of medicinal product is an important facet throughout lifecycle owing to its importance as acceptance criteria at customer's end. Drugs regulatory agencies have issued guidelines for quality risk evaluation, mitigation and review management. Quality risk management has become an integral part of quality management system at manufacturing plants. Procedures for deviation control, change control, investigations of market complaints and batch failures are dealt with the principle of quality risk management at the manufacturing facility. The exploratory study shows a dearth of research on quality risk management during supply chain operation, however, a few study has been carried out by keeping financial risk into account. This study addresses the gap in literature on quality risk management during supply chain operations. There are cases of unresolved customer complaints and batch failures originated due to inadequacies during distribution of pharmaceutical products. In absence of established quality risk management system during product shipment, there is no effective preventive plan related to risk factors. A corollary of manufacturing quality risk management has been drawn to the distribution of pharmaceutical products through this study. The quality risk management during pharmaceutical distribution may be useful to avoid market complaints, drug recalls, and regulatory actions. This study produces one unique model solution for industry professionals and policymakers opening a scope to reduce the product rejection thereby paving the way for substantial business growth.

1. Introduction

The distribution operation of pharmaceutical products has a fundamental obligation to maintain quality till shelf life and deliver a safe product to patients. An understanding of quality risk associated with the product shall enable supply chain managers to handle the pharmaceutical distribution more effectively. Pharmaceutical companies, during supply chain, face much quality risk. The risk disrupts the distribution of medicine in many ways such as their quantity and quality product delivery at the right time. Therefore, quality risk management during the distribution process of pharmaceutical products is highly recommended. Risk management principles are utilized in many areas of business including finance, manufacturing, insurance, occupational safety, public health, pharmacovigilance, and by agencies regulating these industries. Although there are some examples of the use of quality risk management in the pharmaceutical industry today, they do not represent the holistic approach that risk management has to offer across the supply chain network. It has been observed that the majority of risks during operations of the pharmaceutical supply chain are internal risks due to processes, people, and functions mismanagement which could be managed by suitable mitigation strategies [1].

The Quality risk management (QRM) is a systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product. Further, QRM concept depends upon the understanding of terms 'Quality' and 'Risk'. The term Quality means "The degree to which a set of inherent properties of a product, system or process fulfills requirements" (ICHQ9) and as per ISO/IEC Guide 51, the term Risk means "The combination of the probability of occurrence of harm and the severity of that harm" [2]. The quality risk management process involves:

a. Hazards (sources of harm) that can adversely influence drug quality characteristics
b. Extent of harm
c. Sub processes critical for quality

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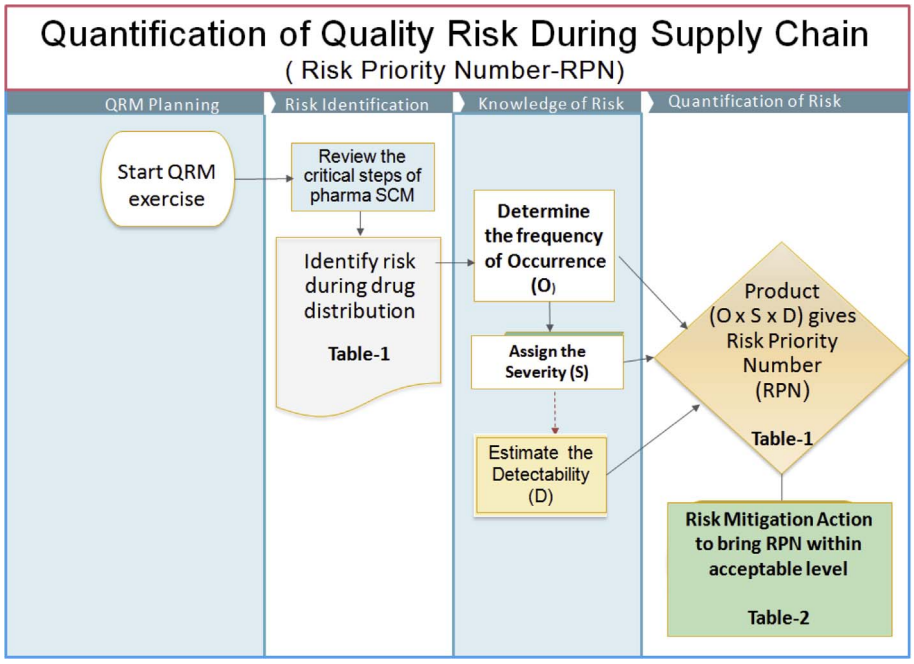

Fig. 1. Scheme for quality risk management.

Use', also known as ICH is an international agency which has issued guidance for the healthcare industry. ICH has described 'Quality Risk Management' in section Q9. The guidance ICH Q9 explains a process and methodology for QRM to add value. US Food & Drug Administration (FDA) has issued an identical guidance paper that serves as a foundation or resource document that supports other ICH Quality documents and complements existing quality guidelines within the pharmaceutical industry and regulatory environment [3,14]. According to corollary drawn from quality management principle there are two primary principles of quality risk management: (i) The evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient; and (ii) The action and documentation of the quality risk management process should commensurate with the level of risk.

A scheme for quality risk management is outlined in the diagram (Fig. 1). The emphasis on each component of the QRM framework might differ from case to case but a robust process will incorporate consideration of all the elements of quality risk.

1.1. Literature review

The quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the drug product across the product lifecycle [2]. This is a proclaimed understanding amongst drugs manufacturers that Pharmaceutical supply chain should deliver medicines in the correct quantity, with the specified quality but the currently available literature have hardly discussed the quality aspects during pharmaceutical distribution management [1].

During the course of study of Mexican pharmaceutical industry Lutz Kaufmann (2005) has stated that An expansion of direct sales to pharmacy chains is certainly an appropriate measure to make the supply chain shorter and more transparent, however, the quality crisis arising due to improper cargo has been grossly overlooked in this study [18]. The quality of pharmaceutical product shall further deteriorate if the risk of temperature excursion is not handled appropriately [7]. As a key role of wholesalers in pharmaceutical products circulation, wholesalers are experiencing the dramatic change in market Macao. Wong (2012) aimed to improve the service of wholesalers and researched the functions of pharmaceutical wholesalers [19]. This indicates that Quality of pharmaceutical products is at higher risk if mitigation is not effectively ascertained [8]. The acceptable risk level can be decided by the manufacturer and its business unit, formulation and research development wings based on the standalone case and risk factor [10].

America based think-tank organization Product Quality Research Institute (PQRI) involves FDA's Center for Drug Evaluation and Research (CDER), industry, and academia in various case studies [21]. One working group was formed under the aegis of PQRI who studied the industry case studies for the purpose of improving and application of ICH: Q9 during 2008 and year 2011 [22,23]. This group comprised of eight experts from leading pharmaceutical manufacturers and US drug regulator. risk management working group of PQRI provided a summary of common risk management principles and best practices, several working tools to nurture consistency about the use of ICH Q9 in risk management process and a series of examples of risk management applications in use by major pharmaceutical multinational companies.

The working paper on drug quality and safety issues in India by Maulik Chokshi [5] observed that there are approximately 20% of pharmaceutical products have serious issues originated during supply chain operation such as:

a. Spurious drugs
b. Falsely labelled drugs
c. Counterfeit drugs

However, the above risk is due to administrative reasons rather than quality system aspects and hence have been considered out of the purview of this study. The issues raised here are perceived from the criminal angle and the quality perspective have been grossly excluded from this study.

1.2. Research gap

Quality risk management (QRM) is practiced by quality professionals of the pharmaceutical manufacturing plant, whereas the concept is not diligently practiced during pharmaceutical distribution operation [4]. Based on inference from review data and survey data, it is observed that there is need of enhanced awareness about the quality of the pharmaceutical product during pharmaceutical goods distribution