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REVIEW

Temperature excursion management: A novel approach of quality system in pharmaceutical industry

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Abstract Quality of pharmaceutical product largely depends upon the environment controls during its storage and handling. Each pharmaceutical product should be handled and stored under specified storage condition labelled on product information data sheet or product pack. Hence the temperature excursions during receipt of raw materials, manufacturing of pharmaceutical products and distribution should be managed during entire product life cycle with holistic approach. The research is based on primary data and exploratory study through literature review. The temperature excursion may be observed during transportation of raw materials manufacturing as well as distribution of pharmaceutical products, which have potential to deteriorate the product quality. Temperature excursion in pharmaceutical industry should be recorded and reported to the manufacturer for further investigation and risk analysis. The concept of temperature excursions, its reasons, consequences and handling mechanism should be well understood to ensure the concerted efforts under the aegis of Quality Management System. Based on the reasons and consequences of temperature excursions during pharmaceutical operations, a system based quality management has been envisaged through this study. The concept and procedure to handle temperature excursion have evolved after this study which shall be useful to pharmaceutical industry as well as to medicine distributors and consumers.

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Contents

1. Introduction

The pharmaceutical product quality largely depends upon the storage environmental conditions. Natural reasons or human negligence could create uncalled-for situation causing temperature excursions. The most important environmental parameter having significant potential to impact quality of pharmaceutical product is temperature. If the temperature excursions are not handled systematically, there shall be an adverse impact on product quality.

There is a growing need to manage the environment excursions during pharmaceutical operations and its impacts on quality of products. In an era of Quality by Design (QbD) for pharmaceutical products, the attention is paid towards inbuilt quality instead of inspected quantity (Roy et al., 2012). As manufacturers have extensive knowledge about critical product and process parameters and quality attributes, the impact assessment has to be extended to temperature excursions. The temperature and relative humidity (RH) beyond limit shall lead to product degradation rate and microbial growth. This concept is the theoretical basis for the pharmaceutical guidelines that provide recommendations for long-term, intermediate, and accelerated storage conditions and for establishing shelf life periods or expiry dates of products (Scrivens, 2012).

Pharmaceutical regulatory bodies expect strict adherence of Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) during plant manufacturing and product distribution processes. GMP and GDP are deemed as synonyms of Quality System in pharmaceutical business. Since temperature excursions are observed during raw material receipt, manufacturing operation and distribution of pharmaceutical products, there is a need of holistic approach of quality system which shall be based on both GMP and GDP.

1.1. Research methodology

The following instruments have been used to generate data for the study:

(a) A survey has been conducted amongst pharmaceutical professionals to understand their experience regarding environmental condition during pharmaceutical manufacturing and that during distribution process.
(b) The guidance papers issued by drug regulatory agencies and related literature and scientific search engines such as Google were searched for pharmaceutical supply chain risk management studies in English language. Searching through databases was done with different keywords: supply chain risk, Good Distribution Practices, Quality Risk Management, and pharmaceutical. Searching in each database was adapted to databases characteristics and additionally pharmaceutical risk. The result studies and meeting abstracts were screened at 4 steps and exclusion process was based on consensus of both the authors.

1.2. Data and analysis

The research survey study amongst pharmaceutical professionals in India reveals that the records of environment condition (EC) monitoring during manufacturing and distribution operations follow a contrast trend (refer Chart 1). The survey alludes that deployment and monitoring of data logger results