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REVIEW

Quality in the pharmaceutical industry – A literature review

Reham M. Haleem [a,*], Maissa Y. Salem [b], Faten A. Fatahallah [a], Laila E. Abdelfattah [c]

[a] The National Organization for Research and Control of Biologicals, Cairo, Egypt
[b] Analytical Chemistry Department, Faculty of Pharmacy, Cairo University, Cairo, Egypt
[c] Faculty of Pharmacy, Misr University for Science and Technology, 6th of October City, Egypt

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Abstract *Objectives:* The aim of this study is to:

a. Highlight the most important guidelines and practices of quality in the pharmaceutical industry.
b. Organize such guidelines and practices to create a guide to pave the way for other researchers who would like to dig deeper into these guidelines and practices.

Design: A review was conducted of 102 publications; 56 publications were concerned with the pharmaceutical quality directly while 46 publications were concerned with the general quality practices. The content of those sources was analyzed and the following themes were identified:

a. Research theme 1: Guidelines of the pharmaceutical quality.
b. Research theme 2: General practices recently applied in the pharmaceutical industry.

Main outcome measures: The following guidelines were identified and reviewed: WHO guidelines, FDA guidelines, EU guidelines and ICH guidelines in the research theme I.

In research theme II; the following topics were identified and reviewed: quality risk management, quality by design, corrective actions and preventive actions, process capability analysis, Six Sigma, process analytical technology, lean manufacturing, total quality management, ISO series and HACCP.

* Corresponding author. Tel.: +20 966565464776.
E-mail address: rehamhaleem@hotmail.com (R.M. Haleem).

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Results: Upon reviewing the previously highlighted guidelines and the practices that are widely applied in the pharmaceutical industry, it was noticed that there is an abundant number of papers and articles that explain the general guidelines and practices but the literature lack those describing application; case studies of the pharmaceutical factories applying those guidelines and significance of those guidelines and practices.

Conclusions: It is recommended that the literature would invest more in the area of application and significance of guidelines and practices. New case studies should be done to prove the feasibility of such practices.

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1. Introduction

The quality in the pharmaceutical industry has become a very important topic. Since the world has gathered together to harmonize its practices and guides and the launching of the FDA current good manufacturing practices – the cGMP; for the 21st century – there has been a growing awareness for the significance of the quality of the pharmaceutical products (Woodcock, 2004). This awareness is represented through the appearance of several definitions defining exactly what the quality of the medicine should be (LEE and Webb, 2009). Many articles were written to demonstrate the special nature of the product-customer relationship of medicine and patients (Woodcock, 2004). Also the important role of governments was emphasized through the joint statement between the international pharmaceutical federation; FIP; and the international federation of pharmaceutical manufacturers associations; IFPMA; to ensure the safety of medicinal products in order to protect the patient (FIP Council, 1999), providing that the pharmaceutical industry is one of the most closely regulated industries for more than 50 years (Woodcock, 2004).

Since 2002, FDA began an initiative to address cGMP for the 21st century (Woodcock, 2004). This effort involved taking new looks at both the regulatory and industrial systems for insuring drug quality (Larson, 2006).

A literature review was conducted on the quality in the pharmaceutical industry, identifying 102 publications that focus on conceptual issues, methodological issues, or the application of different practices and/or guidelines applied in the pharmaceutical industries. The content of these sources was analyzed, and a number of themes were identified.

The literature review has two objectives concerned with the quality guidelines and practices of the pharmaceutical industry and the organization such as practices and guidelines to make a guide for others to use.

A research of this kind serves to integrate past research and can help current and future researchers, and practitioners employing the suitable guideline or practice to develop their methodological decisions in upgrading the industry.

This article introduced some issues regarding what is so special about pharmaceutical quality and different drivers of quality are then identified (Fraser, 2005; Dean and Bruttin, 2001). This is followed by the identified research themes and