Online publication ahead of print, AJMHS Vol 60, 2022

Quality Audits - Viewpoints of Auditing in the Pharmaceutical Industry

Edita Alili Idrizi1*, Sihana Ahmeti Lika1, Dorentina Bexheti1,
Merita Dauti1, Emilija Janevik Ivanovska2

[1] Department of Pharmacy, Faculty of Medical Sciences, University of Tetovo, Republic of North Macedonia
[2] Department of Pharmacy, Faculty of Medical Sciences, Goce Delcev University - Stip, Republic of North Macedonia

Abstract

In the pharmaceutical industry, audits are an essential part of the institutions' quality management system ensuring compliance with regulatory expectations, supporting products quality assurance and customer satisfaction. Depending on the category of the audit, it is usually performed by the qualified group of professionals assigned by management for this intention, external or regulatory agency. This review covers the main viewpoints of auditing in the pharmaceutical industry including its goals, objectives and benefits, mandatory regulatory standards and principles of auditing along with the role and responsibilities of the auditor and their code of conduct during an audit. It outlines the management of an audit program with the main methods of gathering audit information and the key stakeholders of the quality audit. It also emphasises a five-phase process which includes audit planning and preparation, conducting fieldwork, audit reporting, and following up on corrective action plans. In brief, this is a structured summary on the entire process of an audit and the importance of creating an environment of good relationship between stakeholders, employees and auditors in delivering values to audit activities of any size.

Keywords: quality audit, pharmaceutical industry, audit program, audit planning

Address for correspondence: Edita Alili Idrizi*, Department of Pharmacy, Faculty of Medical Sciences, University of Tetovo. Bul. Iliria, 25/18 Tetovo 1200 R. North Macedonia. Email: edita.alili@unite.edu.mk

INTRODUCTION

Auditing is an important activity and a critical function conducted to ascertain the validity and reliability of the information about how effectively the company controls the quality of their processes and products (1). The general definition of an audit is an inspection of a process or a system to ensure that it meets the requirements of its intended use (2). According to the International Organization for Standardization (ISO), the audit is defined as "systematic, independent and documented process for obtaining audit evidence and evaluating them objectively to determine the degree to which the verification criteria are met" (3).

The understanding of the existence and scope of the internal audit can also be increased by investigating academic research on this topic (4). Therefore, the purpose of this review is to cover the main viewpoints of auditing in the pharmaceutical industry and its contribution in achieving corporate goals, by using simple and relatable language, supported by facts, recommendations and references.

MATERIAL AND METHODS

The methodology for this research concerns analysis of review articles, original articles, guidelines, standards concerning the phenomena internal audit and quality control systems in pharmaceutical industry. A bibliographic-research is done using the following databases: PubMed, EBSCO, Scopus, Sage, Science Direct and Google Scholar. Articles and papers were searched on the keywords: internal audit, quality audit, pharmaceutical industry, audit program, audit planning. In addition, references in collected articles linked to other related articles are taken into account. Only articles in English language are selected.

Internal audit in the pharmaceutical industry

Quality audit (control mechanism as an integral part of pharmaceutical institutions' quality management system) aims in resulting corrective actions, clear directions, guidance, clear observations, good recommendations, ensuring all the involved parties that a program has consistency with pharmaceutical regulatory requirements. A company that produces drugs today must be able to demonstrate that it does so with absolute reliability, in optimal conditions and with extreme uniformity, that allows accurate reproduction (1). A complete report of the correctly implemented audit does not only ensure compliance with regulatory expectations, but most importantly supports improving products quality assurance and customer satisfaction.

Type of audits and quality audit system

There are three categories of quality audits in pharmaceutical industries:

- **Internal audit**

This type of audit is also known as First-Party Audit or self-audit. Those auditing and those being audited all belong to the same organization (1). According to regional legislations, the internal audit is defined for EU members as "self-inspection" and as "measurement, analysis and