Comparative Analysis of Drug Registration and Regulation: FDA vs. GCC Approaches for Ensuring Safety and Efficacy-A Narrative Review

Journal of Phytomedicine and Therapeutics • Article • *Open Access* • 2025 •
DOI: 10.4314/jopat.v24i1.16

Bhatti, Zohra [a] ; Siddique, Muhammad Irfan [b] ; Alotaibi, Nawaf M. [c] ; Laghari, Madeeha [d] ; Sundus, Ahlam [e]

[a] Department of Pharmacy Practice, Kulliyyah of Pharmacy, International Islamic University Malaysia, Pahang, Kuantan, 25200, Malaysia

Abstract

The increasing complexity of global pharmaceutical regulations presents significant challenges for drug development and market access across different jurisdictions. The Food and Drug administration (FDA) oversees all aspects related to new drug registration. The criteria for evaluating the efficacy and toxicity of a new drug are critical and require a prolonged duration of approximately 15 years. When comparing the evaluation method of FDA with the Gulf cooperation council (GCC), it is evident that the intellectual framework underlying these regulatory bodies differs significantly, making integration a challenging

task. Despite this, the priority of both regulatory channels is to pledge the safety and efficacy of the candidate drug. GCC conducts all the evaluations considering the International Conference on Harmonization (ICH). Furthermore, marketing and financial strategies are keenly reviewed to improve access to effective treatments at reasonable costs and maintain foreground healthcare system. This study aims to identify and evaluate the differences and similarities in the approaches employed by FDA and GCC during registration and regulation processes of a new drug to ensure its safety and efficacy, and to provide insights into the strengths and weaknesses of each regulatory framework. This comparative analysis of FDA and GCC regulatory frameworks addresses a critical need in global pharmaceutical development. Understanding these distinct approaches to drug approval has immediate practical implications for pharmaceutical companies seeking market access across regions, while offering insights for regulatory harmonization efforts. The findings directly support improved efficiency in drug development pathways and enhanced global public health outcomes through more streamlined regulatory processes. ©2024 The authors.

Author keywords

FDA (Food and Drug Administration); GCC (Gulf Cooperation Council); ICH guidelines (International Conference on Harmonization); new drug approval; regulatory frameworks; safety and efficacy

Indexed keywords

EMTREE medical terms

Article; clinical practice; comparative study; decision making; drug approval; drug efficacy; drug registration; drug regulation; drug safety; ex vivo study; good manufacturing practice; health care system; health outcome; human; in vitro study; in vivo study; narrative; phase 1 clinical trial (topic); phase 2 clinical trial (topic); phase 3 clinical trial (topic); postmarketing surveillance; preclinical study; proof of concept; public health; systematic review

Corresponding authors

Corresponding author: Z. Bhatti

Affiliation: Department of Pharmacy Practice, Kulliyyah of Pharmacy, International Islamic University Malaysia, Pahang, Kuantan, 25200, Malaysia