

## **Review Article**

# **AUDIT AND SELF-INSPECTION IN THE PHARMACEUTICAL INDUSTRY: REGULATORY PERSPECTIVES, PRINCIPLES, AND QUALITY IMPROVEMENT STRATEGIES**

**BHAVIKA SONI, APARNA ARORA, ANJU GOYAL**

**Bhupal Nobles' College of Pharmacy, Udaipur, Bhupal Nobles University Udaipur (313001)**

The pharmaceutical industry works under strict regulatory requirements to make sure that medicines are safe, effective, and of good quality. Audit and self-inspection are important parts of the Pharmaceutical Quality System because they help organizations check their activities, maintain Good Manufacturing Practices (GMP), and identify areas that need improvement. This review aims to bring together and compare different regulatory guidelines related to audit and self-inspection and present their common requirements in a simple and clear manner. It focuses on their classification, basic principles, regulatory requirements, importance, advantages, limitations, and practical challenges. An audit is a systematic and independent evaluation used to check whether an organization follows regulatory requirements and its own procedures, while self-inspection is an internal review carried out by trained and qualified personnel to identify gaps and ensure continued GMP compliance. Regulatory bodies such as WHO, USFDA, and EU GMP give importance to proper audit programs, accurate documentation, clear classification of observations, and timely corrective and preventive actions (CAPA). Effective audit and self-inspection help organizations maintain compliance, reduce risks, improve supplier management, strengthen quality systems, and remain prepared for regulatory inspections. When these activities are properly planned and documented, they also help improve transparency, build a strong quality culture, and support continuous improvement within the pharmaceutical organization.

**KEYWORDS:** Audit; Self-Inspection; GMP; Quality Assurance; CAPA; Regulatory Compliance; Pharmaceutical Industry.

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