IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 2, January 2026
Impact Factor: 7.67

A Review on Pharmacovigilance of Biologics and Biosimilars: Emerging Trends and Clinical Research Perspectives (2021–2025)

Miss. Komal. V. Pathade[1], Mr. Shatrughna U. Nagrik[2], Dr. Shivshankar D. Mhaske[3]
Satyajeet College of Pharmacy, Khandala, Mehkar, Buldhana[123]
Corresponding Author: Komal vaijanath pathade
pathadekomal60@gmail.com

Abstract: *Substantial growth in biologics and biosimilars is occurring between 2021 and 2025 that has significantly changed the paradigm of therapeutics in the world, especially in oncology, autoimmune disease, and chronic inflammatory disorders. They have increasingly become taken up and have therefore increased the need to have strong pharmacovigilance systems that can handle the unique safety issues that emerge because of these complex biologic entities. In contrast to traditional, small-molecule therapeutics, biologics do not possess fixed molecular structure, production, and immunogenicity, and thus make post-marketing surveillance an essential requirement to provide long-term safety and therapeutic reliability. However, biosimilars, though showing a high level of similarity with the reference biologics, require extra care under the fear of interchangeability, traceability, and minute differences that can affect clinical outcomes.*

In 2021-2025, pharmacovigilance practices have changed significantly via incorporation of powerful technologies, real-world evidence, and novel methods of analytical processes. AI, big data analytics, and electronic health solutions have become effective intermediaries in the development of safety signals at an early stage, improved adverse drug reaction reporting, and optimization of risk-management strategies. Regulatory authorities across the globe such as the FDA, EMA, and WHO have strengthened their guidelines to allow harmonized surveillance, to improve biologic traceability and to increase monitoring of immunogenicity. At the same time, the clinical research has progressed through the use of modern trial designs, approved post-marketing safety studies, and patient registries, which create a greater understanding of the long-term safety profiles.

Despite such developments, there are still unresolved questions such as under-reporting of adverse events, inconsistent regulatory frameworks in developing countries and the urgent need to have standard methods of immunogenicity assessments. Maintaining quality manufacturing operations and correct product labeling remain to be one of the issues that should be discussed within the pharmacovigilance system..

Keywords*:* Pharmacovigilance, Biologics, Biosimilars, Immunogenicity, Real-World Evidence, Signal Detection; Traceability, Artificial Intelligence, Regulatory Science.

Copyright to IJARSCT
www.ijarsct.co.in
DOI: 10.48175/IJARSCT-30898