



# AMERICAN JOURNAL OF PHARMTECH RESEARCH

Journal home page: <http://www.ajptr.com/>

## Regulatory Requirements For Biotechnological Products As Per CDSCO In India Comparison With USFDA

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### ABSTRACT

Biotechnological products have transformed modern medicine by providing targeted and innovative therapies, including recombinant proteins, monoclonal antibodies, gene therapies, and vaccines, forming the foundation of precision medicine. However, their biological complexity and structural variability necessitate stringent regulatory oversight to ensure safety, efficacy, and quality. This study presents a comparative analysis of regulatory frameworks governing biotechnological products in India and the United States. In India, the Central Drugs Standard Control Organization (CDSCO) serves as the apex regulatory authority, implementing guidelines under the Drugs and Cosmetics Act of 1940. It mandates rigorous preclinical evaluations, phased clinical trials, adherence to Good Manufacturing Practices (GMP), and robust post-marketing surveillance to ensure product safety and therapeutic benefit. Conversely, the United States Food and Drug Administration (US FDA) regulates biotechnological products under the Public Health Service (PHS) Act and the Food, Drug, and Cosmetic (FD&C) Act. A distinctive feature of the US system is the Biologics License Application (BLA), which requires extensive clinical trials, comprehensive pharmacovigilance, and stringent GMP compliance, reflecting a strong emphasis on scientific validation and patient safety. The comparative analysis highlights key differences in approval timelines, regulatory pathways, clinical data requirements, and pharmacovigilance mechanisms. While CDSCO focuses on accessibility and affordability within India, the US FDA prioritizes exhaustive scientific evaluation and global standardization. Understanding these regulatory nuances is essential for pharmaceutical companies to streamline product development, ensure compliance, and foster public trust. This study underscores the need for harmonization and mutual recognition of standards to accelerate global patient access to life-saving biotechnological therapies.

**Keywords:** CDSCO, FDA, biotechnological products, India USA.

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Received 08 September 2025, Accepted 22 September 2025

Please cite this article as: Kumar A *et al.*, Regulatory Requirements For Biotechnological Products As Per CDSCO In India Comparison With USFDA. American Journal of PharmTech Research 2025.

## INTRODUCTION

Biotechnology has emerged as one of the most transformative scientific disciplines of the 21st century, with applications spanning healthcare, agriculture, industry, and environmental management. In particular, biotechnological products—often referred to as biologics, have reshaped modern medicine through the development of vaccines, therapeutic proteins, monoclonal antibodies, and advanced therapies such as gene and cell-based treatments. Unlike conventional small-molecule drugs, these products are derived from living systems using tools such as recombinant DNA technology, hybridoma techniques, and genetic engineering, which allow precise targeting of molecular pathways involved in disease<sup>1</sup>.

The healthcare sector represents the largest share of biotechnology applications. Recombinant human insulin, the first biopharmaceutical approved in the 1980s, demonstrated the potential of engineered proteins to replace natural hormones. Since then, advances such as monoclonal antibodies, immune modulators, and growth factors have become integral to the treatment of cancer, autoimmune diseases, and genetic disorders. Recent developments in mRNA and recombinant vaccines, particularly during the COVID-19 pandemic, highlight the speed and adaptability of biotechnology in responding to emerging health threats.

Beyond medicine, biotechnology contributes to agriculture and industry by enhancing crop yields, producing safer animal vaccines, enabling environmentally sustainable manufacturing, and introducing diagnostic innovations. Applications in molecular testing, pharmacogenomics, and CRISPR-based genome editing further demonstrate its role in early disease detection, personalized medicine, and next-generation therapies<sup>2</sup>.

Despite remarkable progress, biotechnological products face challenges such as high manufacturing costs, regulatory complexity, and unequal access to therapies across regions. Addressing these issues is critical to fully realizing their global impact. The aim of this article is to review the development, classification, and applications of biotechnological products, with particular emphasis on their role in healthcare and their potential to transform disease prevention, diagnosis, and treatment.

### **Overview of CDSCO in India**

The Central Drugs Standard Control Organization (CDSCO), functioning under the Directorate General of Health Services, Ministry of Health and Family Welfare, serves as the National Regulatory Authority (NRA) of India. Headquartered in New Delhi, with multiple zonal, sub-zonal, and port offices as well as central laboratories, CDSCO enforces the Drugs and Cosmetics

Act, 1940 and Rules, 1945 to regulate the safety, efficacy, and quality of drugs, cosmetics, and biological products across the country<sup>3</sup>.

The major functions of CDSCO include the approval of new drugs, vaccines, recombinant products, and biosimilars; regulation and monitoring of clinical trials; granting licenses for the manufacture and import of specified categories such as blood banks, vaccines, large-volume parenterals, and r-DNA products; and oversight of pharmacovigilance activities to ensure post-marketing safety. In addition, CDSCO coordinates with State Drug Control Authorities to ensure uniformity in the enforcement of regulatory provisions nationwide.

Beyond these regulatory roles, CDSCO aims to safeguard public health by promoting transparency, accountability, and consistency in its decision-making. It also focuses on encouraging research and development in the pharmaceutical and biotechnology sectors while fostering a science-based regulatory framework that is globally aligned and responsive to innovation.

In the case of biotechnological products, CDSCO functions alongside several other regulatory bodies. The Review Committee on Genetic Manipulation (RCGM) under the Department of Biotechnology oversees biosafety during research and preclinical evaluation of recombinant products. The Genetic Engineering Appraisal Committee (GEAC) under the Ministry of Environment, Forest and Climate Change grants environmental clearance for large-scale or commercial use of genetically modified organisms. At the institutional level, Institutional Biosafety Committees (IBSCs) monitor biosafety compliance in research laboratories. The Department of Biotechnology (DBT) further supports these mechanisms by framing biotechnology policies and issuing biosafety guidelines<sup>4</sup>.

Together, these agencies form a comprehensive and multi-tiered regulatory framework that governs the development, evaluation, and commercialization of biotechnological products in India, ensuring scientific progress while safeguarding public health.

### **Overview of regulatory requirements of biotechnological products as per CDSCO in India**

#### **Applicable Guidelines and Regulations of Biologicals in India**

In India, drugs and biotechnological products are regulated under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. Import, manufacture, or marketing of biotechnologicals without a valid license is prohibited. Additionally, the Rules for Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989 govern similar biologics. Several guidelines, including the *Recombinant DNA Safety Guidelines (1990)*, *Preclinical and*

*Clinical Data Guidelines for r-DNA Vaccines (1999)*, and *CDSCO Guidance for Industry (2008)*, outline requirements for clinical trials, approvals, post-approval changes, and quality standards<sup>5</sup>.

### **Approval Process for Biotechnological Products**

The approval of novel biotechnologicals involves preclinical and clinical evaluation to establish safety, efficacy, and quality. Manufacturers first submit an Investigational New Drug (IND) application with preclinical and manufacturing data. Clinical trials follow a phased approach Phase I for safety, Phase II for efficacy, and Phase III for confirmation in larger populations. After successful trials, a New Drug Application (NDA) is submitted, which is reviewed by regulatory authorities for market authorization.

### **Preclinical and Clinical Studies**

Preclinical studies assess pharmacology, pharmacodynamics, toxicity, and immunogenicity using in vitro and in vivo models. Reports must be approved by RCGM, IBSC, and IAEC. Clinical trials confirm pharmacokinetics, efficacy, and safety in humans, often comparing similar biologics with reference products. Regulatory guidance ensures rigorous study design and adherence to ethical and biosafety standards.

### **Post-Market Surveillance**

Even after approval, biotechnological products undergo pharmacovigilance, including submission of Periodic Safety Update Reports (PSURs) and reporting of serious adverse events. Post-marketing studies (PMS) monitor long-term safety and efficacy, helping detect potential risks early.

### **Quality Control and Manufacturing**

Quality control is performed at Central Drugs Laboratory (CDL), Kasauli, and the National Institute of Biologicals (NIB), Noida. Both laboratories test and verify biotechnological products before market release. Schedule M of the Drugs and Cosmetics Act defines Good Manufacturing Practices (GMP) for premises, processes, and materials, aligning Indian standards with international guidelines.

### **Regulatory Oversight**

India's biotechnology products are regulated through a multi-agency system: IBSCs ensure laboratory biosafety, RCGM oversees preclinical research, GEAC handles environmental approvals, and DCGI/CDSCO grants clinical trial and marketing authorizations. This coordinated system ensures safety from research to commercialization while supporting innovation<sup>6</sup>.

### **Overview of FDA in USA**

The U.S. Food and Drug Administration (FDA) is a federal agency under the Department of Health and Human Services (HHS). It is responsible for protecting public health by ensuring the safety, efficacy, and quality of drugs, biologics, medical devices, food, cosmetics, and radiation-emitting products. Established in 1848, the FDA is the federal government's oldest consumer protection agency and has continually evolved to address emerging health challenges and innovation in regulated industries.

The FDA performs multiple functions, including the approval of new drugs, vaccines, and biologics; regulation of food safety, medical devices, cosmetics, dietary supplements, and tobacco products; post-market surveillance; and conducting research to support regulatory decisions. The agency can also issue Emergency Use Authorizations (EUA) during public health crises to allow rapid access to critical products.

In the United States, biotechnological products or biologics, such as recombinant proteins, monoclonal antibodies, gene therapies, cell-based therapies, and biosimilars, are regulated separately from conventional drugs due to their complex structures and manufacturing processes. These products are primarily regulated under the Public Health Service (PHS) Act, which requires a Biologics License Application (BLA) for marketing, and the Federal Food, Drug, and Cosmetic (FD&C) Act, which governs safety, labeling, and manufacturing standards.

The FDA's regulatory oversight of biologics is carried out mainly through the Center for Biologics Evaluation and Research (CBER), which handles vaccines, gene therapies, and cell-based products, and the Center for Drug Evaluation and Research (CDER), which regulates therapeutic biotech products such as monoclonal antibodies and enzymes. The Office of Tissues and Advanced Therapies (OTAT) under CBER specifically focuses on cell and gene therapies.

The regulatory process for biotechnological products includes preclinical testing, submission of an Investigational New Drug (IND) application, clinical trials, review and approval through BLA, and post-marketing surveillance. All products must meet strict standards for purity, potency, safety, and consistency, and comply with Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP) throughout development and commercialization<sup>7</sup>.

### **Overview of regulatory requirements of biotechnological products as per FDA in USA**

In the United States, the regulation of biotechnological products, also known as biologics, is overseen by the U.S. Food and Drug Administration (FDA). This pathway ensures that biologics are safe, effective, and consistently manufactured to high quality standards. The process spans from early preclinical research to post-marketing surveillance<sup>8</sup>.

Before formal submissions, sponsors conduct extensive preclinical studies on pharmacology, toxicology, and ADME (absorption, distribution, metabolism, and excretion) under Good Laboratory Practice (GLP) standards. Manufacturing processes, production cell lines, purification methods, and quality control assays are established according to current Good Manufacturing Practice (cGMP). Sponsors often consult the FDA in Pre-Investigational New Drug (Pre-IND) meetings to discuss nonclinical findings, CMC strategies, early clinical protocols, and potential regulatory pathways, helping to streamline the development process.

To initiate human clinical trials, an Investigational New Drug (IND) application is submitted under 21 CFR Part 312. This includes preclinical safety data, CMC documentation, clinical trial protocols, investigator qualifications, and confirmation of Good Clinical Practice (GCP) and Institutional Review Board (IRB) compliance. The FDA reviews the IND within 30 days, and if no clinical hold is issued, trials may proceed. Sponsors must report adverse events, submit annual progress reports, and update protocols as required.

Clinical development proceeds in phases: Phase I assesses safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) in a small cohort; Phase II evaluates preliminary efficacy and dosage optimization in several hundred patients; and Phase III confirms efficacy and safety in large, pivotal studies. All phases follow GCP guidelines, maintain detailed Trial Master Files, and may involve independent Data Safety Monitoring Boards (DSMBs) for higher-risk studies.

After successful clinical trials, a Biologics License Application (BLA) is submitted under 21 CFR Parts 600, 601, and 610. The BLA includes all clinical, nonclinical, and CMC data, manufacturing facility information, stability studies, potency assays, and proposed labeling. The FDA reviews the application, inspects manufacturing sites for cGMP compliance, and may consult advisory committees for expert input. Approval results in market authorization, while additional information may be requested through a Complete Response Letter (CRL).

Post-marketing surveillance ensures ongoing product safety. Sponsors must comply with Post marketing Requirements (PMRs) and Post marketing Commitments (PMCs), submit periodic safety reports, and maintain pharmacovigilance through systems like MedWatch or VAERS. Risk Evaluation and Mitigation Strategies (REMS) may be required for products with significant safety concerns. Promotional materials must align with FDA-approved labeling, and off-label promotion is strictly prohibited.

Special considerations for biotechnological products include temperature-sensitive cold chain logistics, rigorous immunogenicity testing, and compliance with the Biosimilar Approval Pathway

under the Biologics Price Competition and Innovation Act (BPCIA) for products similar to reference biologics<sup>9</sup>.

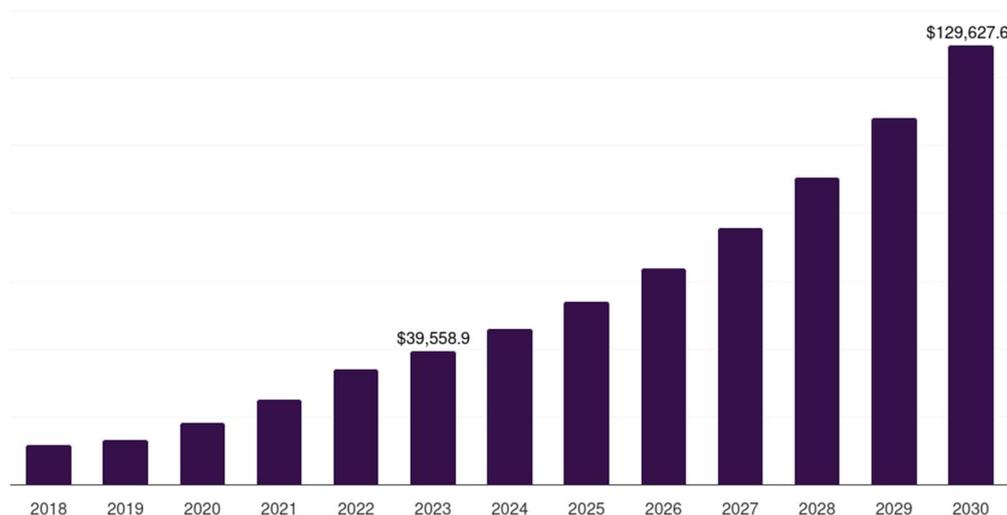
**Comparative tabulation analysis of CDSCO and US FDA**

Sl. No	Regulatory Parameter	India – CDSCO / DBT / RCGM	USA – USFDA (CBER / CDER)
1	Regulatory Authority	CDSCO (MoHFW), DBT, RCGM, GEAC	FDA (CBER for biologics, CDER for biotech drugs), USDA, EPA
2	Legal Framework	Drugs & Cosmetics Act, 1940; NDCT Rules, 2019	Public Health Service (PHS) Act; Food, Drug & Cosmetic (FD&C) Act
3	Product Classification	Biotechnological products classified as biologics	Biologics under Biologics License Application (BLA) pathway
4	Types of Products	Recombinant proteins, monoclonal antibodies, vaccines, gene therapies	Same as India + cell therapies, tissue-based products
5	Application Type	Clinical Trial Application → Market Authorization Application	IND → BLA
6	Dossier Format	CTD (Common Technical Document) Modules 1–5	ICH CTD Modules 1–5
7	Clinical Trial Phases	Phase I–III (as per NDCT Rules); Phase IV (optional or conditional)	Phase I–III mandatory; Phase IV (post-marketing surveillance)
8	Clinical Trial Approval	Form CT-04, Ethics Committee approval, DCGI review	IND submission + IRB approval + FDA clearance
9	GCP Guidelines	Indian GCP (based on ICH E6)	ICH-GCP + 21 CFR Part 312
10	Preclinical Requirements	GLP-compliant studies; DBT & RCGM requirements for rDNA and GMOs	GLP studies as per 21 CFR Part 58
11	Manufacturing Requirements	WHO-GMP or Schedule M compliance	US cGMP – 21 CFR Part 210, 211, 600–680
12	Quality Control Standards	Indian Pharmacopoeia (IP), WHO GMP	US Pharmacopoeia (USP), cGMP
13	Analytical Characterization	Required for biosimilars; comparability with reference biologic	Detailed analytical similarity required using totality of evidence approach
14	Bioequivalence/Bio similarity Studies	Similar Biologics Guidelines (2016, Draft 2022/25)	aBLA (Abbreviated BLA); Biosimilar Guidelines
15	Environmental Clearance (GMO)	GEAC approval required for GMOs and gene therapy	Environmental assessment required; oversight by EPA/USDA
16	Labelling Requirements	As per Drugs and Cosmetics Rules	21 CFR Part 201
17	Risk Management Plan (RMP)	Mandatory PvPI (Pharmacovigilance Program of India)	REMS (Risk Evaluation & Mitigation Strategy)
18	Pharmacovigilance System	PvPI; PSUR every 6 months (2 years), then annually	FDA MedWatch, FAERS; periodic and expedited AE reports
19	Post-Marketing Surveillance	Required by CDSCO; Phase IV studies encouraged	Required under REMS/FAERS

20	Inspection of Manufacturing Sites	CDSCO/State FDA inspections	FDA Pre-Approval Inspection (PAI) and GMP compliance inspections
21	Regulatory Timelines	12–18 months post clinical trials	12–24 months (standard); shorter for fast-track approvals
22	Fast Track / Priority Pathways	Conditional approvals for national health priorities	Fast Track, Accelerated Approval, Breakthrough Therapy, Priority Review
23	Orphan Drug Designation	Not formalized; NDCT allows certain relaxations for rare diseases	Orphan Drug Act (1983); 7-year market exclusivity, fee waivers, tax credits
24	Fees / Cost of Application	Relatively low; varies by type of product	High under Prescription Drug User Fee Act (PDUFA)
25	Public Access to Regulatory Information	Limited; available on CDSCO portal	Public databases: Drugs@FDA, Purple Book, ClinicalTrials.gov

### Overview of market analysis of biotechnological products in India

The Indian biotechnology market has witnessed remarkable growth, with revenues reaching USD 39.6 billion in 2023 and projected to expand to USD 129.6 billion by 2030 at a CAGR of 18.5%. The sector is driven by the rising prevalence of chronic diseases, increasing demand for innovative therapies, and advancements in bioinformatics, which is expected to be the fastest-growing segment. Health remains the largest revenue contributor, while applications extend across food and agriculture, industrial processing, natural resources, and the environment. India is home to leading biotechnology companies such as Biocon, Serum Institute of India, Bharat Biotech, Dr. Reddy's Laboratories, Cipla, Panacea Biotech, Concord Biotech, Lupin, Wockhardt, and Immuneel Therapeutics, alongside strong participation from global players like AstraZeneca, Pfizer, Novartis, Roche, and Johnson & Johnson, underscoring the country's growing role in the global biotech landscape<sup>10</sup>.

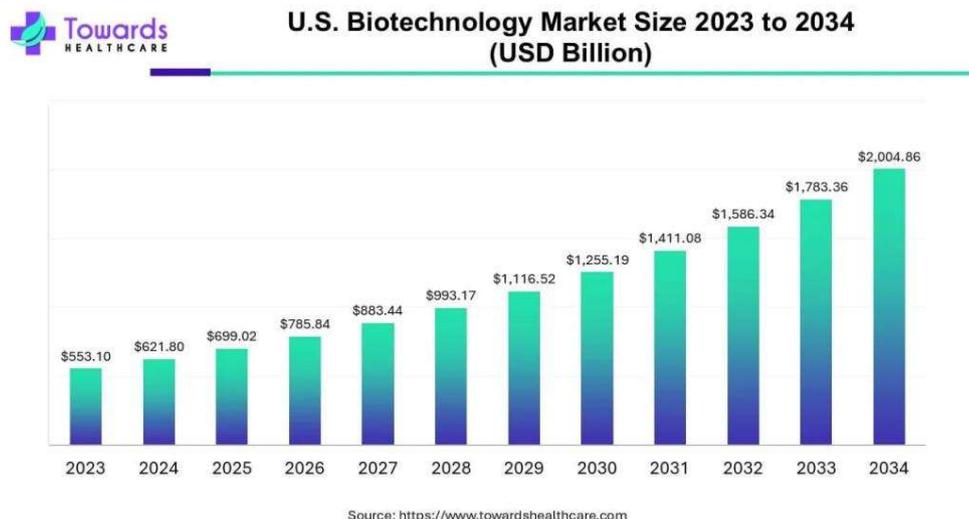


**Figure 1: Market analysis of biotechnological products in India**

### Market analysis of biotechnological products in USA

The United States hosts the world's most dynamic biotechnology market, valued at over USD 550 billion in 2024 and projected to exceed USD 2 trillion by 2034, growing at a CAGR of around 12.5%. Growth is fueled by strong R&D investments, regulatory support from the FDA, and innovation hubs such as Boston and San Francisco. Key drivers include rising demand in oncology, immunology, and metabolic disorders, along with the emergence of cell, gene, and biosimilar therapies. In 2023, DNA sequencing dominated with a 19% share, while nanobiotechnology and bioinformatics are anticipated to be the fastest-growing segments. The health sector contributed nearly half of overall revenues, underscoring its central role in market

expansion. Leading global players shaping the U.S. biotechnology landscape include Pfizer, Amgen, Gilead, Novartis, Roche, Johnson & Johnson, AstraZeneca, and Biogen<sup>11, 12</sup>.



**Figure 2: Market analysis of biotechnological products in USA**

#### Market context Analysis: CDSCO vs USFDA

Factor	India (CDSCO Context)	USA (US FDA Context)
Market Size (2023/2024)	USD 32.6 b (2024, IMARC) or USD 39.6 b (2023, GVR)	USD 552.4 b (2023, GVR/Nova One) or USD 621.5 b (2024, BioSpace)
Projected Size	USD 110.3 b by 2033 (IMARC) or USD 129.6 b by 2030 (GVR)	USD 1,250 b by 2030 (GVR) or USD 1,794 b by 2033 (Nova One/BioSpace)
CAGR	13.8% (2025–2033, IMARC) or 18.5% (2024–2030, GVR)	12.4% (2024–2030) or 12.5% (2025–2033)
Largest Segment	Healthcare / Health biotech	Healthcare (~44% market share)
Fastest-Growing Segment	Bioinformatics	Bioinformatics (~17% CAGR) & DNA sequencing (~18% tech share)
Global Market Share	~2–3%	~35–40%
Scale Comparison	~15× smaller than US market	~15× larger than India market
Key Strengths	Low-cost vaccine & biologics manufacturing; CRDMO growth; policy incentives for novel molecules	Strong R&D spend (~USD 96 b in 2023); venture capital; advanced innovation clusters
Regulatory Emphasis	Manufacturing compliance, quality standards, export facilitation	Expedited pathways for innovation, advanced regulatory designations

#### Import and Sales of Biotechnological Products: India vs. USA

Biotechnological products, including vaccines, monoclonal antibodies, gene therapies, biosimilars, and diagnostic kits, are subject to stringent regulatory oversight due to their complexity and potential impact on health.

#### India

in India, biotechnological products are regulated under the Drugs and Cosmetics Act, 1940. The Central Drugs Standard Control Organization (CDSCO) oversees licensing, import, and sale, while

agencies like the Review Committee on Genetic Manipulation (RCGM) and Genetic Engineering Appraisal Committee (GEAC) manage preclinical research and GMO-related approvals. Import requires an Import License (Form 10/10A) and registration of the foreign manufacturer (Form 41), with compliance to GMP standards. Commercial sale mandates marketing authorization via Form 44, supported by preclinical and clinical trial data. Biosimilars undergo rigorous comparability studies, clinical trials, and post-marketing surveillance. Post-marketing obligations include safety reporting, lot release testing, and monitoring of adverse drug reactions. Additional rules apply for GMO-based products to ensure biosafety and environmental protection<sup>13</sup>.

## USA

in the United States, the FDA regulates a broad range of biotechnological products, including biologics, biotech drugs, medical devices, and food ingredients containing GMOs. Importation requires prior notice, registration of manufacturing facilities, and approval via New Drug Application (NDA), Biologics License Application (BLA), or equivalent pathways. Labelling must comply with 21 CFR standards, and GMP or cGMP compliance is mandatory. Sale is prohibited without FDA authorization, with product-specific pathways for drugs, biologics, devices, and food ingredients. Genetically modified or agricultural biotech products are co-regulated by the FDA, USDA, and EPA, with mandatory labelling for bioengineered foods. Customs and Border Protection (CBP) enforces compliance at import, while FDA conducts inspections and may place non-compliant products on Import Alert.

Both countries emphasize rigorous evaluation, documentation, and post-marketing surveillance, but India involves multiple specialized committees for GMO oversight, whereas the U.S. relies on coordinated agency enforcement with standardized approval pathways<sup>14</sup>.

## Recent Amendments in Biotechnological Product Regulations

**India:** Between 2023 and 2025, India implemented several regulatory amendments to strengthen oversight of biotechnological products, including vaccines, monoclonal antibodies, and emerging cell and gene therapies. Key changes include the 2024 amendment to the New Drugs and Clinical Trials (NDCT) Rules mandating registration of Contract Research Organizations (CROs) with CDSCO to ensure ethical conduct and patient safety. The 2024 Post-Approval Changes (PAC) Guidelines introduced risk-based classifications for biologics modifications, aligning with WHO and ICH standards. The Jan Vishwas (Amendment) Act, 2025, allows certain regulatory violations to be resolved through financial penalties, reducing legal risks for manufacturers. Other reforms include the Uniform Code for Pharmaceutical Marketing Practices (UCPMP, 2024–2025) for ethical marketing, mandatory QR code labeling of APIs to enhance traceability, and Access and

Benefit Sharing (ABS) Regulations, 2025, ensuring fair use of biological resources in R&D. Collectively, these amendments improve clinical trial oversight, lifecycle management, marketing transparency, and biodiversity conservation<sup>15,16</sup>.

**USA:** The United States also introduced several updates in 2024–2025 to enhance regulatory oversight of biotechnological products. The FDA halted certain clinical trials involving international transfers of genetic material in 2025, increasing scrutiny on cell and gene therapies. Transparency in biologics review was improved through the publication of previously redacted Complete Response Letters (CRLs). The modernized Coordinated Framework for Biotechnology Regulation (2024) harmonized oversight among FDA, USDA, and EPA, simplifying approval pathways. USDA-APHIS reinstated a notification pathway for biotech crops (2025), accelerating approvals for low-risk genetically engineered plants. The BIOSECURE Act (2025) restricted collaborations with foreign adversaries to safeguard national security, while the proposed National Biotechnology Coordination Office (NBCO, 2025) aims to centralize policy coordination across federal agencies. These reforms streamline approvals, strengthen safety and compliance, and support domestic innovation in biotech research and commercialization<sup>17, 18</sup>.

## CONCLUSION

This study has examined the regulatory frameworks, approval processes, and market dynamics governing biotechnological products in India and the United States, highlighting both their convergences and distinctions within the global biotechnology ecosystem. Biotechnological products—including vaccines, biosimilars, monoclonal antibodies, gene therapies, and precision medicines—require stringent oversight due to their complexity and potential impact on human health. India and the U.S. have developed comprehensive mechanisms to ensure safety, quality, and efficacy, yet each reflects the structural realities and strategic priorities of its market.

In India, the Central Drugs Standard Control Organization (CDSCO), alongside the Review Committee on Genetic Manipulation (RCGM) and the Genetic Engineering Appraisal Committee (GEAC), ensures compliance with Good Manufacturing Practices, clinical trial regulations, and biosafety standards. This framework supports India's global role in affordable vaccine production, biosimilars, and contract research and manufacturing, leveraging its cost-efficient infrastructure and skilled scientific workforce. Conversely, the U.S. Food and Drug Administration (FDA), supported by agencies such as USDA and EPA, emphasizes innovation, rapid approval pathways, and advanced post-market surveillance, positioning the U.S. as a leader in cutting-edge therapies, high-value biologics, and personalized medicine.

Market analyses highlight complementary strengths: India's biotechnology market is rapidly expanding, driven by healthcare and bioinformatics, whereas the U.S. market leads in scale, R&D investment, and high-value therapeutics. The findings underscore that collaboration between these nations—through technology transfer, joint ventures, and harmonized regulatory practices—can accelerate the development, approval, and global distribution of safe and effective biotechnological solutions. By combining India's affordability and manufacturing capacity with the U.S.'s innovation and regulatory expertise, both countries can advance global healthcare equity and ensure that scientific progress translates into meaningful patient benefits worldwide.

## REFERENCES

1. Deb PK, Al-Attraqchi OHA, Stanslas J, Al-Aboudi A, Al-Attraqchi N, Tekade RK. Biotechnology-Based Pharmaceutical Products. In: Tekade RK, editor. *Biomaterials and Bio nanotechnology*. Advances in Pharmaceutical Product Development and Research series. London: Academic Press; 2019. p. 154–183.
2. Yang P. Applications of biotechnology in medicine. *Int Res J Biotechnol*. 2021 ;11(5):1–2.
3. Central Drugs Standard Control Organization (CDSCO). Medical Regulatory Bodies—CDSCO [Internet]. New Delhi: Directorate General of Health Services, Ministry of Health and Family Welfare; 2024 Nov 5 [cited 2025 Aug 29]. Available from: URL: <https://dghs.mohfw.gov.in/cdscophp>
4. Dhole SD, Darade RB. Indian Pharmaceutical Regulatory Authority: Review. *Int J Pharm Sci*. 2024 May;2(5):1109–1119. doi:10.5281/zenodo.11235269
5. Ashok Kumar P, Divija PM, Reshma BR, Bhoomika KR, Ramya Shree R. Regulatory requirements for approval of biological products as per CDSCO in India comparison with South Korea. *World J Adv Res Rev*. 2023;20(1):758–767.
6. Mindala DP, Bedi YS, Gupta SK, Gandhi SG, Khan IA. Regulations for health care biotechnology products in major markets of the world. In: Saxena A, editor. *Biotechnology Business – Concept to Delivery*. Cham: Springer Nature Switzerland AG; 2020. p. 131–143.
7. Pachala PK, Dharani T, Satya PD, Nagabhushanam MV, Bonthagarala B, Ramakrishna G, et al. Organization structure and functions of US FDA (Food & Drug Administration). *Pharmaceutical Sciences*. 2022 May;9(5).
8. U.S. Food and Drug Administration. Investigational New Drug (IND) Application [Internet]. Silver Spring (MD): FDA; [cited 2025 Sep 8]. Available from:

- URL:<https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application>
9. U.S. Food and Drug Administration. Biologics License Applications (BLA) Process [Internet]. Silver Spring (MD): FDA; [cited 2025 Sep 8]. Available from: URL:<https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process>
  10. Grand View Research. India biotechnology market size & outlook, 2023–2030 [Internet]. San Francisco (CA): Grand View Research; 2023 [cited 2025 Aug 29]. Available from: URL:<https://www.grandviewresearch.com/horizon/outlook/biotechnology-market/india>
  11. Grand View Research, Inc. U.S. Biotechnology Market Size, Share & Trends Analysis Report, 2024–2030: By Technology and Application. San Francisco (CA): Grand View Research; 2024
  12. Precedence Research (via Towards Healthcare). U.S. Biotechnology Market Size Booms 12.42 % CAGR by 2034 [Internet]. 2025 [cited 2025 Aug 29]. Available from: <https://towardshealthcare.com>
  13. Central Drugs Standard Control Organization. *Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India* [Internet]. New Delhi: CDSCO; 2016 [cited 2025 Sep 11]. Available from: <https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadAlertsFiles/BiosimilarGuideline2016.pdf>
  14. U.S. Food and Drug Administration. *Biologics License Applications (BLA) Process (CBER)* [Internet]. Silver Spring (MD): FDA; 2023 [cited 2025 Sep 11]. Available from: <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber>
  15. Central Drugs Standard Control Organization (CDSCO). Guidelines and gazette notifications [Internet]. New Delhi: CDSCO; [cited 2025 Sep 4]. Available from: URL: <https://cdsco.gov.in>
  16. Department of Pharmaceuticals, Government of India. Uniform code for pharmaceutical marketing practices & policy updates [Internet]. New Delhi: DoP; [cited 2025 Sep 4]. Available from: URL: <https://pharmaceuticals.gov.in>
  17. U.S. FDA; Environmental Protection Agency (EPA); USDA. EPA, FDA, and USDA issue joint regulatory plan for biotechnology [Internet]. Silver Spring (MD): FDA; 2024 May 8

[cited 2025 Sep 4]. Available from: URL: <https://www.fda.gov/news-events/press-announcements/epa-fda-and-usda-issue-joint-regulatory-plan-biotechnology>

18. Food Dive. Wildtype's lab-grown salmon receives FDA clearance [Internet]. 2025 Jun 12 [cited 2025 Sep 4]. Available from: URL: <https://www.fooddive.com/news/wildtype-lab-grown-salmon-fda-clearance/750518>

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