

**PRODUCT LIFE CYCLE MANAGEMENT OF DRUGS: A COMPARATIVE ANALYSIS
OF REGULATORY APPROACHES AND HARMONIZATION STRATEGIES BETWEEN
USFDA AND CDSCO****Ashok Kumar P.*, Pavan S., Dhanush D., Harsha C. N., Maruthi C., Jayanth R.**Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, Tumkur – 572103, Karnataka, India.
(Affiliated to Rajiv Gandhi University of Health Sciences, Bengaluru).***Corresponding Author: Ashok Kumar P.**Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, Tumkur – 572103, Karnataka, India.
(Affiliated to Rajiv Gandhi University of Health Sciences, Bengaluru).DOI: <https://doi.org/10.5281/zenodo.23032764>**How to cite this Article:** Ashok Kumar P.*, Pavan S., Dhanush D., Harsha C. N., Maruthi C., Jayanth R. (2026). Product Life Cycle Management Of Drugs: A Comparative Analysis Of Regulatory Approaches And Harmonization Strategies Between Usfda And Cdsco. European Journal of Pharmaceutical and Medical Research, 13(10), 298–305.

This work is licensed under Creative Commons Attribution 4.0 International license.



Article Received on 03/09/2026

Article Revised on 24/09/2026

Article Published on 01/10/2026

ABSTRACT

Product Life Cycle Management (PLCM) governs a pharmaceutical product from development through approval, marketing, post-approval variation, and eventual withdrawal, so that safety, efficacy, and quality are preserved throughout its commercial life. This comparative, document-based study examined and contrasted the regulatory frameworks and PLCM practices of India's Central Drugs Standard Control Organization (CDSCO) and the United States Food and Drug Administration (USFDA), using primary regulatory texts (the New Drugs and Clinical Trials Rules 2019, 21 CFR Parts 314 and 601, ICH Q12), agency guidance, and peer-reviewed literature, supported by two illustrative case analyses. USFDA was found to operate a mature, risk-tiered PLCM system — Prior Approval Supplements, CBE-30/CBE-0, and Annual Reports for major, moderate, and minor changes respectively — with extensive public guidance and defined timelines. CDSCO regulates post-approval changes mainly through case-by-case major/minor variation review, with limited formal adoption of ICH Q12 and no standalone PLCM document. A CDSCO initiative reforming review of imported-drug changes, built on reliance on stringent regulatory authority assessments, reduced review time by over 60% and cut submission deficiencies by about 40%. Formal harmonization of CDSCO's variation-management system with internationally recognized, risk-based PLCM practice is likely to improve efficiency, patient access, and India's integration into global pharmaceutical supply chains.

KEYWORDS: Product Lifecycle Management; Post-Approval Changes; Regulatory Harmonization; CDSCO; USFDA.**INTRODUCTION**

Product Life Cycle Management (PLCM) refers to the strategic and scientific oversight of a pharmaceutical product from early development through regulatory approval, commercial marketing, ongoing post-approval variation, and, eventually, withdrawal from the market. Its purpose is to ensure that a drug's safety, efficacy, quality, and availability are preserved at every stage of its commercial life, and that manufacturing and quality improvements identified after approval can be implemented in a timely, predictable manner.^[1-3]

International harmonization bodies play a central role in shaping PLCM practice. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) issues quality, safety, and efficacy guidelines that are widely adopted by regulators worldwide; ICH Q12, "Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management," specifically addresses the management of.^[4,6]

Chemistry, Manufacturing, and Controls (CMC) changes after approval through tools such as Established Conditions, Post-Approval Change Management

Protocols (PACMPs), and product lifecycle management documents. International Organization for Standardization (ISO) management-system standards (e.g., ISO 9001 for quality management, ISO 14001 for environmental management, ISO 45001 for occupational health and safety, and ISO 27001 for information security) reinforce the broader quality infrastructure within which lifecycle decisions are made, even though none of them is a drug-specific regulatory requirement.

Two regulators anchor the comparison in this study. USFDA, operating principally under the Federal Food, Drug, and Cosmetic Act and Title 21 of the Code of Federal Regulations, has built a mature, risk-tiered system for managing post-approval changes — Prior Approval Supplements (PAS) for major changes, Changes Being Effectuated in 30 days or immediately (CBE-30/CBE-0) for moderate changes, and Annual Reports for minor changes — supported by extensive publicly available guidance and a strong Quality-by-Design (QbD) orientation. CDSCO, functioning under the Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials (NDCT) Rules, 2019, regulates new drugs, clinical trials, and post-approval variations chiefly through major/minor variation categories reviewed on a case-by-case basis, with comparatively limited formal alignment to ICH Q12 and no standalone requirement for a PLCM document.^[6,8,10–13]

Given India's expanding role as a global manufacturer and exporter of generic medicines, and the increasing share of critical and innovative drugs imported into the Indian market, the degree of alignment between CDSCO and internationally harmonized PLCM practice has direct implications for drug availability, supply-chain resilience, and patient safety. This study therefore set out to describe the regulatory framework and PLCM practices of CDSCO, describe those of USFDA, and compare the two systems to identify harmonization gaps and opportunities.^[1,3,15,21]

AIM AND OBJECTIVES

Aim: To examine product lifecycle management of drugs through a comparative assessment of the regulatory approaches of USFDA and CDSCO, and to identify harmonization strategies between the two systems.

- To study the regulatory framework and practices of product lifecycle management (PLCM) of drugs under CDSCO (India).

- To evaluate the regulatory framework and practices of product lifecycle management (PLCM) of drugs under USFDA (United States).
- To compare the approaches of CDSCO and USFDA towards product lifecycle management of drugs and explore possibilities for regulatory harmonization.

MATERIALS AND METHODS

This is a comparative, document-based (desk) study rather than an experimental or clinical investigation. The methodology comprised four sequential steps applied to each of the study's three objectives.^[4,6,8,10–15]

- Regulatory document review: primary legal and regulatory texts were reviewed, including the New Drugs and Clinical Trials Rules 2019, Schedule Y of the Drugs and Cosmetics Rules 1945, CDSCO variation guidance, Title 21 CFR Parts 314 (NDA/ANDA) and 601 (BLA), USFDA guidance on post approval changes (SUPAC), and ICH Q12 and related quality guidelines.^[6,8,10–16]
- Literature synthesis: peer-reviewed articles, agency guidance documents, and industry position papers (e.g., the joint EFPIA–IFPMA–Vaccines Europe position on post-approval change management) were consulted to contextualize regulatory provisions and identify recognized harmonization gaps.^[15,19,21,23]
- Comparative mapping: reporting categories for post-approval changes, PLCM strategies for generics, institutional profiles, regulatory maturity, transparency, approval timelines, and harmonization status were tabulated side-by-side for CDSCO and USFDA.^[1,3,6,13–15]
- Case analysis: two illustrative cases were examined in depth — a CDSCO initiative to streamline post approval changes for imported drugs, and a broader assessment of harmonization gaps between mature (USFDA, EMA) and evolving (CDSCO) regulatory systems — to ground the comparative findings in operational experience.^[13–15]

No patient-level or experimental data were generated or analyzed; the study relies entirely on publicly available regulatory texts, agency websites, and published literature current as of the review period.^[4,8,10,15]

RESULTS AND DISCUSSION

Figure 1 places the study's scope within the overall pharmaceutical product lifecycle, from development through post-market review, highlighting the post-approval change stage that is the principal focus of the comparison that follows.

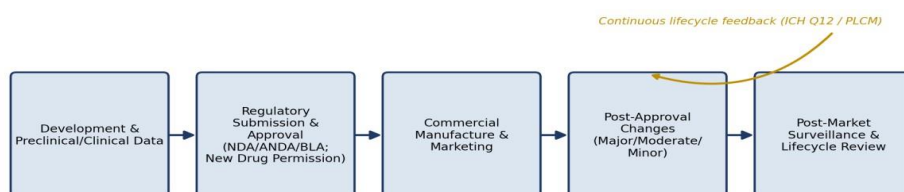


Figure 1: The pharmaceutical product lifecycle, showing the post-approval change and monitoring stage compared across USFDA and CDSCO in this study.

Institutional Profiles

The two agencies differ markedly in scale, budget, and organizational structure, reflecting their different regulatory histories. USFDA traces its origins to the Pure Food and Drug Act of 1906 and now operates as part of the U.S. Department of Health and Human Services, with an annual budget of approximately US \$7.2 billion (2025) and roughly 23,000 employees across constituent centers including the Center for Drug Evaluation and Research

(CDER) and the Center for Biologics Evaluation and Research (CBER). CDSCO, established under the Drugs and Cosmetics Act, 1940 and operational since 1945, functions under the Directorate General of Health Services with a comparatively modest annual budget (of the order of ₹13.7 crore) and a workforce of roughly 500–600, supported by 6 zonal offices, 4 sub-zonal offices, 13 port offices, and 7 Central Drug Testing Laboratories.

Table 1: Institutional profile comparison, USFDA and CDSCO.

Attribute	USFDA	CDSCO
Established	1906 (Pure Food and Drug Act); modern FDA structure evolved thereafter	1940 (Drugs and Cosmetics Act); operational from 1945
Headquarters	White Oak Campus, Maryland, USA	FDA Bhawan, Kotla Road, New Delhi, India
Parent agency	Department of Health and Human Services	Directorate General of Health Services (DGHS)
Approx. workforce	~23,000 (2025)	~500–600
Key constituent units	CDER, CBER, CDRH, CFSAN, and others	6 zonal, 4 sub-zonal, 13 port offices; 7 Central Drug Testing Laboratories

Regulatory Framework and PLCM Practices Under CDSCO

The New Drugs and Clinical Trials (NDCT) Rules, 2019, notified by the Ministry of Health and Family Welfare and effective 19–25 March 2019, superseded Schedule Y and Part XA of the Drugs and Cosmetics Rules. The NDCT Rules comprise 13 chapters and 8 schedules covering ethics committee registration, clinical trial and bioavailability/bioequivalence study conduct, compensation for trial-related injury or death, and the manufacture/import of new and investigational drugs. The Drugs Controller General of India (DCGI) functions as the Central Licensing Authority. A notable feature is the 'deemed approval' provision (Rule 23): applications for domestically discovered, developed, and manufactured drugs are deemed approved if the Central

Licensing Authority does not respond within 30 working days.^[10–13]

Post-approval changes under CDSCO are classified into major and minor variations, as summarized in Figure 2. Major variations — for example, a change in manufacturing site or equipment affecting critical quality attributes, a change in primary packaging material, an extension of shelf life beyond validated stability data, or a change in indication, dosage form, or route of administration — require prior CDSCO approval with comparative data and an updated dossier, and carry a nominal 45-day review timeline (deemed approved if unaddressed). Minor variations, such as non-critical process or secondary-packaging changes, require only notification within 30 days of implementation, without prior approval.^[10,11,13,14]

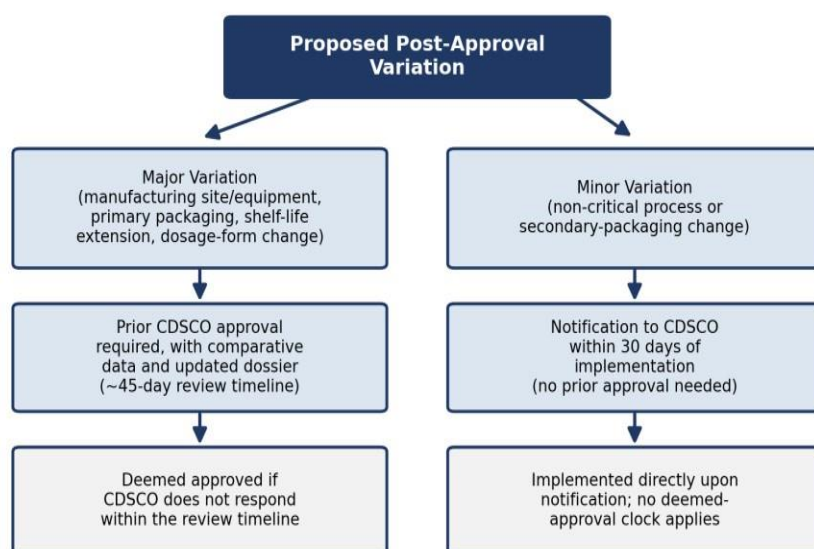


Figure 2: CDSCO classification and reporting pathway for post-approval major and minor variations under the New Drugs and Clinical Trials Rules, 2019.

Rule 2(w) of the NDCT Rules defines a 'new drug' broadly to include a drug not used in India to a significant extent, a previously approved drug now proposed with a modified or new claim, a fixed-dose combination not previously marketed in that ratio, a modified-release or novel delivery form of an approved drug, and biologics such as vaccines, recombinant DNA-derived products, monoclonal antibodies, stem-cell-derived products, genetherapy products, and xenografts. A drug retains 'new drug' status for four years from first approval or from its inclusion in the Indian Pharmacopoeia, whichever is earlier. Every sponsor of a clinical trial, bioavailability study, or bioequivalence study must register an Ethics Committee with the Central Licensing Authority, valid for five years, which reviews serious adverse events and reports to the Authority; compensation for trial-related injury or death is calculated using a formula specified in the Seventh Schedule.^[11,12]

Formal adoption of ICH Q12 and a standalone PLCM document remains limited in India for several structural reasons: India is not yet a full ICH member and harmonizes selectively; the NDCT Rules and existing CDSCO variation guidance do not formally recognize a PLCM document as a submission requirement; the variation management system remains case-by-case rather than lifecycle- and risk-based; and industry readiness — structured change-control systems, digital quality-management systems — varies across domestic manufacturers, many of whom prepare PLCM documentation mainly for export markets rather than for CDSCO.^[6,13–15]

Regulatory Framework and PLCM Practices Under USFDA

USFDA regulation of new drugs has, since 1938, centered on the New Drug Application (NDA), which packages nonclinical and clinical data to allow the agency to judge a drug's safety and efficacy, the adequacy of its proposed labeling, and the robustness of its manufacturing controls. Generic products instead follow the Abbreviated New Drug Application (ANDA) pathway under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, which relies on demonstrated bioequivalence to a reference listed drug rather than repeating full nonclinical and clinical programs. Both pathways, together with the Biologics License Application (BLA) for biological products, are submitted in the internationally harmonized Common Technical Document (CTD) format and, since May 2017, must be filed electronically (eCTD).^[8,16,17]

Post-approval changes under USFDA are tiered by risk under 21 CFR 314.70 (and the parallel biologics provisions in 21 CFR 601.12), as summarized in Figure 3: major changes require a Prior Approval Supplement (PAS) before implementation; moderate changes are filed as Changes Being Effected in 30 days or immediately (CBE-30/CBE-0); and minor changes are simply documented in the product's Annual Report. This tiering is reinforced by early and structured use of Quality-by-Design (QbD) and Quality-by-Report (QbR) concepts, an eCTD-based early-submission culture, and — through the Hatch-Waxman framework — a well-defined interface between patent (Paragraph IV) litigation and generic approval.^[8,16,18,22]

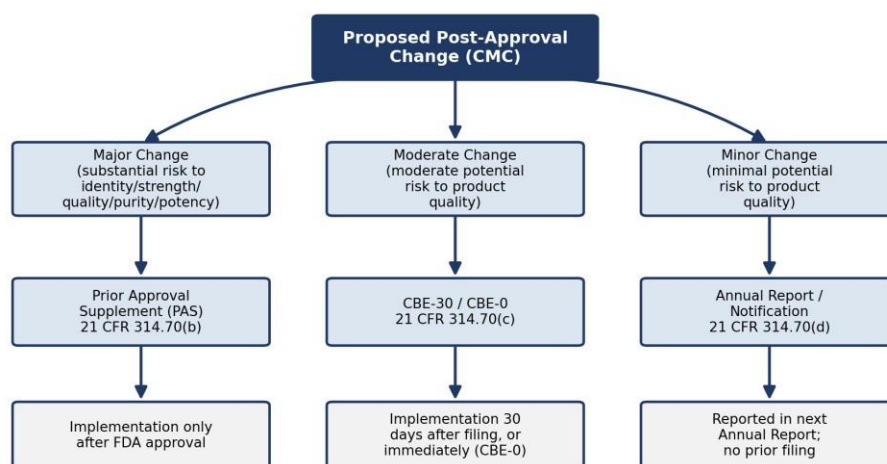


Figure 3: USFDA classification and reporting pathway for post-approval chemistry, manufacturing, and controls (CMC) changes under 21 CFR 314.70.

Economic and Public-Health Context

The comparative regulatory picture sits against a backdrop of rapid growth in India's pharmaceutical sector. India's pharmaceutical industry was valued at approximately US \$13 billion in 2017 and accounted for roughly 20% of global generic-drug exports by volume, making it the world's leading supplier of generic

medicines. National pharmaceutical market revenue was estimated at approximately US \$18.12 billion in 2018 (growing about 9.4% year-on-year), with export earnings of roughly US \$17.9 billion in 2018 and US \$19.1 billion in 2019. This scale of manufacturing and export activity — combined with recurring challenges such as fragmented central–state regulatory compliance and data-

integrity concerns — underscores why the pace and predictability of CDSCO's post-approval change processes carry consequences well beyond India's

domestic market, extending to global supply continuity for generic medicines.^[21,23]

Comparative Analysis: CDSCO versus USFDA

Table 2: summarizes the reporting-category logic for post-approval changes in the two systems, and **Table 3** contrasts early- and late-lifecycle PLCM strategy elements for generic products.

Table 2: Comparison of post-approval change reporting categories, USFDA and CDSCO.

Change category	USFDA reporting mechanism	CDSCO reporting mechanism
Major / high-impact change (e.g., manufacturing site, critical specification, labeling change)	Prior Approval Supplement (PAS); prior approval required	Major variation; prior CDSCO approval required (~45-day timeline; deemed approval if unaddressed)
Moderate change	Changes Being Effectuated in 30 days or immediately (CBE-30 / CBE-0)	Not formally distinguished; generally folded into major/minor categories
Minor change (e.g., non-critical process/packaging change) approval	Annual Report / notification only	Minor variation; notification to CDSCO within 30 days, no prior

Table 3: Environment for early- and late-lifecycle PLCM strategies, USFDA vs CDSCO (generics).

PLCM element	USFDA	CDSCO
Early submission approach	eCTD-based; structured early engagement	No equivalent formal provision
Quality submission approach	QbD / QbR frameworks embedded in review	No formal QbD submission requirement
Patent–approval interface	Hatch-Waxman patent linkage; Paragraph IV litigation common	No formal patent linkage; disputes less frequent but rising
Late-lifecycle change management	Tiered PAS / CBE-30 / CBE-0 / Annual Report system	Major/minor variation system; more detailed tiering only for imported biologicals

Beyond change-reporting mechanics, four broader dimensions distinguish the two systems: regulatory maturity, transparency and guidance, speed and predictability of approval, and harmonization/QbD-based flexibility. USFDA is highly mature and globally referenced, with well-structured IND/NDA/ANDA/BLA pathways, formal PLCM documentation, and strong QbD integration; it publishes extensive, centralized, and regularly updated public guidance and follows clearly

defined review timelines (roughly 10 months for standard review and 6 months for priority review of NDAs). CDSCO is an evolving authority with defined but less structured pathways; guidance is comparatively limited and scattered across circulars and notices; and approval timelines remain comparatively inconsistent despite the NDCT Rules 2019 introducing firmer deadlines such as the 30-workingday deemed-approval clock. Table 4 and Figure 4 summarize this broader comparison.^[6,8,10,13–15,18]

Table 4: Summary comparison of regulatory maturity, transparency, approval speed, and harmonization, USFDA vs CDSCO.

Dimension	USFDA	CDSCO
Regulatory maturity	Highly mature, globally recognized, formal PLCM/QbD integration	Evolving; structured pathways exist but PLCM/QbD adoption is partial
Transparency / guidance	Extensive, centralized, regularly updated public guidance	Limited, scattered across circulars/notices; less frequent updates
Approval speed	Defined timelines (e.g., ~10 months standard, ~6 months priority review)	Comparatively slower and less predictable, despite NDCT 2019 deadlines
Harmonization / risk-based flexibility	ICH Q12–aligned formal PLCM tools; strong QbD orientation	No formal PLCM document; limited QbD integration

	USFDA	CDSCO
Regulatory Maturity	Highly mature; formal PLCM/QbD integration	Evolving; PLCM/QbD adoption partial
Transparency & Guidance	Extensive, centralized, regularly updated guidance	Limited; scattered across circulars & notices
Approval Speed	Defined timelines (~10 mo standard, ~6 mo priority review)	Slower, less predictable, despite NDCT 2019 deadlines
Harmonization / Risk-Based Flexibility	ICH Q12-aligned formal PLCM tools; strong QbD	No formal PLCM document; limited QbD

Figure 4: Visual comparison of regulatory maturity, transparency, approval speed, and harmonization/risk-based flexibility, USFDA vs CDSCO.

Case Analyses

Case 1 — Streamlining post-approval changes for imported drugs (CDSCO). A large share of critical and innovative medicines sold in India are imported, with a local Marketing Authorization Holder (MAH) acting as intermediary for a change originating at an overseas manufacturing site. Historically, this required a lengthy priorapproval process, with communication gaps between the foreign manufacturer, the Indian MAH, and CDSCO contributing to delays and occasional supply disruption. As illustrated in Figure 5, CDSCO addressed this through

a four-phase intervention: structured consultations with multinational companies and their Indian affiliates to identify pain points; development of dedicated guidance for imported-product changes, including reliance on assessment reports from stringent regulatory authorities (SRAs) and a defined documentation checklist; a SUGAM portal module and pilot cohort to test the new workflow; and reviewer training on interpreting SRA assessment reports and global change-control protocols.^[10,15]

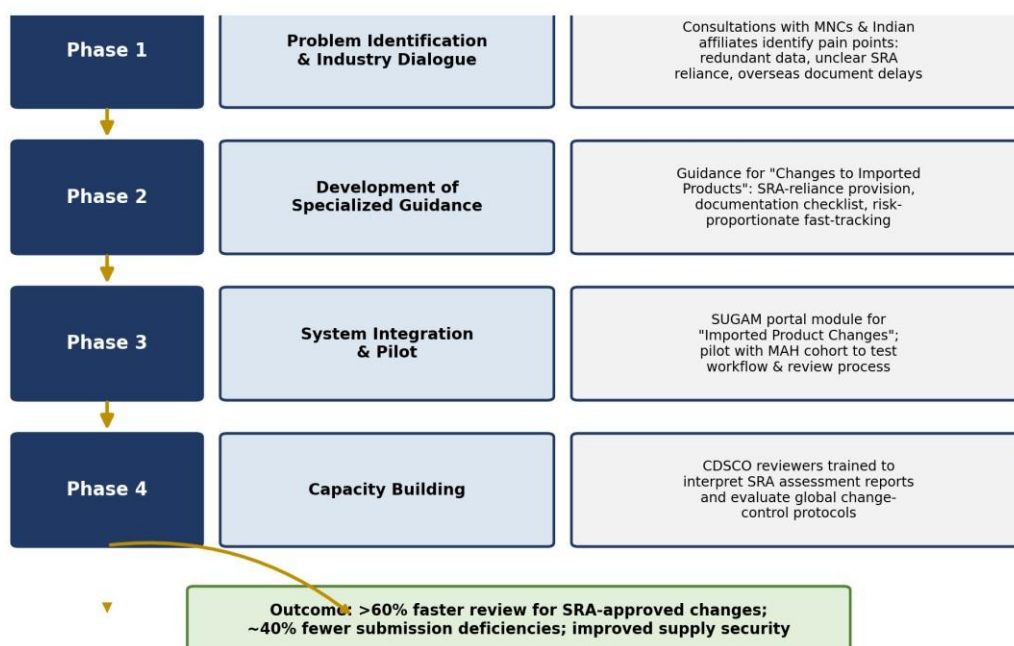


Figure 5: Four-phase CDSCO workflow for streamlining post-approval changes to imported drugs, and its measured outcomes.

The intervention reduced review time for SRA-approved changes by over 60% and cut submission deficiencies (queries/rejection letters due to incomplete applications) by roughly 40%, while also supporting supply-chain security and increasing global manufacturers' confidence in launching new products and quality upgrades in India concurrently with other markets.^[10,15]

Case 2 — Harmonization gaps between mature and evolving regulators. A broader comparative case examined structured-pathway design, approval speed and predictability, public accessibility of guidance, and integration of risk-based/lifecycle approaches across USFDA, the European Medicines Agency (EMA), and CDSCO. FDA and EMA were found to maintain well-defined, structured pathways and detailed public guidance, formal lifecycle management tools aligned with ICH Q12, and integrated QbD elements. CDSCO pathways, by contrast, were found to be evolving and less transparent, with inconsistent timelines, limited structured post-approval flexibility, and minimal formal QbD integration — collectively slowing India's alignment with globally harmonized regulatory science and, per the analysis, adding to industry burden and delaying patient access to certain product improvements.^[6,8,10,13–15]

DISCUSSION

The comparison indicates that CDSCO and USFDA share the same underlying objective — safeguarding drug safety, efficacy, and quality across the product lifecycle — but differ substantially in the tools used to achieve it. USFDA's tiered PAS/CBE-30/CBE-0/Annual Report system, embedded QbD expectations, and extensive public guidance give sponsors a predictable, risk-proportionate pathway for implementing post-approval improvements. CDSCO's major/minor variation system, while functional, remains largely case-by-case, without a formally recognized PLCM document, and with guidance that is less centralized and less frequently updated. This gap is not simply administrative: it has practical consequences, from slower access to manufacturing or quality upgrades to a comparatively higher burden on sponsors preparing region-specific submissions.^[6,8,10,13–15,18]

The imported-drugs case study offers a concrete illustration of how targeted regulatory reliance can close part of this gap without requiring a full ICH Q12 transplant. By accepting SRA assessment reports for changes already approved elsewhere, clarifying documentation expectations, and risk-prioritizing supply-critical changes, CDSCO achieved a measurable reduction in both review time and deficiency rates. This suggests that incremental, reliance-based reforms — rather than a single comprehensive overhaul — may be a pragmatic route toward harmonization given India's current ICH-observer status and industry readiness constraints. At the same time, the harmonization-gap case study underscores that reliance-based fixes for imported products do not, by themselves, resolve the more

systemic gaps in structured pathway design, timeline predictability, and QbD integration that persist across CDSCO's broader post-approval change framework.^[6,10,13,15]

Strengths and Limitations

The principal strength of this analysis lies in its side-by-side mapping of primary legal texts (NDCT Rules 2019, 21 CFR Parts 314/601, ICH Q12) against two operational case studies, which grounds the comparison in demonstrated outcomes rather than in guidance language alone. The study is nonetheless subject to the limitations inherent in a document-based comparative analysis: it relies on publicly available regulatory texts and secondary literature rather than primary quantitative data across a large, representative sample of approvals or variations; it does not independently verify agency-reported performance statistics; and regulatory practice — particularly CDSCO's variation guidance and digital tooling such as the SUGAM portal — continues to evolve. The findings should therefore be read as a structured snapshot of the current comparative landscape, and future work using prospective timeline audits across a larger sample of post-approval change submissions would help quantify the gaps identified here more precisely.^[6,8,10,13–15]

Future Perspectives

- Regulatory harmonization: formal alignment of CDSCO's variation-management system with USFDA/EMA practice, including recognition of PLCM documents, Established Conditions, and PostApproval Change Management Protocols.
- Digital transformation and transparency: expansion of the SUGAM portal for lifecycle tracking and variation submission, together with a centralized, searchable repository of CDSCO guidance.
- Capacity building: continued training of CDSCO reviewers in reliance-based assessment and ICH guidelines, alongside strengthened technical capability among Indian Marketing Authorization Holders.
- Quality-by-Design integration: progressive incorporation of Design Space, Critical Quality Attributes, and Control Strategy elements into dossiers.
- Patient-centric lifecycle oversight: incorporation of real-world evidence and post-marketing surveillance data into lifecycle decisions.

CONCLUSION

Product Life Cycle Management is central to ensuring that medicines remain safe, effective, and of consistent quality from development through post-market use. Both USFDA and CDSCO pursue this goal, but from markedly different positions of regulatory maturity. USFDA's structured, risk-based, and internationally harmonized system supports faster, more predictable post-approval decision-making, while CDSCO's system, though

strengthened by the NDCT Rules 2019 and targeted initiatives such as the imported-drugs reliance pathway, continues to rely mainly on case-by-case variation review and has yet to formally adopt ICH Q12 or a standalone PLCM document. Closing this gap through formal harmonization, expanded regulatory reliance, digital lifecycle infrastructure, and sustained capacity-building would benefit patients, industry, and regulators alike.^[6,8,10,13-15]

ACKNOWLEDGEMENT

The authors thank the Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, Tumkur, and Dr. P. Ashok Kumar for guidance and supervision of the underlying project work from which this article is derived. This work received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors, and the authors declare no conflicts of interest.

REFERENCES

1. Mousavi A, Mohammadzadeh M, Zare H. Developing a system dynamic model for product life cycle management of generic pharmaceutical products: its relation with open innovation. *J Open Innov Technol Mark Complex*, 2022; 8(1): 14.
2. Prajapati V, Dureja H. Product lifecycle management in pharmaceuticals. *J Med Mark*, 2012; 12(3): 150-8.
3. Tripathy S, Murthy PN, Patra BP. Integrating PLCM strategy in pharmaceutical emerging market. *Int J Drug Regul Aff*, 2018; 6(4): 21-32.
4. International Council for Harmonisation (ICH). Quality guidelines [Internet]. Available from: <https://www.ich.org/>
5. International Organization for Standardization (ISO). ISO 9001, 14001, 27001, 45001 [Internet]. Available from: <https://www.iso.org/>
6. ICH. Q12: Technical and regulatory considerations for pharmaceutical product lifecycle management. In: International Conference on Harmonisation, 2017.
7. Venna SR. Overcoming submission challenges in post-market surveillance and lifecycle management. SSRN, 2019.
8. US Food and Drug Administration [Internet]. Available from: <https://www.fda.gov>
9. Reynolds IS, Rising JP, Coukell AJ, Paulson KH, Redberg RF. Assessing the safety and effectiveness of devices after US FDA approval: FDA-mandated postapproval studies. *JAMA Intern Med.*, 2014; 174(11): 1773-9.
10. Central Drugs Standard Control Organization (CDSCO) [Internet]. Available from: <https://cdsco.gov.in>
11. Dubey A, Kotian B, Shriram RG. New drugs and clinical trials rules, 2019: towards fast-track accessibility of new drugs to the Indian population. *Indian J Pharm Educ*, 2019; 53: s451-9.
12. Sahai R, Parveen A. A brief review of amendments Schedule Y (2005-2018) and NDCT Rules, 2019.
13. Moorkoth S, Haldar T. Post-approval change submission: ICH Q12 impact analysis on India and Japan. *Indian J Pharm Sci*, 2020; 82(1).
14. Lokesh MS, Gupta NV, Belagoankar BD. Comparative study of process of post approval change application submission and approval for marketing authorization variations in EU, US, India, Saudi Arabia and Singapore. *Int J Drug Dev Res*, 2015; 7(1): 1022.
15. Deavin A, Adam S, Ausborn S, Nielsen AS, Cappellini S, Colmagne-Poulard I, et al. Path forward to optimise post-approval change management and facilitate continuous supply of medicines and vaccines of high quality worldwide: joint position from EFPIA, IFPMA and Vaccines Europe. *Ther Innov Regul Sci*, 2023; 57(1): 7-11.
16. US FDA. New drug applications [Internet]. Available from: <https://www.fda.gov/drugs/types-applications/new-drugapplication-nda>
17. Sharmila SK, Bonthagarala B, Nagabhushanam MV, Ramakrishna G, Sindhu SY. Abbreviated new drug application (ANDA) filing checklist. *World J Pharm Pharm Sci*, 2021; 10(9).
18. Michaeli DT, Michaeli T, Albers S, Boch T, Michaeli JC. Special FDA designations for drug development: orphan, fast track, accelerated approval, priority review, and breakthrough therapy. *Eur J Health Econ*, 2024; 25(6): 979-97.
19. George B, Kulkarni SK, Kshirsagar NA. Regulatory requirements and quality standards in India's clinical trials journey. In: *Drug Discovery and Drug Development: The Indian Narrative*. Singapore: Springer, 2021; 283-302.
20. Bhaduri S, Kipgen T. 'New drugs' approvals in India: an institutional perspective. *Sci Technol Soc*, 2018; 23(3): 444-62.
21. Pandian PD, Kaliyaperumal R. Global and Indian regulatory frameworks for pharmaceutical excipients, APIs, and formulations: challenges and harmonization strategies. *Recent Adv Drug Deliv Formul*, 2025.
22. Rathore AS, Winkle H. Quality by design for biopharmaceuticals. *Biotechnol Prog*, 2009; 25(1): 40-50.
23. Sharma M, Grover M, Suryavanshi SJ, Sharma N, Shukla VK. Comparative review of clinical trial regulations in different countries: current scenario and future prospect. *Rev Recent Clin Trials*, 2025.