



**INTERNATIONAL JOURNAL OF  
PHARMACEUTICAL SCIENCES**  
[ISSN: 0975-4725; CODEN(USA):IJPS00]  
Journal Homepage: <https://www.ijpsjournal.com>



## Review Article

# Comparative Study Between Regulatory Quality System Of India And USA

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### ARTICLE INFO

Received: 04 Sep 2024

Accepted: 08 Sep 2024

Published: 17 Sep 2024

#### Keywords:

Regulatory quality systems, medical devices, post-market surveillance, enforcement mechanisms, quality assurance practices.

#### DOI:

10.5281/zenodo.13774364

### ABSTRACT

Regulatory quality systems play a critical role in ensuring public safety, product efficacy, and market efficiency across various industries. This comparative study aims to examine and contrast the regulatory frameworks in two significant economies: India and the United States of America. By analyzing the regulatory processes, enforcement mechanisms, and overall quality assurance practices in these countries, this research sheds light on the strengths and weaknesses of each system. The study begins by providing a comprehensive overview of the regulatory landscape in both countries, highlighting the key agencies responsible for overseeing diverse sectors, such as pharmaceuticals, medical devices, food and agriculture, and environmental protection. Subsequently, it delves into the legislative frameworks, guidelines, and standards that govern the approval, marketing, and post-market surveillance of products and services. The research analyzes the efficiency and transparency of the regulatory procedures in India and the USA, assessing factors such as time-to-market for new products, adherence to international standards, and opportunities for stakeholder engagement. It also evaluates the degree of coordination and cooperation between regulatory agencies, public-private partnerships, and efforts to combat corruption and undue influence on the decision-making process.

### INTRODUCTION

The term "regulatory system" includes a complete set of guidelines, organized processes, and clinically proven mechanisms that are designed to uphold and standardized the upcoming product [1]. The main motto of creating a regulatory

system is to control the quality variation as well as maintain the specification of a complex system. Various domains like biological, financial, and technical are more-over government-specified areas, like business and commercialization so the

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



quality system is all about safety, efficacy, and standardization. In this globe, two giant nations India and USA have their regulatory committees and they have remarkable stake holding bodies responsible for manufacturing and supply chain management of pharmaceutical products. Albeit the regulatory systems of the two nations are well-established, there are some remarkable differences between them. [1,2] In the US, the Food and Drug Administration (FDA) is a prestigious directing body. FDA rules must be trailed by pharmaceutical products to guarantee their quality, safety, and efficacy. The FDA implements severe guidelines through different cycles, including pre-market approval, post-market surveillance, inspections, and enforcement actions [3]. The severe standards and broad assessment cycles of the American regulatory system can be credited for their importance in the pharmaceutical business [4]. The FDA needs broad clinical trials and data before endorsing new drugs. By doing this, the strictest safety and efficacy standards are fulfilled before pharmaceutical products are made accessible on the market. Moreover, to guarantee that GMPs and quality control standards are being adhered to, the FDA regularly inspects manufacturing destinations [5, 6]. The Central Drugs Standard Control Association (CDSCO), under the course of the Ministry of Health and Family Welfare, is responsible for managing pharmaceutical control. The CDSCO is liable for managing all parts of pharmaceutical item import, manufacture, distribution, and deals in India. The regulatory framework for the pharmaceutical industry in India is critical because it endeavours to combine the requirements for available pharmaceuticals at sensible rates with maintaining elevated expectations of quality. The flourishing generic pharmaceutical industry in India has given the country the moniker "pharmacy of the creating scene." [7,8] The CDSCO is a crucial participant; it in guaranteeing that generic drugs meet quality

requirements by directing inspections, requiring licenses, and performing surveillance activities. In any case, it's important to remember that the validity and effectiveness of the Indian regulatory system have proactively been addressed. Because of allegations of subpar and fake pharmaceuticals, concerns have been raised about the overall quality assurance in the Indian pharmaceutical industry [9, 10].

#### **OBJECTIVE:**

The prime agenda of these comparative studies is to identify as well as analyze the area of similarity & dissimilarity and the approaches towards implementation of the new regulation. The purpose of these studies includes:

- Identifying best practices: The policymakers uphold in introducing new policies by comparing studies between two major countries. These will be more beneficial as the applicability is justified and produce improved and efficient guidelines.
- Learning from failures: The analytical data about shortcomings or the failure mode analysis outcome is beneficial for avoiding implementation mistakes of policies. Thus, it acts as a safeguard against potential risk. Analyzing the failures or shortcomings of regulatory systems in both countries can help avoid repeating similar mistakes and implement safeguards to prevent potential issues.
- Encouraging regulatory convergence: Analysis and differences and similarities can uphold the cooperation between two major countries in a regulatory sector which leads to enhanced smooth cross-border business, easy investment, and legal issues.
- Informing international organizations: The comparative study can facilitate the formation of standard guidelines on the international stage. This will develop a better and standard



international guideline that can be applicable throughout the globe.

## COMPARATIVE STUDY BETWEEN REGULATORY SYSTEM-USA & INDIA

**Table 1. Comparative study between regulatory system-USA & India [6]**

CONTENTS	INDIA	USA
Authority	CDSCO (Central Drug Standard Control Organisation) /SDSCO (state Drug standard Control Organisation) (responsibilities is divided on centralized and state authorities)	Food Drug and Administration (FDA) (single body regulates the drugs and responsible for all regulatory tasks)
Guidelines	Schedule Y and ICMR bioethics guidelines.	ICH-GCP
Legal framework	Indian directives applicable to all members.	Federal status and regulations applicable to all 50 states.
	National Laws apply.	Individual state laws apply.
	Legal representative required  DCGI written approval required to commence Clinical trials	Authorized representative required  IND written approval not required to proceed commences Clinical trials.
	Approval time frame varies, before that Clinical Trials not proceeds further.	May proceed 30 days after FDA receives IND unless notified otherwise.
	Progress report required to submit every six month.	IND annual report required
	Schedule Y Format paper or electronic (CTD format is optional)	It is mandatory that the dossier prepared in CTD format
	Fees apply	No fees apply
IRB/IEC (Institutional Ethics Committee)	Single review process	2 review process : Normal and accelerated review process
	Registered IEC approval required  EC appointed or authorized	IRB (Institutional Review board) approval required  IRB registration required
EC Composition	-At least 5-7 members.  - The quorum should have a minimum 5 members.  - Member secretary belongs to the same institution.	- At least 5 members.  - Not detailed.  - Not recommended.

Conduct of Clinical trials	Undertaking by the Principal Investigator as per Appendix VII of Schedule Y of Drug and Cosmetic Rules.	Form FDA 1572 is required to be signed by the PI, if study is conducted in US and submitted to IND.
	Form 44, 12, Certification of Analysis, PIS & JCF as per Appendix V of Schedule Y.	Form FDA 3674 certification that all requirements of section 402 (j) of PHS Act are met.
	Protocol amendment implementation varies.  Protocol waivers considered a breach of GCP (Good Clinical Practice).	Protocol amendments may be implemented once received by FDA, with exceptions (eg. safety issued or protocol study design issues).  Protocol waivers are acceptable under certain circumstances.
Informed Consent Process	Patient & Investigator's should sign in the consent form. Investigator, subject & subject's LAR audio video consent recording would be mandatory.	Any one designated by the investigator to conduct and to sign the consent form.
Record Retention	Record retention for at least 3 years.	Record retention 2 yrs after marketing application is approved.  Record retention 2 yrs after last shipment and delivery of Investigational Manufacturing Product if marketing application is not approved. <sup>4</sup>
IMP requirement	Label language requirement varies between states.	Label must be in English, except for Puerto Rico.
	Label should include the name and contact numbers of investigator and name of the institute.	The following statement is required "Caution: New drug united by federal law to investigational use."
Regulatory Compliance	Schedule Y (Refer to Rules 122A, 122B, 122D, 122DAA & 122E)	All clinical trials must comply with 21 CFR parts 50, 54, 56, 58 and 312.
Time for Regulatory Approval of Clinical Trial Agreement/ IND Application	Category A: 2-4 Weeks Category B: 8-12 Weeks.	30 days
Time for Evaluation of MAA (marketing authorisation application)	8-12 weeks	180 days
MAA Fee	50,000 INR	\$217,787

A Site Master File is well-prepared documentation containing factual information and specification about the product and manufacturing control process [11, 12]. These two major countries have

their own GMP guidelines for Site Master File. The comparison of similarity and dissimilarity are as follows-

**Table 2. General compares between Schedule M (INDIA) and USFDA guidelines[8]**

Sl No	SCHEDULE M	USFDA
1	"General information"	"General information on the manufacture"
2	"Employee"	"Employee"
3	"Manufacturing Premises"	"Manufacturing Premises"
4	"Require Document"	"Require Document"
5	"Production"	"Production"
6		"Quality management system on the manufacture"
7	"Quality control"	"Quality control"
8	"Product Distribution & complaints and recalls"	"Product Distribution & complaints and recalls"
9	"Self-inspections"	"Self-inspections"
10	"Loan license"	

	manufacture and licensee”	
11	“Sanitation”	
12	“Export of drugs”	

**Table 3. Working process comprise between Schedule M (INDIA) and USFDA guidelines [10]**

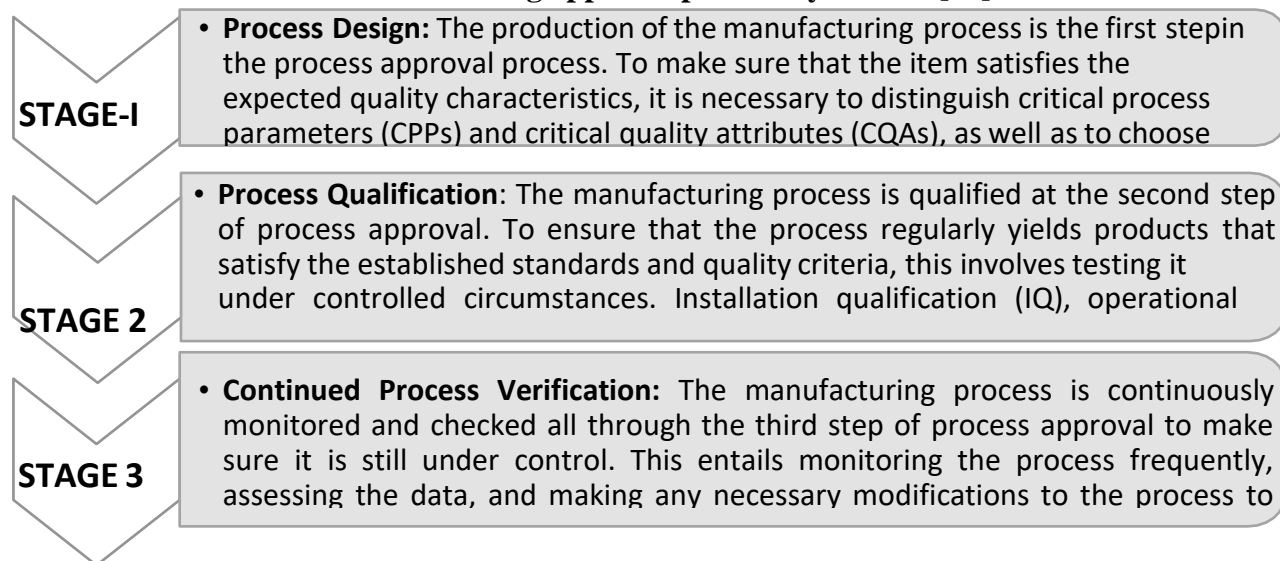
Schedule M (INDIA)	USFDA
<ul style="list-style-type: none"> <li>Schedule M details the development of PART1</li> <li>GMP for premises and materials</li> <li>GMP and requirements of premises Plant and equipment for pharmaceutical products</li> </ul>	<ul style="list-style-type: none"> <li>USFDA outlines the manufacturing section in 211-cGMP for the finished product</li> <li>e-CFR Title 21</li> <li>Chapter I Subchapter C</li> </ul> <b>PART 21 SUBCHAPTER F- Production and process control.</b>
<p><b>3. Area of production</b></p> <p>The area of development is designed to enable the production, ideally in unit-flow also with a logical number of operations. Separate dedicated and self-contained manufacturing facilities for a critical medicinal drug such as penciling or live micro-organism biological preparation shall be made available to order to prevent possible cross-contamination. Working and in-process space shall be sufficient to allow orderly, and placement of equipment and material and movement of staff to prevent cross-contamination and risk of any manufacturing or wrongly applied.</p> <p>3.4. Piping, electrical connection and air leakage, and common services line are planned, fixed, and built for the avoidance purpose.</p> <p>* (Part 1 – Schedule M, 2019)                  ** (Part 211— USFDA, 2016)</p>	<p>Production and process control</p> <p>211.100: Written procedure; deviation</p> <p>211.101: Charge in of compound</p> <p>211.103: Calculation of yield</p> <p>211.105: Equipment of identification</p> <p>211.110: Sampling and testing of in-process material and drug product</p> <p>211.113: Control of microbiological contamination</p> <p>211.115: Reprocessing [2] [4]</p>

**Drug Approval process by respective regulatory bodies (USFDA & CDSCO)**

The FDA's Current Good Manufacturing Practices (cGMP) requirements mandate process approval. It is a formalized methodology for ensuring that a

manufacturing process consistently results in an item that satisfies established requirements and standards for quality [13,14]. The FDA's process approval guidelines are momentarily described below:

**Table 4. Drug approval process by USFDA[11]**



The need of taking on a risk-backed strategy for process approval is emphasized in the FDA's process approval recommendations. This implies that the amount of approval required for a specific strategy should be determined by its possible impact on persistent safety and item quality. The recommendations emphasize the benefit of documenting during the process of process

approval, including the production of test plans, reports, and protocol development[15, 16].

**Drug Approval Process by CDSCO:**

The Central Drugs Standard Control Organization (CDSCO), India's public regulatory organization for pharmaceuticals and medical devices, oversees the licensing process for drugs [17, 18]. Here is a fast once-over of India's medication approval methodology:

**Table 5. Drug approval process by CDSCO [12]**

<p><b>Pre-Clinical Examination:</b> Pre-clinical research, which incorporates laboratory testing and animal experiments to ascertain the safety and effectiveness of the medicine, is the first step in the drug development process</p>
<p><b>Investigational New Drug (IND) Application:</b> Before human clinical trials can start, the drug sponsor must submit an IND application to the CDSCO, which includes data from pre-clinical testing and a proposed clinical preliminary protocol.</p>
<p><b>Review and Approval:</b> The CDSCO reviews the NDA and makes a decision on whether to support the drug for marketing in India. The review process can require as long as 12 months, contingent upon the complexity of the drug</p>
<p><b>Post-Marketing Surveillance:</b> When a drug is supported, the CDSCO monitors its safety and efficacy through post-marketing surveillance programs. These programs are designed to recognize and manage any adverse events associated with the use of the drug.</p>
<p><b>Clinical Trials:</b> Clinical trials in India adhere to worldwide guidelines for Good Clinical Practice (GCP). Clinical trials are conducted in three phases, with each phase designed to give extra data on safety and efficacy.</p>
<p><b>New Drug Application (NDA) Submission:</b> When the clinical trials are complete, the drug sponsor submits a NDA to the CDSCO, which includes data from the clinical trials, as well as information on the manufacturing process, naming, and packaging.</p>
<p><b>Review and Approval:</b> The CDSCO reviews the NDA and makes a decision on whether to support the drug for marketing in India. The review process can require as long as 12 months, contingent upon the complexity of the drug.</p>
<p><b>Post-Marketing Surveillance:</b> When a drug is supported, the CDSCO monitors its safety and efficacy through post-marketing surveillance programs. These programs are designed to recognize and manage any adverse events associated with the use of the drug.</p>

It is important to take note that the drug approval process in India is persistently advancing, with efforts being made to streamline the process and make it more productive. Moreover, India has as of late implemented a system for sped-up review of specific drugs, such as those for uncommon diseases, to assist with ensuring that patients have timely access to inventive treatments [19, 20].

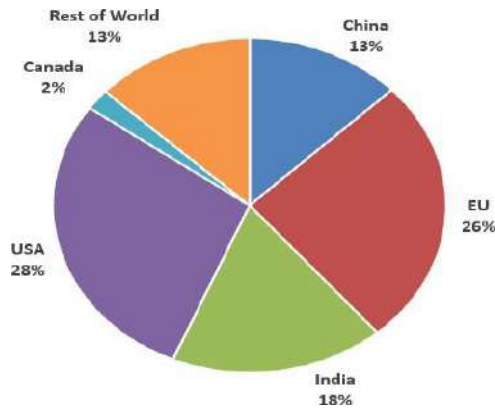
### **India and USA pharmaceutical market improvement up to the current situation**

The pharmaceutical industries in the two India and the US have seen progress and development as yet [21]. With a fixation on research and development

as well as a developing emphasis on quality control and regulatory compliance, the pharmaceutical sector in India has been contributing significantly to the development of the country's economy [22].

The Indian pharmaceutical industry, which developed at a CAGR of 14.5% from 2015 to 2020, was estimated to be worth \$41 billion in 2020, according to research by the India Brand Value Establishment[23].





**Fig 1. Percentage of API manufacturing facilitates for all drugs Region [13]**

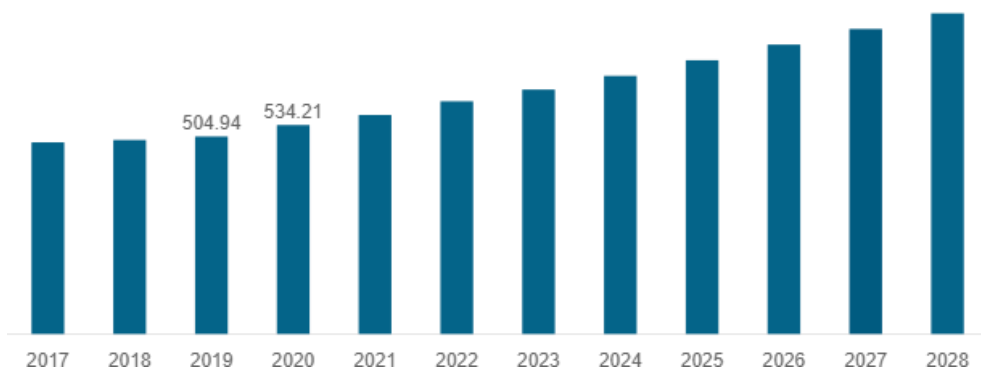
By 2030, the market is projected to increase at a CAGR of 15% to \$130 billion, impelled by factors including rising healthcare awareness, rising demand for generic medications, and government measures to overhaul the healthcare system. [24,25] The pharmaceutical industry in the US has also continued to expand, with an emphasis on innovation and legitimate compliance. According to a Statistic analysis, the market was estimated to be worth \$445.6 billion in 2020 and is expected to rise at a CAGR of 5.6% from 2021 to 2025 to reach \$625.4 billion. With programs like the Affordable Consideration Act and the current drive to reduce prescription prices, the market has seen a rising

emphasis on accessibility and affordability of healthcare.[26,27,28] The COVID-19 pandemic has also impacted the two sectors, driving rising demand for pharmaceuticals and medical equipment [29]. With multiple Indian firms working in partnership with foreign businesses to research and deliver vaccinations, the Indian pharmaceutical sector has been actively engaged in the manufacturing of COVID-19 medications and vaccines [30,31]. Also, the US pharmaceutical sector has created COVID- 19 medications and vaccinations, with many businesses getting FDA emergency use authorizations.[32]



**Fig 2. Business growth for Indian Pharmaceutical market [19]**

## U.S. Pharmacy Market Size, 2017-2028 (USD Billion)



**Fig 3. Marketing Growth analysis of US**

In conclusion, the pharmaceutical markets in two India and the US have continued to expand and create up to the present, driven by elements like innovation, regulatory compliance, and a developing focus on healthcare accessibility and cost[34]. The two markets have been affected by the COVID-19 epidemic, which has raised demand for pharmaceuticals and medical supplies [35].

## REFERENCES

1. TGA/Pics 2018. Describes the Production in a guide to good manufacturing Practice for medicinal products. Part I. Chapter 5 – Production. Describes the Production in a guide to good manufacturing. Pages: 54. [Accessed On 1 July 2018]
2. Barton, P. 2007. The Great Quinine Fraud”: Legality Issues in the “Non-Narcotic” Drug Trade in British India. *The Social History of Alcohol and Drugs* 22(1):6–25.
3. Harper, I. 2007. Good Manufacturing Practice in the Pharmaceutical Industry—Working Paper 3, prepared for Workshop on 'Tracing Pharmaceuticals in South Asia', 2–3 July. The University of Edinburgh. The Centre for International Public Health Policy. [http://www.csas.ed.ac.uk/data/assets/pdf\\_file/0011/38828/GMPinPharmaIndustry.pdf](http://www.csas.ed.ac.uk/data/assets/pdf_file/0011/38828/GMPinPharmaIndustry.pdf) Pages: 02-35
4. Part 211— USFDA 2016. Current Good Manufacturing Practice for Finished Pharmaceuticals -e-CFR data is current as of January 12,2016. <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations> [Accessed on 21 September 2020]
5. Part 1 – Schedule M 2019. Good Manufacturing Practices for Premises and Materials of Good Manufacturing Practices and Requirements of Premises. <https://ipapharma.org/wp-content/uploads/2019/02/schedule-m-1.pdf> Plant and Equipment for Pharmaceutical Products. [Accessed on February 2019]
6. MHRA 2020. Manufacturers. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/400232/Guidance\\_for\\_specials\\_manufacturers.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/400232/Guidance_for_specials_manufacturers.pdf) Medicines and Healthcare Products Regulatory Agency. Pages: 41. [Accessed on 15 January 2015]
7. EU GMP guide part II 2006. Guidance on Good Manufacturing Practice (GMP)-Production. Humaregulatory. <https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/guidance-good-manufacturing-practice-good-distribution-practice-questions-answers> European



- Medicines Agency. [Accessed on 15 July 2006].
8. Singh, S H. 2005. Government of India Ministry of Health and family welfare department of Health and family welfare Lok Sabha unstarred question no. 655.
  9. Haleem, RehemM. 2015. Quality in the pharmaceutical industr – A literature review. *Saudi Pharmaceutical Journal* 23(5):463–469.
  10. Food and Drug Administration - Sterile Drug Process Inspection. Accessed 26 September 2013.2.
  11. Schedule M, Part I-A, Specific Requirements for Manufacture of Sterile Products, Parenteral Preparations and Sterile Ophthalmic preparations. Accessed 26 September 2013.3.
  12. Guidance for Industry for Sterile Drug Products Produced by Aseptic Processing and accessed 1 November 2013.4.
  13. 21 CFR 211 - Current Good Manufacturing Practice In Manufacturing, Processing, Packing or Holding of Drugs; Current Good Manufacturing Practice For. Accessed 27 September 2013.5.
  14. J. E. Enders. Quality assurance and control, In Gennaro A. R. (Eds), Remington: The Science and Practice of Pharmacy, Vol. I, Lippincott Williams & Wilkins, New York, 2000, pp. 980-985.
  15. L. Lachman, S. A. Hanna, and K. Lin. Quality control and assurance, In Lachman L, Lieberman H. A, Kanig J. L. (Eds.), The Theory and practice of industrial pharmacy, Verghese Publishing House, Bombay, 1976, pp. 804-855.
  16. Rose and H. Kenneth. Project Quality Management: Why, What and How, J. Ross Publishing, Fort Lauderdale, Florida, 2005, pp. 41.
  17. S. K. Mandal. Introduction to TQM: In TQM, Principles and practice, Vikas publishing house, New Delhi, Second reprint, pp. 1-18.
  18. Lakshmana Rao, M. Bharani, Y. Madhu and G. G. Sankar. TQM: The Need of New Era, *Indian J. Pharm. Educ. Res.* 39(4): 203-206 (2005).
  19. Hoyle and David. Quality Management Essentials, Oxford, United Kingdom: Butterworth-Heinemann, 2007, pp. 200.
  20. Pfeifer and Tilo. Quality Management: Strategies, Methods, Techniques, Munich, Germany: Carl Hanser Verlag, 2002, pp. 5.
  21. L. Rao. TQM: The need for a new era, *Indian Journal of Pharmaceutical Education* 39(4): 203 (2005).
  22. M. Bhaskar, B. Sanjib and Y. Abhishek. TQM in pharmaceuticals: A review, *Int. J. Pharm Tech Res.*
  23. De Feo, A. Joseph and W. Barnard. Juran Institute's six sigma breakthrough and beyond - quality performance breakthrough methods, Tata McGraw-Hill Publishing Company Limited, 2005.
  24. J. F. Krafcik. Triumph of the lean production system, *Sloan Management Review*, 30 (1): 41–52 (1988).
  25. T. Ohno. Toyota Production System, Productivity
  26. B. Zhou, "Lean principles, practices, and impacts: a study on small and medium-sized enterprises (SMEs)," *Annals of Operations Research*, pp. 457-474, 2012.
  27. M. Demirbag, E. Tatoglu, M. Tekinkus and S. Zaim, "An analysis of the relationship between TQM implementation and organizational performance: Evidence from Turkish SMEs," *Journal of Manufacturing Technology Management* 17(6), pp. 829-847, 2006.

28. M. Trahan and V. Kapoor, "TQM journey of an Indian milk-producing cooperative," *The TQM Journal* 23(4), pp. 423-434, 2011.
29. M. Hizballah, L. Gutiérrez-Gutiérrez and J. F. M. Rosas, "Total quality management practices, competitive strategies, and financial performance: the case of the Palestinian industrial SMEs," *Total Quality Management & Business Excellence* 25(5-6), pp. 635- 649, 2014.
30. V. R. Kannan and K. C. Tan, "Just in time, total quality management, and supply chain management: understanding their linkages and impact on business performance," *Omega* 33(2), pp. 153-162, 2005.
31. Sila, "Examining the effects of contextual factors on TQM and performance through the lens of organizational theories: an empirical study," *Journal of Operations Management* 25(1), pp. 83-109, 2007.
32. R. Sousa and C. Voss, "Contingency research in operations management practices," *Journal of Operations Management* 26(6), pp. 697-713, 2008.
33. Yang, C. W. Y. Wong, K. -H. Lai and A. N. Ntoko, "The antecedents of dyadic quality performance and its effect on buyer-supplier relationship improvement," *International Journal of Production Economics* 120(1), pp. 243-251, 2009.
34. M. Kumar and J. Antony, "Comparing the quality management practices in UK SMEs," *Industrial Management & Data Systems* 108(9), pp. 1153-1166, 2008.

**HOW TO CITE:** Rahul Patra , Souvik Kundu , Debraj Paul , Jaydip Ray, Comparative Study Between Regulatory Quality System Of India And USA, *Int. J. of Pharm. Sci.*, 2024, Vol 2, Issue 9, 837-847. <https://doi.org/10.5281/zenodo.13774364>

