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Good Manufacturing Practices (Gmp) And Regulatory Challenges In The Pharmaceutical Industry: A Comprehensive Review

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ABSTRACT

Good Manufacturing Practices (GMP) form the cornerstone of quality assurance in the pharmaceutical industry, ensuring that medicinal products are consistently produced and controlled according to established quality standards. Compliance with GMP is critical for safeguarding patient safety, maintaining product efficacy, and ensuring regulatory approval across global markets. However, the pharmaceutical industry faces increasing regulatory scrutiny due to evolving guidelines, frequent inspections, globalization of supply chains, and rising concerns related to data integrity and quality culture. Regulatory agencies worldwide continuously update GMP requirements to address technological advancements and emerging risks, which poses significant compliance challenges for pharmaceutical manufacturers, particularly in developing economies. This review provides a comprehensive overview of GMP principles and examines the regulatory frameworks governing pharmaceutical manufacturing. Major GMP requirements, common compliance challenges, and inspection-related deficiencies are discussed in detail. The impact of regulatory non-compliance on product quality, business sustainability, and public health is also highlighted. Furthermore, the review explores future perspectives, including digitalization, risk-based regulatory approaches, and the role of advanced technologies in strengthening GMP compliance. This article aims to provide a clear understanding of current GMP expectations and regulatory challenges, serving as a useful reference for academia, industry professionals, and regulatory stakeholders.

KEYWORDS: Good Manufacturing Practices; Regulatory Compliance; Pharmaceutical Industry; Quality Assurance; Validation; Regulatory Inspections.

1. INTRODUCTION:

The pharmaceutical industry is a very vital segment in healthcare at a global level. It involves various pharmaceutical products that are developed, processed, and delivered to meet paramount requirements. To ensure that medicinal products conform to a given quality standard, all countries worldwide demand strict adherence to Good Manufacturing Practices (GMP). Good manufacturing practices are guidelines that govern a manufacturing system in various entities, thereby reducing risks or errors during a manufacturing process [1, 4, 26].

In the past few years, pharmaceutical industry regulations have been stringent due to a rise in product recall cases, breach of data integrity, and globalization of pharmaceutical manufacturing units across various countries. The globalization of pharmaceuticals reveals that when pharmaceutical manufacturers are required to adhere to different regulations during production, it becomes complicated for industry leaders to keep pace with regulations. In spite of this challenge, governments are enhancing regulations by improving the quality of inspections within pharmaceutical units [2,7,24,25].

While GMP principles are well-grounded, frequent changes to regulatory expectations continue to pose enormous challenges for pharmaceutical companies in their efforts to achieve and maintain regulatory compliance. In addition, the complexity of documentation, non-availability of sufficient resources, and scant training have resulted in significant gaps in compliance. Therefore, in-depth knowledge of GMP requirements and the challenges at the regulatory level is required to maintain sustainable pharmaceutical manufacturing. This review critically analyzes GMP principles, their regulatory frameworks, and major challenges faced by the pharmaceutical industry in maintaining compliance [5,8,16,20].

2. OVERVIEW OF GOOD MANUFACTURING (GMP)

2.1 Definition and Objectives of GMP

Good Manufacturing Practices: a set of legislation, guidelines, and practices aimed at ensuring the consistent manufacture, control, and quality of pharmaceutical materials to the quality required for their intended use. GMP is a set of practices aimed at minimizing the risk involved in the manufacture of pharmaceuticals, which cannot be eliminated by testing the final product [1,4,26].

GMP is concerned with building quality into the product rather than relying solely on product inspection. This is achieved by controlling the manufacturing process, equipment, manpower, and documentation. By enforcing the law, the regulatory agency protects the patient from consuming defective, contaminated, and ineffective products [3,27,28].

2.2 Evolution of GMP Regulations

The term GMP was developed in response to certain incidences related to medicine quality and manufacturing process issues in the past. Looking forward, it is clear that quality has to be ensured throughout the entire process of manufacture, and hence, GMP directives are not just about basic hygiene and sanitation but also about quality management systems [24,26,29].

Today, GMPs focus on lifecycle management, continual improvements, and the incorporation of quality risk management principles. Another factor that has shaped developments in GMP is the impact of technology, such as automation, computer systems, electronic data management practices, etc., in relation to electronic records and system validations [2, 31, 39].

2.3 Importance of GMP in Pharmaceutical Manufacturing

Compliance with GMP ensures product quality, regulatory approval, and access to market. On the other hand, violations of GMP may draw serious effects on regulatory aspects, such as product recalls, regulatory warnings, import bans, and loss of public trust. From a public health point of view, GMP ensures that patients get safe, effective, high-quality medicines [5,7,10].

In addition, GMP compliance contributes to improving operational efficiency, reducing manufacturing errors, and promoting sustainability of production. Therefore, for pharmaceutical companies in competitive global markets, compliance with GMP is not only a matter of regulatory requirements but one of strategic need linked to their goal of long-term sustainability [19,25,32].

3. Regulatory Authorities Governing GMP

Pharmaceutical manufacturing is regulated by a number of national and international agencies to ensure that the implementation of GMP requirements is uniform. These agencies provide guidelines, inspect companies, grant licenses, and even take action in case of any violation of GMPs. Even though the GMP guidelines are universal in nature, regional variations may occur in terms of requirements [1,3,4,28].

3.1 United States Food and Drug Administration (US FDA)

The enforcement of GMP regulations by the FDA is ensured by The Code of Federal Regulations, which consists of "21 CFR parts 210 + 211." These regulations provide the minimum requirements for the methods used for, as well as facilities and controls employed for, pharmaceutical manufacturing, processing, packaging, or holding. The FDA checks compliance via routine examinations as well as for-cause examinations. Warning letters are used to resolve FDA violations during the course of its examination. US FDA regulations on GMP are vital for access to the pharmaceutical market of America [2,6,11].

3.2 World Health Organization (WHO)

Good Manufacturing Practice guidelines in the form of internationally recognized Good Manufacturing Practice guidelines by the World Health Organization (WHO), which appear to be of critical significance in relation to the quality, safety, and efficacy of pharmaceutical products, notably in developing and low- and middle-income countries, in which the WHO Good Manufacturing Practice is normally implemented by the National Drug Regulatory Authorities [1,4].

WHO GMP requirements have been broadly adopted by pharmaceutical companies involved in supplying medications to various procurement agencies, which provide medications as part of various global health programs on diseases such as HIV/AIDS, tuberculosis, and malaria, as well as immunization programs. WHO GMP is most commonly a prerequisite to prequalification as well as to ensure the provision and accessibility of essential medications to resource-challenged countries [4].

3.3 European Medicines Agency (EMA)

The European Medics Administration, F, monitors good manufacturing practice in terms of EU GMP guidelines, which is perfectly presented in EU legislation on good manufacturing practice, also known as EudraLex Volume 4, which is thorough and constantly updated to reflect new developments in terms of new technologies and advances in different aspects of pharmaceutical manufacturing [1, 7, 28].

The EMA works closely with various competent authorities from member state organizations, focusing on GMP inspections, evaluation, and inspection regulations. This enables effective, harmonized EU regulations for inspection, ensuring that inspection outcomes can be recognized across all regions within the EU, focusing on improving quality throughout [7,29].

3.4 Central Drugs Standard Control Organization (CDSCO)

Compliance to GMP in India is exercised under the aegis of the Central Drugs Standard Control Organization through the Drugs and Cosmetics Act, Schedule M, defining regulatory requirements covering manufacturing premises, equipment, personnel qualifications, documentation practices, and quality control systems. Schedule M acts as the statutory framework for the pharmaceutical product's quality and safety in the domestic market[4,26].

Exporting Indian pharmaceutical manufacturers will have to comply with Schedule M, as well as with international GMP standards such as those prescribed by WHO, EMA, and other regulatory authorities of other countries. This makes a dual complacency and enhances the regulatory burden and further demands on infrastructure, documentation, validation, and inspection-readiness [1,25,28].**3.5 International Council for Harmonisation (ICH)**

International Council for Harmonisation plays a crucial role in the harmonization of quality guidelines, specifically in relation to Good Manufacturing Practice, in the European region, United States, and other participating countries. However, the main aim of ICH is to achieve a harmonization of pharmaceutical quality standards globally in order to limit duplication of regulations in the trade of pharmacy products[3,18,20].

A similar trend has also been noted within the quality guidelines provided by the ICH, for example, the Q8 document: Guidelines for the Pharmaceutical Development, Q9: Quality Risk Management, and the Q10: Pharmaceutical Quality System guidelines, which incorporate a science-based and risk-oriented strategy for GMP regulatory compliance, offering an enhanced pharmaceutical understanding, risk assessment, and lifecycle management for pharmaceuticals, beyond the conventional pharmaceutical regulatory compliance model [3,24]. Complying with these guidelines aids the strategy for enhanced quality and flexibility, thereby enhancing GMP regulatory compliance within the pharmaceutical manufacturing industry worldwide.

Table 1. Major Regulatory Authorities and Their GMP Guidelines

Regulatory Authority	Region	Key GMP Guidelines	Primary Focus
US FDA	United States	21 CFR Parts 210 & 211	cGMP compliance, inspections
WHO	Global	WHO GMP Guidelines	International quality standards
EMA	European Union	EU GMP (EudraLex Vol. 4)	Harmonized EU regulations
CDSCO	India	Schedule M	Domestic & export compliance
ICH	Global	ICH Q8, Q9, Q10	Quality by design & risk management

4. CORE GMP REQUIREMENTS IN PHARMACEUTICAL MANUFACTURING

GMP requirements encompass all aspects of pharmaceutical manufacturing, from raw material procurement to finished product distribution. These requirements ensure consistent product quality and regulatory compliance.

4.1 Personnel and Training

Qualified and adequately trained personnel are fundamental to GMP compliance. Employees involved in manufacturing and quality operations must receive initial and continuous training related to GMP principles, SOPs, hygiene practices, and job-specific responsibilities. Inadequate training is a common root cause of GMP violations during inspections.

4.2 Premises and Equipment

Manufacturing facilities must be designed and maintained to prevent contamination, cross-contamination, and mix-ups. Equipment should be appropriately qualified, calibrated, and maintained. Facility layout, environmental controls, and material flow must support GMP-compliant operations.

4.3 Documentation and SOPs

It has been noted in the field of pharmaceutical sciences that documentation is the backbone of Good Manufacturing Practices, and the documentation like written procedures for operating, manufacturing records, logbooks, and validation records are the documentary evidence to show the implementation of the pharmaceutical manufacturing processes in a consistent manner and the correct manner, i.e., correctly, according to the approved procedures [27,29].

Poor documentation practices, including inadequate documentation, uncontrolled document revisions, back dating, and data manipulation, are some of the commonest causes of regulatory issues after conducting Good Manufacturing Practice (GMP) audits. The lack of data integrity arising from poor documentation comes with a wide range of consequences, including inspection issues and even warning letters.

4.4 Validation and Qualification

Validation allows for the confirmation that pharmaceutical manufacturing processes, equipment, and computerized systems are employed to ensure that pharmaceutical products able to conform to desired quality characteristics. Qualification of various facilities, utilities, equipment including installation qualification, operational qualification, and performance qualification are considered fundamental prerequisites for pharmaceutical validation processes [34-36, 39].

There is a clear expectation by regulatory agencies that a lifecycle approach to validation will be one that incorporates a basis of scientific rationale, process understanding, and quality risk management into product development, manufacturing, and postapproval changes. The focus will continue on monitoring, change control, and periodic evaluation to maintain the validated state and comply with cGMP aspects on a continuous basis [3,19,40-43].

4.5 Quality Control and Quality Assurance

The main function of Quality Control (QC) is the testing, sampling, and verification of materials and finished pharmaceutical preparations for ensuring conformance with given quality specifications. The main intention of conducting QC activities is to have objective evidence that the product being tested meets the standards for safety, identity, strength, purity, and quality[26,31].

Quality Assurance, on the contrary, manages the whole Pharmaceutical Quality System with the purpose of confirming the favorable application of the GMP requirements for all processes within manufacturing operations. A good quality assurance activity is instrumental to the control of deviations, change control, and the application of CAPA in combination with the review of quality-related documents. A good combination between quality assurance activities is prime for the maintenance of the state of control with GMP compliance [19, 21, 35].

4.6 Change Control and CAPA

Any changes in materials, manufacturing processes, equipment, utilities, or facilities must be controlled and approved through an effective change control system so that it does not impact or affect product quality or regulatory requirements in any adverse manner. An effective change control system facilitates in maintenance of validated state with regard to assessment of potential risks associated with such changes [19,34,40].

Corrective action/preventive action (CAPA) systems are designed to investigate deviations, nonconformances, and audit observations by understanding their root causes and then take appropriate corrective and preventive action to prevent their repeat occurrences. Insufficient implementation of CAPA, particularly ineffective root cause analysis, inattention to timeliness in taking corrective action, and lack of adequate follow-up, is reportedly among the most common GMP noncompliances issued by regulators after inspections [5, 21, 35].

Table 2. Core GMP Requirements and Their Objectives

GMP Element	Objective	Impact on Quality
Personnel & Training	Ensure skilled workforce	Reduced human error
Premises & Equipment	Prevent contamination	Product consistency
Documentation & SOPs	Traceability & control	Regulatory compliance
Validation & Qualification	Process reliability	Reproducible results
Quality Control	Product testing	Assured safety
CAPA	Prevent recurrence of deviations	Continuous improvement

5. Major Regulatory Challenges in the Pharmaceutical Industry

Despite well-defined GMP guidelines, pharmaceutical manufacturers face numerous challenges in maintaining continuous regulatory compliance.

5.1 Frequent Updates to Regulatory Guidelines

Generally, there are continuous evolving regulatory requirements for pharmaceutical manufacturing that respond to advances in technologies, newly identified quality risks, and changing public health policy priorities. This updating by various regulatory authorities to their GMP guidelines is a response to advances in manufacturing technologies, data management systems, approaches to quality, etc. [2,24]

Keeping abreast with constant changes to regulations can prove to be costly to an organization in terms of resources to ensure that they are equipped with adequate regulatory intelligence assistance tools to cover staff training needs as well as alterations to quality documentation. Failure to appropriately execute changes to regulations may result in instances of non-compliance, leading to violations for manufacturers operating in multiple jurisdictions or regulatory domains [5,25].

5.2 Data Integrity Issues

Data integrity has emerged as one of the most critical regulatory concerns. Issues such as incomplete data, uncontrolled access to computerized systems, and manual data manipulation have led to serious enforcement actions. Ensuring compliance with data integrity principles requires robust IT systems, procedural controls, and a strong quality culture.

5.3 Global Regulatory Variability

Pharmaceutical companies operating in multiple markets must comply with different regulatory requirements simultaneously. Variations in inspection practices and expectations across regions increase compliance complexity and operational burden.

5.4 Resource and Cost Constraints

Implementing and maintaining GMP compliance involves substantial financial investment in infrastructure, training, validation, and quality systems. Small and medium-sized manufacturers often struggle to meet global GMP standards due to limited resources.

5.5 Inspection Readiness and Compliance Pressure

Regulatory inspection of pharmaceutical manufacturing facilities has also become more intense and frequent as the regulatory authorities strengthen their oversight to ensure continued GMP compliance. Manufacturers are called upon to demonstrate routine and for-cause continuous compliance with regulatory requirements rather than short-term compliance in anticipation of inspection preparation [10,15].

The constant pressure to stay in a state of readiness for inspection can be very stressful for organizational resources, especially for facilities with complex operations or thinly stretched staff. As long as GMP compliance is not fully integrated into daily operational practices, inspections often expose weaknesses in documentation, training effectiveness, deviation management, and CAPA implementation, which may lead to regulatory observations and enforcement actions.

Table 3. Major GMP and Regulatory Challenges Faced by the Pharmaceutical Industry

Challenge	Root Cause	Regulatory Concern
Frequent guideline updates	Evolving regulations	Non-compliance risk
Data integrity issues	Manual & legacy systems	Warning letters
Global regulatory diversity	Different regional rules	Market delays
High compliance costs	Infrastructure investment	SME burden
Skilled manpower shortage	Limited training	Inspection failures

6. Common GMP Deficiencies Observed During Regulatory Inspections

Regrettably, routine inspections often identify repeating Good Manufacturing Practice (GMP) failings in quality systems of pharmaceutical products, citing weaknesses in their systems. These failings represent ineffective implementation of GMP principles as opposed to procedural shortcomings. [5,10,20]

Most frequent issues detected during an inspection include inadequate documentation practices, lack of adherence to approved standard operating procedures by the company, inadequate handling of deviations with poor corrective and preventive action system practices, inadequate validation practices, lack of data integrity, and inadequate training for the employees by the organization [5,21,31].

The absence in these areas in the implementation of good manufacturing practices often leads to various actions by the authorities in the regulation and inspection of the respective drugs or products, such as the issuance of a Form 483, a warning letter, an import alert, suspension of a license to manufacture drugs, and even withdrawal from the market [5,6,15].

Common inspection observations include:

- Inadequate documentation and record-keeping
- Failure to follow approved SOPs
- Poor deviation and CAPA management
- Incomplete validation activities
- Data integrity violations
- Insufficient training programs

These deficiencies frequently result in regulatory actions such as Form 483 observations, warning letters, import alerts, and license suspensions.

Table 4. Common GMP Deficiencies Observed During Regulatory Inspections

Inspection Area	Typical Deficiency	Regulatory Outcome
Documentation	Incomplete batch records	Form 483
Data Integrity	Backdating, deletion	Warning letter
Validation	Inadequate process validation	Import alert
SOP Compliance	Procedures not followed	Major observation
Training	Lack of effectiveness checks	Repeat findings

7. Impact of Regulatory Non-Compliance

Non-compliance with GMP regulations can have severe consequences for pharmaceutical manufacturers. Regulatory actions may include product recalls, manufacturing shutdowns, export bans, and financial penalties. Beyond regulatory consequences, non-compliance damages company reputation, erodes stakeholder trust, and poses significant risks to patient safety. From a public health perspective, substandard medicines can lead to therapeutic failure and adverse health outcomes.

Table 5. Consequences of GMP Non-Compliance

Non-Compliance Type	Short-Term Impact	Long-Term Impact
Quality failures	Product recall	Loss of trust
Regulatory action	Warning letters	License suspension
Data falsification	Import alerts	Market exclusion
Poor CAPA	Repeat violations	Business shutdown

8. Future Perspectives in GMP and Regulatory Compliance

The future of GMP compliance in pharmaceutical companies can be seen in terms of embracing new, risk-based, and technology-driven GMP compliance models. There are great possibilities of achieving greater efficiency in pharmaceutical GMP compliance, along with greater data integrity, low rates of human error, using the digitalization of pharmaceutical quality management; in other words, using computerized GMP, computerized quality management, eBR, etc. [30-32].

Models of risk-based inspections, guided by quality metrics and historic non-conformance data, appear to be gaining support across regional regulatory agencies to target riskier operations during inspections. Concurrently, international initiatives to standardize regional GMP regulations have been made in order to avoid duplication of effort during inspections while operating in different regions, thereby simplifying the process with manufacturers [18,20,24].

Yet another factor is the maintenance of an effective quality culture in an organization, which is very important in sustaining GMP compliance in an organization in the long term. Integration of quality culture with advanced technology systems is also expected to play an integral role in supporting sustainable pharmaceutical manufacturing in an organization in light of present-day dynamics in the pharmaceutical GMP arena [25, 26, 32].

Table 6. Future Trends in GMP and Regulatory Compliance

Emerging Trend	Description	Expected Benefit
Digital GMP	Electronic batch records	Error reduction
Risk-based inspections	Focus on critical risks	Efficient oversight
Data integrity tools	Audit trails & controls	Regulatory confidence
AI in compliance	Predictive quality systems	Proactive compliance
Global harmonization	Unified GMP standards	Faster approvals

9. CONCLUSION

The role of Good Manufacturing Practices (GMP) in providing safety, efficacy, and quality in respect to medicinal products throughout their lifecycle has been acknowledged by all, and GMP systems in relation to medicinal products have been well established by global regulatory authorities. The problems associated with the effective implementation of GMP systems in pharmaceutical manufacturing enterprises, however, cannot be ignored, and a considerable rise in pharmaceutical quality system standards has been observed due to increasing complexity in manufacturing, globalization, and regulations [1, 4, 24, 26].

Within such review articles, one of the challenges emphasized is the transition of traditional compliant systems toward a system of risks and sciences in regulatory systems. Thus, it becomes important for such manufacturing industries to have effective understanding mechanisms of manufacturing processes, effective quality management of risks, along with lifecycle-based systems of validations rather than traditional process controls, since failure in such transitions often results in repeated observations from inspections or regulatory actions [2,3,19,24].

Data integrity has been identified as one of the key areas of concern in regulations, especially with increasing reliance on technologies and e-documents in pharmaceutical manufacture. The absence of proper control in generating, storing, and reviewing data has raised several concerns, creating apprehensions with regard to quality and safety issues. Development of robust data control mechanisms, with a sense of transparency and accountability, has become important in achieving GMP certification [5, 31, 32].

Organizational Quality Culture plays a decisive role in GMP activities. Even if a GMP system is fully developed, there can be no guarantee of its successful implementation if employees are not properly training, aware, and committed to GMP concepts and philosophies. In this regard, training and management involvement are a must to integrate GMP into daily activities rather than restricting its activities to inspection responses [21,25,26].

Advances in digital technology, including electronic batch records, real-time systems, and emerging artificial intelligence-based tools, provide opportunities to increase GMP strength with regards to young technology, including artificial intelligence. To do so properly, there must be a competent staff with regards to validation and regulatory matters [30-32].

Thus, it is evident that in conclusion, for a persistent compliant state in GMP, one must look at a forward-looking approach that takes into consideration quality systems, associated risks, innovation, and quality culture. Enhancing GMP practices enables easy clearance by drug regulatory authorities, apart from improving public health protection and sustaining pharmaceuticals in a rapidly changing environment including a rigorous drug approval system [24-26,32].

REFERENCE

1. European Medicines Agency (EMA). (2020). Good manufacturing practice and good distribution practice. Retrieved from https://www.ema.europa.eu
2. FDA. (2021). Pharmaceutical quality for the 21st century: A risk-based approach. U.S. Food and Drug Administration. Retrieved from https://www.fda.gov
3. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (2020). ICH Q10: Pharmaceutical quality system. Retrieved from https://www.ich.org
4. World Health Organization (WHO). (2019). Quality assurance of pharmaceuticals: A compendium of guidelines and related materials. Retrieved from https://www.who.int
5. Lebanova, H, Stoev, S, and Petrova, G. Analysis of non-compliances identified in GMP inspections between 2013 and 2022. *Pharmacia*. (2024) 71:1–6. doi: 10.3897/pharmacia.71.e120053PubMed Abstract | Crossref Full Text | Google Scholar
6. PharmOut. PIC/S GMPs vs WHO GMPs - what's the difference? (2020). Available online at: https://www.pharmout.net/pic-s-gmps-vs-who-gmps-whats-the-difference/ (Accessed February 19, 2025)Google Scholar
7. European Medicines Agency (EMA). Good manufacturing practice | European medicines agency. (2024). Available online at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice (Accessed February 19, 2025)
8. Chen, H, Qin, L, Jiang, C, Qin, M, Sun, Y, and Luo, J. Characteristics, risk management and GMP standards of pharmaceutical companies in China. *Front Public Health*. (2023) 11:1103555. doi: 10.3389/fpubh.2023.1103555 PubMed Abstract | Crossref Full Text | Google Scholar
9. Venkatesh, C, and Puranik, SB. Importance of self–inspection in pharmaceutical industry as per various regulatory guidelines. *Biomed Pharmacol J*. (2018) 11:387–90. doi: 10.13005/bpj/1384 Crossref Full Text | Google Scholar
10. GMP Inspections | Medicines for Human Use. (2017). HPRA. Available online at: https://www.hpra.ie/regulation/human-medicine/manufacturers/good-manufacturing-practice-(gmp)-inspections (Accessed March 4, 2025) Google Scholar

11. A Basic Guide to Good Manufacturing Practice (GMP) Audits. Avaialble online at: https://www.thefdagroup.com/blog/gmp-audits (Accessed February 19, 2025) Google Scholar

12. Bozorgian, M. How to prepare for GMP inspection in 5 steps - Zamann pharma support GmbH. (2024). Zamann Pharma Support GmbH. Available online at: https://zamann-pharma.com/2024/04/24/how-to-prepare-for-gmp-inspection-in-5-steps/ (Accessed March 4, 2025) Google Scholar

13. Munn, Z, Peters, MDJ, Stern, C, Tufanaru, C, McArthur, A, and Aromataris, E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Med Res Methodol*. (2018) 18. available from::143. doi: 10.1186/s12874-018-0611-x PubMed Abstract | Crossref Full Text | Google Scholar

14. Cooke, A, Smith, D, and Booth, A. Defining your question for finding qualitative Allan Murphy Bruun. How GMP Compliance Is Reflected in QMS (and Role of eQMS) (2023). SimplerQMS. Available online at: https://simplerqms.com/quality-management-system-gmp/ (Accessed February 19, 2025) Google Scholar

15. Rönninger, SR, Kurz, A, and Raya, F. GMP/GDP inspections: challenges and opportunities revealed by the COVID-19 pandemic. (2021). Available online at: https://www.pharmtech.com/view/gmp-gdp-inspections-challenges-and-opportunities-revealed-by-the-covid-19-pandemic (Accessed February 19, 2025)

16. at: https://www.nccmt.ca/knowledge-repositories/search/191 (Accessed February 19, 2025) Google Scholar

17. Research Guides. (2025). Grey Literature: Getting Started. Available online at: https://guides.library.ubc.ca/greylitforhealth (Accessed March 4, 2025) Google Scholar

18. Tricco, AC, Lillie, E, Zarin, W, O'Brien, KK, Colquhoun, H, Levac, D, et al. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. *Ann Intern Med*. (2018) 169:467–73. doi: 10.7326/M18-0850

19. Ahmed, S, Kundu, S, Patra, R, and Ray, J. Change control from initiation to implementation in the pharmaceutical industry: a comprehensive review. *Int J Res Pharm Sci*. (2024) 15:21–33. doi: 10.26452/ijrps.v15i3.4681Crossref Full Text | Google Scholar

20. Prasanna, GB, and Kamaraj, R. Pharmaceutical Inspection Co-operation Scheme An overview *Cureus* (2024) 16:e69043. doi: 10.7759/cureus.69043 Crossref Full Text | Google Scholar

21. Kavina, S, Charmy, K, Chirag, M, and Manan, S. Deviations handing and corrective actions and preventive actions: case studies for parenteral dosage form. *J Generic Med*. (2019) 15:165–76. doi: 10.1177/1741134319869404 Crossref Full Text | Google Scholar

22. Male, T, Vinod Kumar, K, Chithra Shekar, C, and Srinkanth,. A comprehensive review on comparison of gdocp in pharmaceutical manufacturing unit as per European and WHO guidelines. *Int J Curr Pharm Res*. (2021) 13:21–4. doi: 10.22159/ijcpr.2021v13i4.42736 Crossref Full Text | Google Scholar

23. Varin, T, Waranon, C, and Narueporn, S. Risk assessment of good manufacturing practice inspection of overseas pharmaceutical manufacturers based on desktop inspection as required in Thailand. *Thai J Pharm Sci* (2023) 47:5–10. doi: 10.56808/3027-7922.2790Crossref Full Text | Google Scholar

24. Daniel, T, Michael, W, Juan-Antonio, R, Simon, B, and Stephan, B. Recent Regulatory Trends in Pharmaceutical Manufacturing and their impact on industry. *Chimia*. (2018) 72:146–50. doi: 10.2533/chimia.2018.146

25. Tauqeer, F, Myhr, K, and Gopinathan, U. Institutional barriers and enablers to implementing and complying with internationally accepted quality standards in the local pharmaceutical industry of Pakistan: a qualitative study. *Health Policy Plan*. (2019) 34:440–9. doi: 10.1093/heapol/czz054 PubMed Abstract | Crossref Full Text | Google Scholar

26. Reis, C, Gouveia, B, Rijo, P, and Gonçalo, T. Good manufacturing practices for medicinal products for human use. *J Pharm Bioallied Sci*. (2015) 7:87–96. doi: 10.4103/0975-7406.154424PubMed Abstract | Crossref Full Text | Google Scholar

27. Patel, KT, and Chotai, NP. Documentation and records: harmonized GMP requirements. *J Young Pharm*. (2011) 3:138–50. doi: 10.4103/0975-1483.80303

28. European Commission. EudraLex - Volume 4. [Internet]. health.ec.europa.eu. Available online at: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en (Accessed February 19, 2025)Google Scholar

29. Italian Medicines Agency (AIFA). GMP guidelines: regulatory framework and compliance requirements. (2016). Rome, Italy: AIFA. Available online at: https://www.aifa.gov.it/sites/default/files/2016-05-13_BACCARELLI_13_05_2016_GMP.pdf (Accessed February 19, 2025)Google Scholar

30. GMP Software | QM in the pharmaceutical industry. (2025). Available online at https://www.caq.de/en/solutions/gmp-software (Accessed March 4, 2025)Google Scholar

31. Doneski, L, and Dong, M. Current good manufacturing practice (cGMP): an overview for the analytical chemist. (2023). Available online at: https://www.chromatographyonline.com/view/current-good-manufacturing-practice-cgmp-an-overview-for-the-analytical-chemist (Accessed February 19, 2025)Google Scholar

32. Moradi, E, and Mastering, GMP Compliance in the pharma industry - Pharmuni. (2024). Pharmuni. Available online at: https://pharmuni.com/2024/07/01/exploring-the-impact-of-gmp-compliance-on-the-pharmaceutical-industry-a-comprehensive-guide-for-specialists/ (Accessed March 4, 2025)Google Scholar

33. Casti, J, Ilmola, L, Rouvinen, P, and Wilenius, M. Extreme Events. (2011). Available online at: https://www.etla.fi/wp-content/uploads/extreme_events.pdf

34. Jena S., Arjun G., Ravipati A. K., kumar D. S., Vinod K. R., David B., Industrial process validation of solid dosage forms – an overview. International Journal of Pharmaceutical Sciences Review and Research, 4(2): 145-154, (2010)

35. Jadhav K. M., Mulla J. A. S., Doijad R. C., Comprehensive study of pharmaceutical process validation of solid dosage forms: quality assurance point of view. Indian Journal of Novel Drug Delivery, 9(4): 214-222, (2017).

36. Singh SP, Dhaker K, Namdev A, Khinchi MP, Bhatnagar S. A Review on Process Validation. PharmaTutor. 2016;4(12):9–19.

37. Kulkarni S, Panda A, Tiwari R. Pharmaceutical process validation: A key requirement for quality attribute. Research Journal of Pharmacy and Technology. 2014;7(1):74–7.

38. Shubhrajit Mantry, Ramya, I, Anil Kumar. S. An Overview: Pharmaceutical Validation. Int J Innovative Pharm Sci Res 2014;2:2476-97.

39. Sharma PP. Validation in Pharmaceutical Industry. 6th ed. United Kingdom: Informa Healthcare Publication; 2016. p. 51-70

40. Quality Management System – Process Validation Guidance GHTF/SG3/N99-10:2004 (Edition 2)

41. Guide to Inspections of Oral Solid Dosage Forms pre/post Approval Issue for Development and Validation; issue (1/94); January, 2010

42. Kathiresan K*, Moorthi C, Prathyusha Y, Gade B. R, Reddy B. K, Manavalan R, ; An overview of pharmaceutical validation; Research Journal of Pharmaceutical, Biological and Chemical Sciences; ISSN: 0975-8585; October – December 2010; RJPBCS 1(4); Page No. 1026.

43. Validation Master Plan Installation and Operational Qualification – Pharmaceutical Inspection Convention; Pharmaceutical Inspection Co-Operation Scheme; PI 006 – 2; July, 2004