WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.63
Volume 15, Issue 17, 403-414. Review Article ISSN 2277–7105

REVIEW ON CURRENT GOOD MANUFACTURING PRACTICE: ENSURING QUALITY, SAFETY AND REGULATORY COMPLIANCE

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Article Received on 29 July 2026,
Article Revised on 19 August 2026,
Article Published on 01 Sept. 2026,

https://doi.org/10.5281/zenodo.22159224

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How to cite this Article: Kandi Dinesh Kumar*, Karrothi Akash[1], Charamcharla Bhanu Chandu[2], Kadali Jaya Durga Prasanna[2] (2026). Review On Current Good Manufacturing Practice: Ensuring Quality, Safety And Regulatory Compliance. World Journal of Pharmaceutical Research, 15(17), 403-414.
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ABSTRACT

Current Good Manufacturing Practice (cGMP) represents a fundamental regulatory and quality framework for ensuring that pharmaceutical products are consistently manufactured and controlled according to predefined standards of quality, safety, efficacy, identity, strength, and purity. With increasing complexity in pharmaceutical manufacturing, globalization of supply chains, adoption of advanced technologies, and growing regulatory expectations, cGMP compliance has evolved from a predominantly inspection-oriented approach to a comprehensive, science- and risk-based pharmaceutical quality system. This review provides an overview of the principles, regulatory framework, and essential components of cGMP applicable to pharmaceutical manufacturing. Major areas discussed include the Pharmaceutical Quality System (PQS), personnel and training, premises and equipment, documentation and data integrity, material management, production and in-process controls, quality control, qualification and validation, deviation management, Corrective and Preventive Action (CAPA), change control, Quality Risk Management (QRM), Product Quality Review (PQR), supplier management, and self-inspection. The review also highlights the roles of major regulatory authorities and guidance frameworks, including the U.S. Food and Drug Administration (FDA), European Medicines Agency

(EMA), World Health Organization (WHO), International Council for Harmonisation (ICH), and Central Drugs Standard Control Organization (CDSCO). Particular emphasis is placed on ICH Q9(R1) and ICH Q10 as important frameworks supporting risk-based decision-making, lifecycle management, continual improvement, and effective pharmaceutical quality systems. Emerging trends such as digitalization, continuous manufacturing, Process Analytical Technology (PAT), automation, artificial intelligence, and advanced data analytics are also considered. Effective implementation of cGMP should extend beyond procedural compliance to establish a sustainable quality culture capable of maintaining process control, preventing quality failures, protecting patients, and supporting continuous improvement throughout the pharmaceutical product lifecycle.

KEYWORDS: Current Good Manufacturing Practice; cGMP; Pharmaceutical Quality System; Quality Risk Management; ICH Q10; CAPA; Data Integrity; Validation; Regulatory Compliance; Pharmaceutical Manufacturing; Quality Assurance; Patient Safety

1. INTRODUCTION[1]

The pharmaceutical industry has a fundamental responsibility to manufacture medicinal products that consistently meet established requirements for quality, safety, and efficacy. Unlike many consumer products, deficiencies in pharmaceutical manufacturing can directly affect patient health and may result in product recalls, treatment failure, adverse events, regulatory action, or shortages of essential medicines. Consequently, pharmaceutical manufacturing is governed by stringent Good Manufacturing Practice requirements.

Current Good Manufacturing Practice, commonly referred to as cGMP, establishes minimum requirements for the methods, facilities, systems, equipment, controls, documentation, and personnel involved in pharmaceutical manufacturing. The term **"current"** emphasizes that manufacturers should maintain appropriate contemporary systems and technologies rather than relying solely on outdated practices that may technically have been acceptable in the past.

Modern cGMP extends beyond testing finished products. Quality must be designed, built, monitored, and maintained throughout the product lifecycle. This philosophy has progressively shifted pharmaceutical quality management toward science-based decision-making, Quality Risk Management, process understanding, knowledge management, lifecycle validation, and continual improvement.

2. Concept and Objectives of CGMP[2]

The principal objective of cGMP is to ensure that pharmaceutical products are consistently produced and controlled according to appropriate quality standards and their intended use. Compliance provides assurance that manufacturing processes operate within a controlled environment and that potential risks to product quality and patients are appropriately identified and managed.

Major objectives include

- Ensuring consistent product identity, strength, quality, and purity.
- Preventing contamination, cross-contamination, mix-ups, and manufacturing errors.
- Establishing reproducible and controlled manufacturing processes.
- Maintaining reliable and traceable documentation.
- Ensuring personnel are appropriately qualified and trained.
- Establishing effective investigation and CAPA systems.
- Maintaining validated processes, methods, systems, and equipment.
- Protecting data integrity throughout the data lifecycle.
- Supporting continual improvement and maintenance of a state of control.
- Protecting patients from defective or substandard pharmaceutical products.

3. Global Regulatory Framework for cGMP[3]

Pharmaceutical manufacturers operate within a global regulatory environment involving national authorities and internationally harmonized standards. The U.S. FDA enforces cGMP requirements principally through **21 CFR Parts 210 and 211** for finished pharmaceutical products. Within the European Union, GMP requirements are described primarily through **EudraLex Volume 4**, including Part I, Part II, and applicable GMP Annexes.

WHO GMP guidance provides an important international framework, particularly for global pharmaceutical manufacturing and procurement. In India, pharmaceutical manufacturing is regulated through CDSCO and applicable requirements under the Drugs Rules, including revised Schedule M requirements.

ICH guidelines further support internationally harmonized pharmaceutical quality approaches. Particularly important are **ICH Q8** on pharmaceutical development, **ICH Q9(R1)** on Quality Risk Management, **ICH Q10** on the Pharmaceutical Quality System, and **ICH Q12** on pharmaceutical product lifecycle management.

4. Pharmaceutical Quality System[4]

An effective Pharmaceutical Quality System is central to modern cGMP compliance. The PQS integrates organizational structure, responsibilities, processes, procedures, resources, quality controls, and management oversight necessary to achieve and maintain pharmaceutical product quality.

ICH Q10 provides a lifecycle-oriented model covering pharmaceutical development, technology transfer, commercial manufacturing, and product discontinuation. Important PQS elements include process performance and product quality monitoring, CAPA, change management, management review, knowledge management, and Quality Risk Management. Senior management plays an essential role in ensuring that the PQS is adequately resourced, supported, periodically reviewed, and continuously improved. Quality therefore should not be regarded solely as the responsibility of the Quality Unit; it requires organizational commitment and an effective quality culture.

5. Personnel, Training and Quality Culture[5]

Competent personnel are fundamental to cGMP implementation. Employees should possess appropriate education, training, experience, and technical competence for their assigned responsibilities.

Training programs should cover applicable GMP principles, approved procedures, hygiene requirements, contamination control, documentation practices, data integrity, safety, and job-specific operations. Training effectiveness should be periodically evaluated rather than relying only on attendance records.

An effective quality culture encourages personnel to report deviations, errors, and potential risks without inappropriate pressure to conceal problems. Management behaviour, communication, resources, accountability, and commitment to patient protection significantly influence the maturity of the organization's quality culture.

6. Premises, Facilities and Equipment[6]

Pharmaceutical premises should be appropriately designed, constructed, maintained, and operated to minimize risks of contamination, cross-contamination, mix-ups, and errors. Facility design should provide suitable material and personnel flows and adequate environmental controls.

Manufacturing equipment should be appropriately designed, installed, qualified, calibrated, cleaned, maintained, and used according to approved procedures. Equipment lifecycle management generally incorporates qualification activities such as Design Qualification, Installation Qualification, Operational Qualification, and Performance Qualification where applicable.

Preventive maintenance and calibration programs are essential for maintaining equipment reliability and ensuring that critical process parameters remain under control.

7. Documentation and Data Integrity[7]

Documentation provides evidence that pharmaceutical operations have been performed as intended. cGMP documentation includes specifications, Standard Operating Procedures, master manufacturing instructions, batch records, analytical records, validation protocols, investigation reports, training records, and quality-system documentation.

Good Documentation Practices require records to be clear, accurate, contemporaneous, traceable, controlled, and readily retrievable.

Data integrity has become a major regulatory focus. The **ALCOA+ principles** require data to be attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available. Appropriate controls should be established for both paper-based and electronic records throughout the data lifecycle.

8. Material and Supplier Management[8]

The quality of pharmaceutical products depends significantly on the quality of starting materials, packaging components, and services obtained from suppliers. Appropriate supplier qualification and material-control systems are therefore essential.

Supplier management may include risk-based qualification, audits, quality agreements, performance monitoring, change notification, incoming-material testing, and periodic reassessment. Materials should be appropriately received, identified, quarantined, sampled, tested, approved or rejected, stored, and distributed under controlled conditions.

9. Production and In-Process Controls[9]

Manufacturing operations should be conducted according to approved procedures and validated processes. Critical process parameters and critical quality attributes should be appropriately identified and controlled.

In-process controls provide information on process performance before completion of manufacturing and may include parameters such as weight variation, blend uniformity, pH, temperature, pressure, moisture content, hardness, viscosity, fill volume, and other product-specific attributes.

Appropriate line clearance, status labeling, reconciliation, yield monitoring, contamination controls, and process documentation are essential to reduce manufacturing errors and maintain traceability.

10. Quality Control and Laboratory Systems[10]

Quality Control is responsible for sampling, specifications, testing, analytical methods, stability evaluation, and decisions related to the acceptance or rejection of materials and products within its authorized responsibilities.

Laboratory controls should ensure that analytical methods are scientifically appropriate, validated or verified as required, and performed using qualified instruments. Out-of-Specification and atypical results should be scientifically investigated rather than invalidated without adequate justification.

Stability programs are also necessary to demonstrate that medicinal products continue to meet established specifications throughout their assigned shelf life.

11. Qualification and Validation[11]

Validation provides documented evidence that systems, processes, procedures, equipment, and methods consistently perform according to their intended purpose.

Important validation activities include.

- Process validation
- Cleaning validation
- Analytical method validation
- Equipment qualification

- Utility qualification
- Computerised-system validation
- Packaging-process validation
- Transport validation, where applicable

Modern process validation applies a lifecycle approach involving **process design, process qualification, and continued process verification**. Continued monitoring allows manufacturers to detect process variability and emerging trends before they develop into significant quality failures.

12. Deviations, Investigations and CAPA[12]

Deviations and quality events should be documented, scientifically investigated, and assessed for potential impact on product quality and patient safety. Investigations should determine the root cause or most probable cause using appropriate scientific evidence.

Corrective actions address identified problems, while preventive or systemic actions seek to reduce recurrence or occurrence of related failures. CAPA effectiveness should subsequently be verified.

Repeated deviations attributed simply to “operator error” without adequate investigation may indicate weaknesses in procedures, training, process design, equipment, supervision, or the overall quality system.

13. Quality Risk Management[13]

ICH Q9(R1) provides a systematic framework for the assessment, control, communication, and review of risks to pharmaceutical quality. QRM enables organizations to allocate resources and controls according to the significance of identified risks.

Common tools include

- Failure Mode and Effects Analysis (FMEA)
- Failure Mode, Effects and Criticality Analysis (FMECA)
- Hazard Analysis and Critical Control Points (HACCP)
- Fault Tree Analysis (FTA)
- Risk ranking and filtering
- Preliminary Hazard Analysis

Risk-based decisions should be scientifically justified and proportionate to the potential risk to product quality and ultimately the patient. ICH Q9(R1) also emphasizes appropriate management of subjectivity and avoidance of excessive formality where it does not add value.

14. Change Control and Lifecycle Management[14]

Pharmaceutical manufacturing inevitably undergoes changes involving materials, suppliers, equipment, facilities, analytical methods, processes, software, specifications, or packaging systems. Uncontrolled changes may introduce new risks and compromise validated conditions.

An effective change-control system should therefore include scientific justification, quality-risk assessment, impact assessment, regulatory evaluation, implementation planning, required qualification or validation, approval, and post-implementation effectiveness assessment.

Lifecycle-oriented change management allows companies to improve processes while maintaining regulatory compliance and product quality.

15. Product Quality Review and Continual Improvement[15]

Periodic Product Quality Review provides an important mechanism for evaluating whether manufacturing processes remain consistent and in a state of control. Relevant information may include deviations, OOS results, complaints, recalls, stability results, process trends, yields, changes, CAPA, supplier performance, and validation status.

Trend analysis can identify gradual deterioration even when individual batches continue to comply with specifications. Consequently, successful batch testing alone should not be considered sufficient evidence of continuing process control.

PQR findings should contribute to CAPA, change management, management review, process optimization, and continual improvement.

16. Regulatory Inspections and cGMP Compliance[16]

Regulatory inspections assess whether pharmaceutical manufacturers maintain systems capable of consistently producing compliant products. Inspectors may evaluate facilities, documentation, laboratory controls, manufacturing processes, investigations, validation, data integrity, supply-chain controls, and management oversight.

Significant deficiencies may result in regulatory observations, Warning Letters, product recalls, import restrictions, suspension of manufacturing activities, or other enforcement measures depending on jurisdiction and severity.

Inspection readiness should therefore represent an ongoing organizational state rather than a short-term activity initiated immediately before an inspection.

17. Emerging Trends in cGMP[17]

Pharmaceutical manufacturing is increasingly adopting digital and advanced manufacturing technologies. Automation, electronic batch records, advanced process-control systems, continuous manufacturing, Process Analytical Technology, real-time monitoring, artificial intelligence, machine learning, and advanced analytics can strengthen process understanding and facilitate earlier detection of quality signals. However, technological advancement also introduces new challenges related to computerised-system validation, cybersecurity, algorithm governance, electronic records, data integrity, and management of complex digital systems. Future cGMP frameworks will increasingly require integration of technological innovation with robust risk management and lifecycle governance.

18. Challenges in cGMP Implementation[18]

Despite established regulatory frameworks, pharmaceutical manufacturers continue to face challenges including complex global supply chains, inadequate investigations, recurring deviations, ineffective CAPA, insufficient quality resources, weak supplier oversight, data-integrity vulnerabilities, aging facilities, technology-transfer failures, and resistance to organizational change.

Achieving sustainable compliance requires movement from a reactive approach—correcting observations after inspections—to a proactive approach based on risk identification, process understanding, quality metrics, management oversight, and continual improvement.

19. Future Perspectives[19-22]

Future pharmaceutical quality systems are expected to become increasingly predictive, integrated, data-driven, and risk-based. Real-time process information and advanced analytics may enable organizations to identify emerging process deterioration before product failure occurs.

The continuing integration of ICH Q8, Q9, Q10, and Q12 principles with advanced manufacturing technologies provides an opportunity to move from traditional compliance-focused manufacturing toward enhanced process understanding and lifecycle quality management. Regulatory compliance and pharmaceutical innovation should therefore be viewed as complementary objectives rather than competing priorities.

20. CONCLUSION

Current Good Manufacturing Practice remains the foundation of pharmaceutical quality assurance and patient protection. Modern cGMP extends beyond compliance with written procedures and finished-product specifications; it requires an integrated Pharmaceutical Quality System supported by competent personnel, controlled facilities, reliable documentation, validated processes, robust data integrity, Quality Risk Management, effective CAPA, change management, and strong management commitment. The evolution of pharmaceutical regulation toward science- and risk-based lifecycle approaches reinforces the principle that quality must be built into pharmaceutical products and manufacturing processes rather than tested only at the final stage. Effective implementation of cGMP, ICH Q9(R1), and ICH Q10 principles can strengthen process control, reduce quality failures, facilitate continual improvement, and enhance regulatory confidence. As pharmaceutical manufacturing becomes increasingly digital and technologically advanced, maintaining a strong quality culture and patient-focused approach will remain essential. Ultimately, sustainable cGMP compliance is not merely a regulatory obligation but a fundamental responsibility for ensuring that every pharmaceutical product reaching the patient is consistently safe, effective, and of the intended quality.

REFERENCES

1. U.S. Food and Drug Administration. Current Good Manufacturing Practice for Finished Pharmaceuticals. Code of Federal Regulations, Title 21, Part 211. Silver Spring, MD: U.S. Food and Drug Administration.
2. U.S. Food and Drug Administration. Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General. Code of Federal Regulations, Title 21, Part 210. Silver Spring, MD: U.S. Food and Drug Administration.
3. European Commission. EudraLex—Volume 4: EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. Brussels: European Commission.

4. European Commission. EudraLex Volume 4, Part I, Chapter 1: Pharmaceutical Quality System. Brussels: European Commission.
5. European Commission. EudraLex Volume 4, Part I, Chapter 4: Documentation. Brussels: European Commission.
6. European Commission. EudraLex Volume 4, Annex 15: Qualification and Validation. Brussels: European Commission.
7. European Commission. EudraLex Volume 4, Annex 11: Computerised Systems. Brussels: European Commission.
8. World Health Organization. WHO Good Manufacturing Practices for Pharmaceutical Products: Main Principles. WHO Technical Report Series. Geneva: World Health Organization.
9. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Q8(R2): Pharmaceutical Development. Geneva: ICH, 2009.
10. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Q9(R1): Quality Risk Management. Geneva: ICH, 2023.
11. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Q10: Pharmaceutical Quality System. Geneva: ICH, 2008.
12. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management. Geneva: ICH, 2019.
13. U.S. Food and Drug Administration. Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations. Silver Spring, MD: FDA, 2006.
14. U.S. Food and Drug Administration. Guidance for Industry: Process Validation—General Principles and Practices. Silver Spring, MD: FDA, 2011.
15. U.S. Food and Drug Administration. Data Integrity and Compliance With Drug CGMP: Questions and Answers—Guidance for Industry. Silver Spring, MD: FDA, 2018.
16. U.S. Food and Drug Administration. Guidance for Industry: Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production. Silver Spring, MD: FDA.
17. European Medicines Agency. Guideline on Process Validation for Finished Products—Information and Data to be Provided in Regulatory Submissions. London: European Medicines Agency, 2014.
18. Medicines and Healthcare products Regulatory Agency. GxP Data Integrity Guidance and Definitions. London: MHRA, 2018.

19. Pharmaceutical Inspection Co-operation Scheme. Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments. PI 041. Geneva: PIC/S.
20. Pharmaceutical Inspection Co-operation Scheme. Guide to Good Manufacturing Practice for Medicinal Products. PE 009. Geneva: PIC/S.
21. Government of India, Ministry of Health and Family Welfare. Drugs Rules, 1945: Schedule M—Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products. New Delhi: Government of India.
22. Government of India, Ministry of Health and Family Welfare. Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products—Revised Schedule M. New Delhi: Government of India, 2023.