WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 14, Issue 16, 116-119. Review Article ISSN 2277–7105

COMPUTERISED SYSTEM VALIDATION: REGULATORY COMPLIANCE AND PHARMACEUTICAL INDUSTRY

Shaik Abida*, G. Ramakrishna and M. V. Nagabhushanam

Department of Pharmaceutical Regulatory Affairs, Hindu College of Pharmacy, Amaravathi Road, Guntur-522002, Andhra Pradesh, India-522002.

*II/II M.Pharmacy, Department of Pharmaceutical Regulatory Affairs, Hindu College of Pharmacy, Amaravathi Road, Guntur, Andhra Pradesh, India-522002.

Article Received on
24 June 2025,

Revised on 13 July 2025,
Accepted on 03 August 2025,

DOI: 10.20959/wjpr202516-37888

***Corresponding Author**
Shaik Abida
II/II M.Pharmacy, Department of Pharmaceutical Regulatory Affairs, Hindu College of Pharmacy, Amaravathi Road, Guntur, Andhra Pradesh, India-522002.

ABSTRACT

Computerised System Validation (CSV) is a critical process in the pharmaceutical industry, ensuring that computer-based systems used in the manufacture, testing, and distribution of pharmaceutical products operate in a consistent and compliant manner. This review highlights the principles of CSV, its role in meeting regulatory expectations, and its application across the pharmaceutical sector. Emphasis is placed on Good Automated Manufacturing Practice (GAMP), data integrity, and the alignment with regulatory frameworks such as FDA 21 CFR Part 11, EU Annex 11, and ICH guidelines.

KEYWORDS: Computerised System Validation (CSV), Pharmaceutical industry, pharmaceutical products, Good Automated Manufacturing Practice (GAMP), FDA 21 CFR Part 11, EU Annex 11, and ICH guidelines.

1. INTRODUCTION[1]

With the increasing reliance on digital systems in pharmaceutical manufacturing and quality assurance, the need for robust validation has never been greater. CSV is the documented process of ensuring that a computerised system performs reliably, securely, and as intended throughout its lifecycle.

2. Regulatory Framework[2]

Computerised systems are governed by stringent regulatory requirements:

- **FDA 21 CFR Part 11** – Governs electronic records and signatures.
- **EU GMP Annex 11** – Outlines requirements for computerised systems in EU.
- **ICH Q8, Q9, Q10** – Provide frameworks for quality risk management and system lifecycle.

These regulations ensure data integrity, system reliability, and patient safety.

3. Key Components of CSV[3]

1. **Validation Plan** – Defines the scope, approach, and responsibilities.
2. **Risk Assessment** – Determines validation depth based on system complexity and impact.
3. **User Requirement Specifications (URS)** – Describe what the system should do.
4. **Functional & Design Specifications** – Outline how the system will meet URS.
5. **Testing Phases**
   - Installation Qualification (IQ)
   - Operational Qualification (OQ)
   - Performance Qualification (PQ)
6. **Traceability Matrix** – Links requirements to test results.
7. **Validation Report** – Summarizes the outcome and evidence.

4. Good Automated Manufacturing Practice (GAMP)[4]

GAMP 5 provides a risk-based approach to CSV

- **Category-based system classification**
- Emphasizes system lifecycle management
- Promotes scalable validation activities.

5. Importance of Data Integrity[5,7]

Data must be **ALCOA**

- **Attributable**
- **Legible**
- **Contemporaneous**
- **Original**
- **Accurate**

Regulators expect pharmaceutical companies to ensure that data is complete, consistent, and accurate throughout its lifecycle.

6. Challenges in CSV[8,10]

- Constant evolution of technology
- Managing legacy systems
- Cloud computing and SaaS compliance
- Cybersecurity threats
- Keeping up with changing regulations

7. Benefits of Effective CSV[10,12]

- Ensures regulatory compliance
- Minimizes product and patient risks
- Enhances data integrity
- Reduces errors and downtime
- Improves system performance and reliability.

8. Emerging Trends[13]

- **CSA (Computer Software Assurance)**: An FDA pilot that proposes a more efficient, risk-based approach.
- **AI & Machine Learning Systems**: Introducing new complexities in validation.
- **Blockchain**: Enhancing data transparency and integrity.

9. CONCLUSION

Computerised System Validation is a foundational element of regulatory compliance in the pharmaceutical industry. Adopting a risk-based, lifecycle-oriented, and data-integrity-focused approach ensures not only compliance but also operational excellence. As digital transformation accelerates, the validation process must evolve to encompass new technologies and paradigms while maintaining its core objective—patient safety and product quality.

10. REFERENCES

1. FDA 21 CFR Part 11
2. EU GMP Annex 11
3. ISPE GAMP 5 Guide
4. ICH Q9: Quality Risk Management
5. MHRA Guidance on GxP Data Integrity

6. Brahmaiah Bonthagarala, Comparison of Regulatory Requirements for Generic Drugs Dossier Submission in United States and Canada, International Journal of Pharmaceutical Science and Health Care, ISSN 2249 – 5738, November-December 2016; 6(6): 1-10.
7. Brahmaiah Bonthagarala, Regulatory process and ethics for clinical trials in India (CDSCO)- A Review, The Pharma Innovation Journal, ISSN (E): 2277- 7695, ISSN (P): 2349-8242, 2017; 6(4): 165-169.
8. Brahmaiah Bonthagarala, Evaluation of Pharmaceutical Regulatory Systems & Present Scenario of Indian Pharmaceutical Industry, World Journal of Pharmaceutical Research, ISSN 2277–7105, 2017; 6(5): 368-379.
9. Brahmaiah Bonthagarala, Evaluation of Pharmaceutical Regulatory Systems & Present Scenario of Indian Pharmaceutical Industry, World Journal of Pharmaceutical Research, ISSN 2277–7105, 2017; 6(5): 368-379.
10. Brahmaiah Bonthagarala, Regulatory Requirements of 'Similar Biologics' for Marketing Authorization in India, International Journal of Drug Regulatory Affairs, ISSN, 2321-6794; 2017; 5(1): 20-24.
11. Brahmaiah Bonthagarala, Guidelines for bioavailability and bioequivalence studies: A Review, The Pharma Innovation Journal, 2018; 7(7): 661-666, ISSN (E): 2277- 7695.
12. Brahmaiah Bonthagarala, A Review on global harmonization task force (GHTF) - principles of in vitro diagnostic (IVD) medical devices classification, The Pharma Innovation Journal, 2018; 7(7): 667-672, ISSN (E): 2277-7695.
13. Gautam CS, Utreja A, Singal GL. Spurious and counterfeit drugs: A growing industry in the developing world. Postgrad Med J, 2009; 85(1003): 251–6.