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Review Article

An Extensive Review Of Validation In The Pharmaceutical Industry: Principles, Applications, Regulatory Framework And Future Perspectives

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ABSTRACT

This review synthesises contemporary literature on pharmaceutical validation, examining principles, methodologies, evolution, and trends in process, equipment, cleaning, analytical, and computer system validation, while identifying challenges and future directions that support patient safety and operational excellence. Validation is a cornerstone of GMP, ensuring quality, safety, efficacy, and compliance. It has evolved into a science- and risk-based lifecycle framework integrating QbD, PAT, and ALCOA+ principles, guided by FDA, EMA, WHO, and ICH. Structured synthesis covered process validation (three-stage lifecycle), equipment qualification (DQ–PQ), cleaning validation (PDE/ADE, MACO, sampling), analytical method validation (ICH Q2 parameters, AQbD), computer system validation, and applications in biopharmaceuticals and herbal products, emphasising risk-based strategies and Validation Master Plans. Pharmaceutical validation is a dynamic, science-driven process that mitigates risk and safeguards patients. Digitalisation, automation, AI, and lifecycle management address current challenges and enable future excellence and sustained compliance.

INTRODUCTION

The pharmaceutical industry is striving to continuously deliver safe, effective, and high-quality therapeutic products in accordance with set standards at the lowest feasible price.(1) Good Manufacturing Practices (GMP) enforcement has been instrumental in reducing risks to patients and operators. Validation is an inherent part of GMP compliance and product quality dependability. (2)

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Historical Evolution of Validation:

The idea of validation came from FDA officials, Ted Byers and Bud Loftus, in the 1970's to address sterility concerns for large volume parenteral (LVP) drugs. Large-scale contamination episodes revealed the limitations of depending exclusively on testing after production.(3) The concept of process validation was formalised by the U.S. FDA in 1978, and the 1987 guidance emphasised that quality should be built into the product by means of controlled procedures and not assessed at the end. The concept of validation has changed over the decades from a static, documentation-intensive activity to a more dynamic lifecycle approach and was heavily influenced by ICH Q8 (Pharmaceutical Development), Q9 (Quality Risk Management) and Q10 (Pharmaceutical Quality System). This sophisticated approach integrates science- and risk-based concepts throughout the entire product lifecycle.(4)

Definitions of Validation:

The basic idea of validation is the same everywhere, but the different regulatory bodies have worded their definitions slightly differently. Examining these definitions together helps us to appreciate both the similarities and the slight differences in emphasis.

The **US FDA** describes process validation as the process of producing documentary evidence which provides reasonable assurance that a particular process will consistently deliver a product, which conforms to its predetermined specifications and quality attributes. Clear written proof that the method works reliably every time is required by the FDA.(5)

The **European Commission** has a similar, but somewhat more functional, view. It defines validation as the documented evidence that provides assurance that a process, when operated within specified limits, can be demonstrated to be capable of repeatedly and reliably operating within those limits. The emphasis is on the process producing the same good results within limits.(6)

The **World Health Organization (WHO)** defines it more broadly. Validation, according to the World Health Organization, is the documented action that shows that any procedure, process, equipment, material, activity or system achieves the intended result. This wording is beneficial in that it covers both production methods and associated systems and operations.(7)

Despite the differences in wording, all three definitions share the same fundamental tenet: validation involves the generation of credible, written evidence that a given entity consistently and reliably fulfills its intended purpose. In today's regulatory environment, validation is no longer viewed as a one-time, stand-alone activity completed prior to the product being introduced into the marketplace. On the other hand, it is seen as a continuing life-time effort. It begins in the design and development phase of the process, continues through process qualification and commercial production, and carries through ongoing monitoring and validation during the product's market life. This view of the lifespan ensures that the knowledge and power gained in the beginning are maintained and improved over time.(8)

Principles and Significance of Validation:

The basic idea behind validation is simple but important: quality cannot be added to a product after it has been made; it has to be built in at every stage of the process. Practically, the domain adopts an orderly and systematic manner of qualifying that proceeds from conception to performance.

The procedure starts with **Design Qualification (DQ).** In this case, teams assess the adequacy of the proposed design of equipment, infrastructure, or systems for its intended use and in meeting user requirements and regulatory requirements.

Figure 1: Explains the basic design features of the pharmaceutical buildings and equipment to meet GMP requirements, to ensure dependability of operation, safety and best performance.

Once the design is approved, Installation Qualification (IQ) ensures that the installation has been performed properly according to the approved designs and the manufacturer's instructions.

Figure 2: Includes important design specifications for Installation Qualification (IQ) including equipment specifications, installation conditions, calibration, safety features, supplier documentation and software documentation.

Then the Operational Qualification (OQ) checks that the equipment or system works correctly over the full range of operations, including alarms, interlocks and "what if" situations.

Figure 3: Illustrates the key elements that are considered in the process design phase, namely process control limits, raw material requirements, operating procedures, material handling requirements, failure modes, statistical improvement and process capability analysis.

Finally, Performance Qualification (PQ) proves that the equipment or process can consistently deliver the desired results during actual production runs.

Figure 4: Shows the process performance qualification step, which demonstrates product acceptance, verified process capability, consistency and sustained process stability under the defined operating conditions

The **VMP (Validation Master Plan)** is the first step in all individual research. This strategic paper describes the validation framework, roles and responsibilities, systems and processes to be validated and a practical schedule. The VMP provides a holistic overview, and the details are elaborated in separate validation processes. Each protocol defines the objectives, the methods to be used, the criteria of acceptability, the sampling scheme and the exact documentation to be collected. The clear master plan and detailed protocols keep the validation program organized, consistent and inspection ready.(9)

The many real benefits of doing validation correctly This gives great confidence that each batch will hit its targets for quality, safety and efficacy. Less rework, lower evaluation cost and less rejection rate. It meets the requirements for market authorisation and for continued compliance as set out in the rule . It is important to stress the validation process in combination with a good risk management and Quality by Design (QbD). This leads to a better understanding of the process and forms a solid base for continuous improvement. These protocols guarantee compliance with the requirements of GMP and the

consistent use of equipment, facilities and methods. Validation Master Plan (VMP) is the key document which defines the strategy, responsibilities and schedule. The objectives, methods, acceptance criteria, sampling plans and documentation requirements for all validation processes must be defined.

Key Significance:

I. Product safety, efficacy and quality.
II. Reduction of rejections, re-works and production costs.
III. Regulatory compliance and market acceptance.
IV. Quality by Design (QbD) and risk management for improved understanding and control of the process.

Types and Scope of Validation:

Validation covers wide areas in pharmaceutical operations:

a) Equipment Validation (Installation Qualification, Operational Qualification, Performance Qualification).

b) Process Validation (Prospective, Concurrent, Retrospective, and Revalidation).

c) Analytical Method Validation.

d) Cleaning Validation.

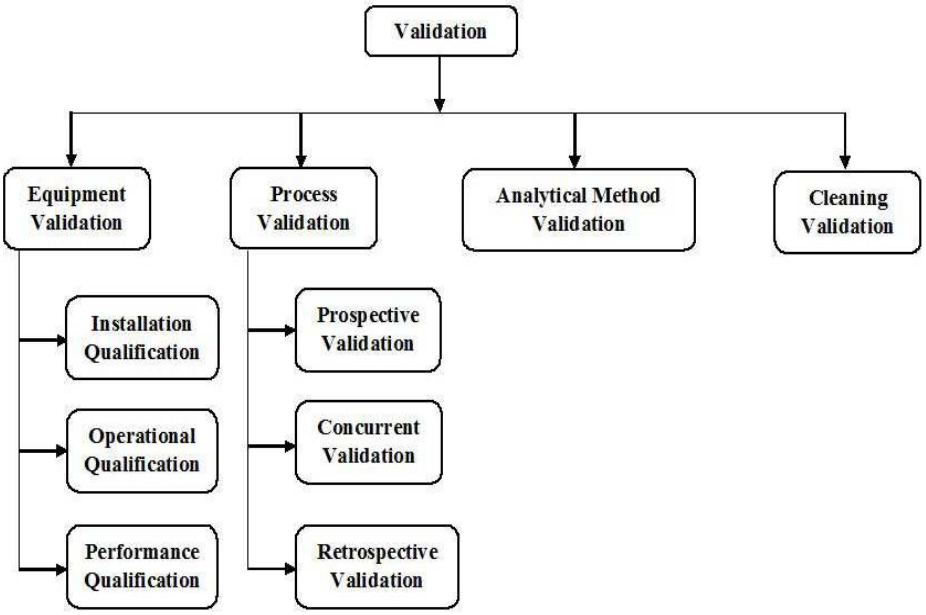

Figure 5: This figure displays the main types of pharmaceutical validation such as equipment validation, process validation, analytical method validation and cleaning validation, as well as the main stages of qualification and process validation.

The modern lifecycle organises validation into three stages:

I. Process Design (Stage 1)
II. Process Qualification (Stage 2)
III. Continued Process Verification (Stage 3)

Regulatory Framework:

Regulatory authorities worldwide are expecting pharmaceutical companies to take a scientific, risk-based approach to validation, rather than a simple checklist approach. The quality can no longer be assessed only at the end of production but must be carefully designed and controlled throughout the whole manufacturing process. This is reflected in the main directions of the main organizations. Some of the key directives are:

a) U.S. Food and Drug Administration (21 CFR Parts 210 and 211)
b) EMA/EU Good Manufacturing Practice (GMP)
c) WHO Good Manufacturing Practices and Schedule M (India).
d) PIC/S, ICH and ISO 9000 norm.

All these regulations have some recurring themes. Companies are expected to maintain comprehensive, accurate documentation, implement robust change-control and deviation-management systems, safeguard data integrity (per ALCOA+ principles), and reassess processes when significant changes are made or when ongoing monitoring indicates a potential problem. And the message from regulators across the board is the same: build quality in from the start, understand your process in depth, manage risk intelligently and keep checking the process is in control throughout the product's commercial life.(10)

Challenges and Future Perspectives:

Despite clear guidance from regulators and a well-defined lifecycle approach, a significant number of firms still struggle to get validation done efficiently. One common problem is the partial or superficial analysis of risks. If teams do not take their time in this stage or treat it as a routine procedure, they often miss key process factors and have inadequate control techniques. A frequent mistake is to design sampling protocols poorly: taking too few samples, or sampling in the wrong places, can give a false sense of security and fail to capture real variability. The problem in inspections is still bad or badly structured documentation. For regulators globally, data integrity is a critical issue, particularly with hybrid paper and computer systems.

Other real barriers are demonstrating the number of process-performance-qualification batches, exercising change control without unnecessary bureaucracy, and having a sufficient pool of trained personnel who understand the scientific principles of the process and the regulatory requirements. Many organizations are unable to move beyond the old "three batches in a row and we are done" approach to real continuous process verification.

The road to validation clearly points to more sophisticated, data-informed approaches in the future. Manufacturers are using Process Analytical Technology (PAT) and real-time release testing to monitor critical quality attributes during the process, rather than waiting until after manufacturing is completed to test. Tools such as machine learning and artificial intelligence are beginning to help with predictive monitoring, allowing teams to identify small patterns of behaviour and intervene before a process goes off the rails. Traditional end-point assessments are increasingly being replaced by continued manufacturing, virtual twins and improved process control mechanisms. (8)

Also, increased international regulatory harmonization through initiatives like ICH Q12 and mutual recognition agreements should reduce wasteful duplication and accelerate the delivery of high-quality pharmaceuticals to patients. The end goal is still to speed innovation, with patient safety first and product quality front and centre. The review of the criticism is good and covers all basic

principles, types, uses, controlling factors, issues and recent trends in pharmaceutical validation. It is a good source of information for pharmaceutical professionals and researchers.

Table 1: Challenges and Recommended Solutions in Pharmaceutical Validation.

Sr. No.	Current Challenges	Recommended Solutions
1.	Increasing complexity of global regulatory requirements (FDA, EMA, ICH, WHO).	Increasing complexity of global regulatory requirements (FDA, EMA, ICH, WHO).
2.	High cost and time associated with validation activities.	Adoption of risk-based and lifecycle validation to improve efficiency and reduce costs.
3.	Maintaining data integrity and compliance with ALCOA+ principles.	Implementation of secure digital systems, electronic records, and automated audit trails.
4.	Validation of advanced pharmaceutical products (biologics, gene therapies, personalised medicines).	Development of specialised validation frameworks for emerging therapies.
5.	Cross-contamination risks in multi-product manufacturing facilities.	Enhanced cleaning validation using HBEL, PDE/ADE, MACO, and advanced analytical techniques.
6.	Limited integration of Artificial Intelligence (AI), automation, and digital technologies.	Wider adoption of AI, machine learning, Process Analytical Technology (PAT), and real-time monitoring.
7.	Validation of computerised systems and rapid technological changes.	Transition from Computer System Validation (CSV) to Computer Software Assurance (CSA) and continuous system updates.

REVIEW OF LITERATURE

Major pharmaceutical guidelines by official and reported Research/Review for validation in the pharmaceutical industry:

Literature search for Validation in the Pharmaceutical Industry:

1. Kakad et al. (2020): This article defines validation as a documented process that provides a high degree of assurance that equipment, processes, and procedures will consistently meet quality standards. Discussion of the pharmaceutical business and the significance of process validation, equipment qualification (IQ/OQ/PQ), cleaning validation, and analytical method validation as critical GMP elements for ensuring product quality and regulatory compliance.(11)

2. Sabale and Thorat (2021): They gave a detailed explanation of validation in pharmaceutical industry, its background, definitions (FDA, EU, WHO) and its importance for cost cutting and quality control. The basic concepts of design qualification (DQ), installation qualification (IQ), operational qualification (OQ), performance qualification (PQ) and the role of the Validation Master Plan (VMP) in systematic validation activities were discussed.(12)

3. Choudhary and Sehgal (2021): They traced the evolution of pharmaceutical validation from FDA

activities during the 1970s and considered it a vital quality assurance tool. They summarised the requirements, the benefits, the accountable authorities and the different types of validation, e.g. the analytical technique validation with criteria like accuracy, precision, specificity, LOD and LOQ, based on the ICH recommendations.(13)

4. Raja et al. (2024): They gave a critical manual on Computer System Validation (CSV) in pharmaceutical industry, focusing on its role in maintaining data integrity, reliability and compliance with 21 CFR Part 11 and GLP. The V-model was used to describe the whole CSV lifecycle including the DQ, IQ, OQ, PQ stages, Validation Master Plan, GAMP 5 software/hardware categories, the recurring reviews. The writers emphasised benefits including higher quality, lower prices and regulatory compliance.(14)

5. Dahiya et al. (2022): Authors and co-authors discussed cleaning validation as an important GMP aspect for avoiding cross-contamination in the production of pharmaceuticals. It included goals, types of contamination, cleaning agents, sampling methods (swab, rinse), criteria for acceptance (MACO, 10 PPM) and levels of cleaning. The authors emphasised the need for documented evidence of consistently achieving residue removal below acceptable limits and described the regulatory expectations (FDA), lower prices and regulatory challenges.(15)

6. Wangpo et al. (2019): The researchers presented an outline of the pharmaceutical process validation highlighting the significance of consistent product quality and regulatory compliance. They discussed lifecycle stages, types (prospective, concurrent, retrospective, revalidation), IQ/OQ/PQ, Validation Master Plan and protocol elements. The authors cited benefits such as fewer failures, optimisation of processes and the need for documented evidence during the product development lifecycle.(16)

7. Isane et al. (2022): These co-authors investigated specificity, linearity and robustness. The importance of this technique in quality assurance, impurity evaluation and reliable quantitative analysis of pharmaceuticals has been stressed by writers. Wednesday: Development, validation and application of HPLC methods in pharmaceutical analysis. It included concepts, classifications (normal/reverse phase, ion-exchange), instrumentation, optimization parameters (column, mobile phase, detector) and ICH validation attributes (accuracy and precision).(17)

8. Ullagaddi (2024): The author researched cloud validation in the pharmaceutical industry and the difficulties of Computerized System Validation (CSV) for cloud systems. The author talked about risk-based approaches, data integrity (ALCOA+), shared accountability models and the evolution of traditional validation approaches to dynamic cloud environments. The study demonstrated strategic benefits including cost-effectiveness, innovation and global scalability while complying with FDA, EMA and GAMP 5 standards.(18)

9. Vaware et al. (2026). The investigators examined how procedures are validated in the pharmaceutical industry. They described the transition from the traditional 3-batch validation to today's stages of Process Design, Process Qualification and Continued Process Verification. The authors discussed the importance of Quality by Design (QbD), Quality Risk Management and continuous monitoring to ensure consistent quality, safety and compliance using sterile injectables as an example.(19)

10. Gorana and Choudhary (2026): They provided current perspectives on equipment qualification (IQ, OQ, PQ) and process validation. They discussed the shift toward risk-based, lifecycle-driven approaches incorporating digitalisation, PAT, AI, and continuous manufacturing. The authors emphasised regulatory frameworks (FDA, EMA) and the importance of documented evidence for equipment reliability and process consistency to ensure patient safety and GMP compliance.(20)

11. Bompelliwar et al. (2026): The authors reviewed analytical strategies for cleaning validation using chromatographic methods. They focused on health-based exposure limits (PDE/ADE), MACO calculations, sampling techniques, and ICH/FDA guidelines. The authors highlighted risk-based worst-case selection, residue control for APIs and cleaning agents, and the integration of cleaning validation into pharmaceutical quality systems for preventing contamination.(21)

12. Jawa et al. (2024): The authors evaluated acceptable exposure limits for inactive therapeutic-protein fragments in biopharmaceutical cleaning validation. They demonstrated protein degradation and inactivation during cleaning/sanitization using SDS-PAGE and cell-based immunogenicity assays. The study showed that higher ALs for inactive fragments simplify validation while maintaining patient safety, offering a science-based alternative to active protein limits.(22)

13. Makraduli et al. (2023): The researchers conducted cleaning validation of an electronic counting machine using two different cleaning agents (Deconex CIP wash-x and COSA CIP 90). They employed swab and rinse sampling with HPLC analysis for API residues, cleaning agent residues, and microbiological testing. The study confirmed effective, reproducible cleaning within acceptance limits and established an 8-hour time limit between cleaning and reuse.(23)

14. Kochova et al. (2023): The author and co-authors developed and validated an RP-HPLC method for determination of betamethasone residues on manufacturing equipment surfaces during cleaning validation. They calculated PDE for topical administration and established MACO limits. The sensitive, selective method was validated per ICH Q2(R1) and proved suitable for quantitative residue analysis supporting cleaning validation acceptance criteria.(24)

15. Vaghela (2025): The researchers presented a comprehensive review of risk-based cleaning validation in pharmaceutical manufacturing. The author examined ICH Q9 principles, health-based exposure limits (PDE/ADE), FMEA tools, lifecycle approaches, and strategies for cross-contamination prevention in multi-product facilities. Emphasis was placed on science-based, patient-protective methodologies over traditional compliance-driven practices.(25)

16. Chavan and Desai (2022), in their review article Analytical method validation: A brief review, highlighted the significance of analytical method validation for ensuring accuracy, precision, specificity, linearity, LOD, LOQ, robustness, and reproducibility of pharmaceutical analysis. The authors discussed ICH, USP, and FDA guidelines, validation parameters, statistical tools, and presented a case study on RP-HPLC method validation for Paracetamol, guiding young researchers for quality analytical practices(26)

17. Shinde and Khulbe (2025), in their review titled Analytical Method Validation: A Comprehensive Review of Current Practices and Applications, provided a detailed overview of analytical method validation as per ICH Q2(R2),

USP, and EMA guidelines. They discussed key validation parameters, AQbD, automation, AI/ML integration, matrix effects, method transfer issues, lifecycle management, and industrial applications in pharmaceuticals, biologics, food safety, and environmental monitoring.(27)

18. Dewi et al. (2022): In their mini review "Quality By Design: Approach to Analytical Method Validation", discussed the implementation of Analytical Quality by Design (AQbD) for robust analytical method development. The authors emphasised the use of ATP, CQA risk assessment, DoE, MODR, control strategy, and continuous monitoring throughout the method lifecycle to ensure quality, reduce variability, and enhance regulatory compliance in pharmaceutical analysis.(28)

19. Amrutkar et al. (2022): The authors presented a comprehensive review on "Analytical Method Development and Validation" highlighting the necessity of validated analytical procedures for ensuring quality, safety, and efficacy of pharmaceuticals. The authors detailed steps of method development, various validation parameters (accuracy, precision, specificity, linearity, robustness, etc.), types of validation, and their significance in the pharmaceutical industry from raw material to finished products.(29)

20. Meher et al. (2022): In their review "A Recent Review on Analytical Method Development and Validation", outlined the critical role of analytical methods in drug discovery, development, and quality control. The authors described method development strategies, key validation parameters as per ICH guidelines (linearity, accuracy, precision, specificity, LOD, LOQ, robustness), and various case studies on HPLC and other techniques for pharmaceutical analysis.(30)

21. Bhagwat et al. (2024): The authors reviewed method development and validation for various pharmaceutical dosage forms, emphasising the role of analytical techniques like HPLC, RP-HPLC, UPLC, UV-Visible spectroscopy, and HPTLC. The authors highlighted steps in method development, key validation parameters as per regulatory standards, and the importance of robust, specific, and sensitive methods for ensuring drug quality, safety, and efficacy in quality control laboratories.(31)

22. Chowdhury (2023): "Study of the development and validation for specific and sensitive analytical methodologies". The investigator presented. The author reviewed the stages of method development and validation parameters such as accuracy, precision, specificity, linearity, limit of detection (LOD), limit of quantification (LOQ), robustness and ruggedness following ICH standards. The evaluation underlined the significance of these techniques in drug production to guarantee product excellence and compliance with regulations.(32)

23. Parmar and Patel (2022): The authors reviewed the recent developments in analytical methods of some newly FDA-approved drugs in 2021 by means of UV Spectrophotometry, HPLC, HPTLC, RP-HPLC and LC-MS/MS methods. The authors presented detailed case studies of different pharmaceuticals for which chromatographic conditions and validation parameters were described and their applications in quality control and bioanalysis indicated.(33)

24. For Vishwakarma and Mudgal (2026): They had conducted a comparative study of analytical method validation parameters as per ICH Q2(R1) and updated Q2(R2) guidelines. The authors discussed key parameters (specificity, accuracy, precision, linearity, range, LOD, LOQ, robustness) along with lifecycle management, Quality by

Design (QbD), and applications in pharmaceutical quality control.(34)

25. Urade et al. (2026): The authors presented a comprehensive review on analytical method development and validation for anticancer drugs. The authors focused on RP-HPLC, LC-MS/MS, and UV-Vis methods for drugs like Temozolomide, Capecitabine, and Gemcitabine, covering optimisation, ICH s parameters, stability-indicating assays, and forced degradation studies for quality control of antineoplastic agents.(35)

26. Girase et al. (2024): The authors comprehensively reviewed the evolution of analytical method development and validation for fexofenadine, a second-generation antihistamine. The authors discussed various chromatographic techniques including HPLC, UHPLC, and RP-HPLC, along with key validation parameters such as accuracy, precision, specificity, linearity, LOD, LOQ, and robustness to ensure reliable quality control of the drug.(36)

27. Uppar et al. (2023): The researchers provided an overview of analytical method development and validation for Amitriptyline HCl using HPLC. The authors emphasised ICH guidelines for parameters like accuracy, precision, specificity, linearity, range, robustness, LOD, and LOQ. They highlighted forced degradation studies and the importance of stability-indicating methods for quality control of this tricyclic antidepressant.(37)

28. Venkatesh et al. (2025): The authors reviewed analytical parameters in quality management systems within the pharmaceutical industry. The authors discussed key validation parameters (accuracy, precision, specificity, linearity, LOD/LOQ, robustness) per ICH Q2(R2), their integration with QbD, lifecycle management, ALCOA data integrity principles, and their role in ensuring regulatory compliance and product quality.(38)

29. Thapar et al. (2023): The authors presented a comprehensive review on method development and validation for Ophthalmic formulations containing antibiotics used in bacterial conjunctivitis. The authors covered HPLC techniques for various antibiotics (e.g., ciprofloxacin, tobramycin), ICH validation parameters, stability-indicating methods, and challenges in analysing complex ophthalmic matrices.(39)

30. Tanpure et al. (2023): The investigators developed and validated an RP-HPLC method for simultaneous quantification of Domperidone and Omeprazole. The researchers optimized chromatographic parameters (methanol:acetonitrile:buffer mobile phase) and validated that the method followed ICH criteria for linearity, accuracy, precision, robustness, LOD, LOQ and specificity. The method was found to be stability indicating by degradation studies.(40)

31. Tayde et al. (2024): The writers and colleagues have extensively reviewed the forced degradation studies highlighting the importance of these studies in elucidating degradation pathways, validating stability-indicating methods, and determining molecular stability of pharmaceuticals. The contributors covered analytical methodologies, stress factors (acidic, basic, oxidative, thermal, photolytic), regulatory views from ICH/FDA, and implementation challenges. The importance of these in the formulation development, packaging and shelf-life assessment to ensure the quality and safety of the medicine.(41)

32. Jadhav et al. (2024): The authors have developed and validated an X-ray powder diffraction (XRPD) method for the determination

of Rasagiline Hemitartrate as an active pharmaceutical ingredient in 1 mg tablets. In the case of placebo, the specificity was demonstrated by the identification of a characteristic peak at 2θ = 6.6°. The six replicate formulations containing 10% Rasagiline Tartrate API were used to confirm the accuracy of the method which gave consistent results with a %RSD of 0.25 confirming the reliability of the method for polymorphism analysis and quality control purposes.(42)

33. Kawarkhe (2025): The author explored the modernization of pharmaceutical validation through Computer System Assurance (CSA), Artificial Intelligence (AI) and life cycle management principles. The writer elaborated more on some types of validation (process, equipment, cleaning, CSV, analytical), regulatory bodies (FDA, EMA, WHO), risk assessment, data integrity principles (ALCOA), and new trends indicating continuous verification and automation to enhance compliance and efficiency.(43)

34. Muharomah and Saputra (2025). The authors discussed validation and qualification methods for pharmaceutical equipment for GMP/CPOB requirements. The authors described the stages such as Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ), emphasizing the need for systematic documentation, risk management and issues like technical limitations and lack of resources to ensure consistent quality of the product and compliance with efficiency.(44)

35. Bhatia et al. (2023): The authors and co-authors provided a comprehensive study on process validation of Paracetamol tablets based on ICH guidelines. The authors covered the three stages (process design, qualification, continued verification), critical process parameters (CPP), critical quality attributes (CQA), and the role of ICH Q8(R2), Q9, Q10 in ensuring consistent quality, safety, and efficacy through systematic control and documentation.(45)

36. Kumari et al. (2025): According to the authors, they performed process validation and evaluation of critical process parameters for Atorvastatin 40 mg tablets. The authors focused on stages of manufacturing (dispensing, sifting, mixing, granulation), in-process controls, and documentation to ensure consistency in identity, strength, quality, and purity as per cGMP and ICH guidelines, providing high assurance of reproducible product quality.(46)

37. Pore et al. (2023): The authors reviewed quality aspects of herbal drugs and their formulations. The authors emphasised standardisation, quality control parameters, factors affecting quality (pesticides, microbes, adulteration), and the need for modern analytical methods to ensure safety, efficacy, and consistency of herbal medicines in the global market.(47)

38. Saxena et al. (2022): The researchers reviewed process validation of pharmaceutical dosage forms. The authors highlighted its importance in cGMP, stages of validation, documentation requirements, and specific protocols for solids (tablets/capsules), liquids, and semisolids to ensure consistent quality, safety, and efficacy as per USFDA and ICH guidelines.(48)

39. Shaikh et al. (2023). Equipment validation of the moist heat sterilisation (steam steriliser) for an injectable chamber was performed by the authors. The authors performed a Bowie-Dick test, a vacuum leak test and a swab test, confirming a uniformity of heat (121-124°C), and steam penetration. The investigation confirmed the process in compliance with the GMP regulations and gave the sterility assurance and consistent

performance for the pharmaceutical manufacture.(49)

SUMMARY OF REVIEW OF PATENT SEARCH ANALYSIS REPORT (PSAR):

Following is the Deposited Brief Review of Summary of Patent Search Analysis Report (PSAR):

TABLE 2: Review Of Patent Search Analysis Report (PSAR)

SR. NO.	PATENT APPLICATION NO.	TITLE OF PATENT	REFERENCE NO.
1.	US 20200334921A1	Methods for Process Validation.	50
2.	US 011619619B2	Methods for Validating Medication.	51
3.	US 20140350945A1	System and Method for Validation of Pharmaceutical Composition Formulations.	52
4.	USOO8639527B2	Validated Healthcare Cleaning and Sanitising Practices.	53
5.	US011170884B2	Control System for Radiopharmaceuticals.	54
6.	US011184356B1	System And Method for Seamless User Equipment Authentication.	55
7.	US008209495B2	Storage Management Method and Storage Management System.	56

1. METHODS OF PATENT PROCESS VERIFICATION US 20200334921A1: This patent pertains to methods for improving validation of processes for producing drugs and the like. It's based on the three-stage lifecycle approach of FDA: design, certification, and continued monitoring. Among the useful tools developed by Apotex inventors is a technical risk assessment system that provides a score for the influence of the different materials and process conditions on the product quality. This enables teams to calculate a clear "risk ratio" and more easily identify and control crucial areas, even as they scale up or change. A key piece is a statistical way to get the right number of certification batches, instead of guessing. In addition, it includes Probability of Acceptance analysis to estimate the probability that future batches will meet quality criteria. Together these techniques allow for more objective verification, reduce unnecessary testing and help maintain uniform product quality in batch or continuous production.(50)

2. US 011619619B2 PATENT METHODS FOR MEDICATIONS VERIFICATION: This patent provides a practical way to avoid counterfeit and substandard pharmaceuticals in the supply chain. Valisure's model is to verify the chemistry of the pharmaceuticals right before they reach the pharmacy or patient, rather than through a patchwork of tests along the production and distribution chain. Validation labs use sophisticated instruments such as Raman spectroscopy to test the medicine to make sure the right active ingredients are present, that all inert components are present, that they are in the exact proportions required, and that the medicine dissolves well. Batches that meet strict reference requirements are the only ones to be issued a Certificate of Analysis and released for dispensing. This procedure provides real trust to

pharmacies and end users that the medicine is authentic and correctly manufactured. It decreases the chances of faulty medications getting through and provides a far more stringent quality control layer near the end consumer. The complete process can be done with prescription and over-the-counter products.(51)

3. SYSTEM AND METHOD FOR VALIDATION OF FORMULATIONS OF PHARMACEUTICAL COMPOSITIONS US 20140350945A1: This patent describes a Smart Barcode based system for verification of unique medicine compositions for compounding pharmacies. "Quality control begins at the inventory entry, not at the end when you check quality. Once a batch is formulated and made each product is labelled with a barcode containing all the details such as ingredients, strength and lot info. Once the system scans the system, it compares the actual composition to the original recipe. If anything is off, wrong chemical, wrong amount, potency issues, it flags it immediately so the batch can be corrected before it is completed. This saves money, reduces waste and eliminates the human error of entering in lot numbers manually. In general, it makes for more accurate and efficient pharmaceutical compounding, but only ensures the right pharmaceuticals are dispensed to patients.(52)

4. US PATENT (10) PATENT NO.: 8639527B2 APPROVED SANITATION AND DISINFECTION METHODS IN HEALTHCARE: The Ecolab patent is a comprehensive and dependable system to improve cleaning and sterilization procedures in healthcare settings. Unlike the traditional methods, it designs advanced facilities grouped into cleaning sectors. Each sector has its own procedure, schedule and quality check with tools such as ATP bioluminescence or indicators to ensure that surfaces are properly sterilized. The system measures compliance, collects data, identifies barriers, and helps employees make immediate changes. This is the name given to systematic, demonstrable hygiene criteria which considerably reduce the spread of illnesses. Medical institutions can employ it for staff training, administrative reporting, and proving compliance with hygiene regulations. It brings responsibility and science into the daily work of hospital sanitation on a large scale.(53)

5. PATENT, SYSTEM FOR RADIOACTIVE DRUG MANAGEMENT US011170884B2: This patent discloses a better system for controlling the manufacturing of radiopharmaceuticals, specialized radioactive substances used in diagnostic imaging. It combines the equipment, testing facilities and personnel at the various sites to collect data during the manufacturing process. The system performs this analysis in real time and identifies any quality discrepancies or irregularities and delivers clear feedback for rapid resolution. And it ensures that the product is made to all safety and quality standards before a batch is released. This helps ensure that poor quality medicines do not reach health facilities and the hands of patients. The innovation increases the reliability, traceability and regulatory compliance of industrial processes through the integration of data, analytical instruments and automated alerts. That’s a smart move in an industry where small mistakes can have big consequences.(54)

6. US011184356B1 A SYSTEM AND METHOD FOR EFFORTLESS USER EQUIPMENT AUTHENTICATION: This patent presents a smart process to smoothen the authentication of mobile devices over modern networks such as 4G and 5G. On each move of a device from one node to another node in the network, the system quickly verifies the user’s identity by means of encrypted

values on both sides. It works with many core network elements. It checks if authentication values match before permitting access. This avoids service interruptions and enhances security in handovers or roaming. The innovation is especially useful for operators that want a seamless user experience, while keeping things safe in complex mobile environments. It improves the speed, reliability and appropriateness of network authentication in today's high velocity mobile environment in general.(55)

7. US PATENT US008209495 B2 STORAGE ADMINISTRATION TECHNIQUE AND STORAGE ADMINISTRATION SYSTEM: This Hitachi patent discloses an improved storage management technique in large scale computer systems. It keeps management functionalities in shared memory allowing several users to access storage resources with more flexibility according to their needs. The system tightly controls who can do what and when, thus improving overall security and efficiency. Helps businesses optimize storage strategies and reduce complexity. It draws a clear distinction between program execution and resource distribution, which reduces misuse and improves overall efficiency. This type of technology was important for corporate storage systems that had to process very large amounts of data reliably.(56)

RATIONALE:

Validation is an integral part of pharmaceutical quality assurance that guarantees processes, equipment, analytical methods and systems consistently generate products that adhere to the desired quality, safety and efficacy standards according to current Good Manufacturing Practices (cGMP) and the FDA, EMA, ICH and WHO regulatory requirements. An extensive review of modern literature suggests that validation methods have been developed significantly from traditional three-batch methods to today's risk-based, lifecycle-centric approaches.(57)

This transition includes Quality by Design (QbD), Quality Risk Management (QRM), Process Analytical Technology (PAT), and digital innovations including Artificial Intelligence (AI) and cloud computing, which enable continuous process validation and improvement in efficiency while maintaining data integrity (ALCOA+ principles). Many studies stress the critical need of equipment qualification (DQ, IQ, OQ, PQ) and process validation in different dosage forms. Scholars have stressed the importance of the validation master plan (VMP), critical process parameters (CPPs) and critical quality attributes (CQAs) for achieving consistent manufacturing outcomes.(58)

Cleaning validation remains a key area of focus to prevent cross contamination. Advanced approaches include health-based exposure limits (PDE / ADE), MACO calculations, advanced sampling techniques (swab and rinse) and chromatographic techniques (HPLC, RP-HPLC) for residue testing. There has been research demonstrating the utility of scientifically based thresholds and extreme-case selection approaches for certain apparatus and API research. The validation of analytical methods is of great concern, and many publications have described the criteria of ICH Q2(R1/R2) including accuracy, precision, specificity, linearity, range, LOD, LOQ, robustness and stability-indicating properties. The importance of reliable and reproducible approaches throughout the product life cycle is highlighted by advances in HPLC, UPLC, LC-MS/MS and other techniques for drugs such as Paracetamol, Atorvastatin, anti-cancer drugs and antibiotics.(59)

Analytical Quality by Design (AQbD), forced degradation studies and automation increase the reliability of the procedure. Emerging themes in the literature include Computer System Validation (CSV), validation of cloud-based systems and the implementation of Computer System Assurance (CSA) to improve compliance and drive innovation. The studied research consistently demonstrates that systematic validation reduces risks and costs, and facilitates regulatory approval and, therefore, patient well-being. The body of literature provides a solid base for understanding current best practices and identifies opportunities for further improvements through digital transformation and risk-oriented initiatives in pharmaceutical manufacturing.(60)

Table 3: Major Themes from Literature Review on Pharmaceutical Validation

Sr. No.	Key Theme	Major focuses areas highlighted in literature.	Supporting references
1.	Process Validation & Lifecycle Approach	Shift from traditional 3-batch to Process Design, Process Qualification & Continued Process Verification; integration with QbD and QRM	Vaware et al. (2026), Bhatia et al. (2023), Wangpo et al. (2019)
2.	Equipment Qualification	DQ, IQ, OQ, PQ stages; risk-based approaches and documentation	Muharomah & Saputra (2025), Gorana & Choudhary (2026), Sabale & Thorat (2021)
3.	Cleaning Validation	Health-based limits (PDE/ADE), MACO calculations, swab & rinse sampling, chromatographic methods	Dahiya et al. (2022), Bompelliwar et al. (2026), Vaghela (2025), Makraduli et al. (2023)
4.	Analytical Method Validation	ICH Q2 parameters (accuracy, precision, specificity, linearity, LOD, LOQ, robustness); AQbD and stability-indicating methods	Chavan & Desai (2022), Shinde & Khulbe (2025), Dewi et al. (2022), Urade et al. (2026)
5.	Computer System Validation & Digital Trends	CSV, CSA, cloud validation, data integrity (ALCOA+), AI and automation	Raja et al. (2024), Ullagaddi (2024), Kawarkhe (2025)

AIM AND OBJECTIVE:

AIM:

The present study aims to explore and review the principles, practices, regulatory requirements and recent trends associated with validation in pharmaceutical industry with special emphasis on process validation, equipment qualification, cleaning validation, analytical method validation and computer system validation. The purpose of this assessment is to underscore the significance of validation as a key aspect of Good Manufacturing Practices (GMP) for ensuring product quality, safety, efficacy, data integrity and compliance with regulations during manufacturing of pharmaceuticals.(61)

OBJECTIVES:

1. A thorough analysis of the evolution, definitions and regulatory frameworks (FDA, EMA, WHO, ICH) of pharmaceutical validation including the transition from the traditional three batch

validation to current lifecycle and risk-based approaches.

2. To evaluate the importance and methods of critical validation categories such as Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), Process Validation (Process Design, Qualification, Continued Process Verification), Cleaning Validation and Computer System Validation (CSV).

3. To study the principles and criteria of Analytical Method Validation (accuracy, precision, specificity, linearity, LOD, LOQ, robustness) in accordance with ICH Q2(R1/R2) recommendations and their integration into Analytical Quality by Design (AQbD).
4. To discuss current trends in the field of health-related exposure thresholds (PDE/ADE), Quality by Design (QbD), risk management (ICH Q9), digital transformation, Artificial Intelligence, Process Analytical Technology (PAT), and validation of cloud-based systems.
5. The focus is on case studies, practical challenges and best practices in cleaning validation, equipment qualification and analytical method development to assure cross-contamination prevention and uniform product quality.

SUMMARY

Validation is an important requirement in the pharmaceutical industry to ensure that the products are of consistent quality, safety and efficacy with strict regulatory compliances. A thorough review of the existing literature shows that validation is a well-established, evidence-based methodology that gives a high measure of assurance that manufacturing processes, equipment, cleaning procedures and analytical methods are operating reproducibly during the product's life cycle. The basic concepts of pharmaceutical validation, process validation, equipment qualification (DQ, IQ, OQ and PQ), cleaning validation and analytical method validation have been studied in detail in many investigations.(62)

These components are essential for compliance with Good Manufacturing Practices (GMP) and regulatory guidelines from authorities such as FDA, EMA, ICH and WHO. The literature describes the evolution of validation from traditional three-batch approaches to contemporary lifecycle approaches such as Process Design, Process Qualification and Continued Process Verification. Modern methodologies are highly focused on risk-oriented tactics, Quality by Design (QbD), Quality Risk Management (QRM) and integration of high-end technology such as Process Analytical Technology (PAT), Artificial Intelligence (AI) and cloud computing platforms. Cleaning validation has received considerable attention, and researchers have focused on health-based exposure limits (PDE/ADE), Maximum Allowable Carryover (MACO), swab and rinse sampling methods, and chromatographic methods (HPLC, RP-HPLC) for identification of residues. Additional investigations focus on scientifically supported acceptance criteria and methods to prevent cross-contamination in facilities processing more than one product. (63)

The analytical technique validation literature extensively covers the ICH Q2(R1/R2) criteria such as accuracy, precision, specificity, linearity, robustness, limit of detection (LOD) and limit of quantification (LOQ). Development and validation of stability indicating methods using HPLC, UPLC, LC-MS/MS and other techniques for different pharmaceutical dosage forms like tablets, injectables, ophthalmic solutions and anticancer drugs have many studies. Forced degradation studies and Analytical Quality by

Design (AQbD) have become indispensable tools to guarantee the robustness of the method.

Computer System Validation (CSV), data integrity (ALCOA+), and modernization via Computer System Assurance (CSA) are some of the key topics that address challenges in digital transformation while complying to regulations. The reviewed literature shows that strict validation procedures reduce manufacturing errors, enhance processes, reduce costs and ultimately secure patient safety.(62)

Table 4: Summary of Main Validation Categories and Key Areas of Focus

Sr. No.	Types of Validation	Key Stages	Primary Objectives	Regulatory Empasis
1.	Equipment Validation	Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ)	Ensure equipment is suitable, correctly installed, operates properly and performs consistently	FDA, EU GMP Annex 15, WHO
2.	Process Validation	Prospective, Concurrent, Retrospective, Revalidation + Lifecycle Stages (1, 2 & 3)	Demonstrate that the manufacturing process consistently produces product meeting predetermined quality attributes	FDA Process Validation Guidance (2011), ICH Q8–Q10
3.	Cleaning Validation	Swab & rinse sampling, MACO / PDE-based limits, worst-case selection	Prevent cross-contamination and ensure residue levels are within acceptable limits.	FDA, EMA, PIC/S, ICH Q9
4.	Analytical Method Validation	Accuracy, Precision, Specificity, Linearity, Range, LOD, LOQ, Robustness	Ensure analytical methods are reliable, accurate and suitable for their intended purpose	ICH Q2(R1/R2), USP, FDA
5.	Computer System Validation (CSV)	V-model (DQ–IQ–OQ–PQ), GAMP 5 categories, data integrity	Ensure computerized systems maintain data integrity, reliability and regulatory compliance	21 CFR Part 11, GAMP 5, ALCOA+

CONCLUSION

A thorough literature review on validation in the pharmaceutical industry clearly points out to it as an integral part of quality assurance and regulatory compliance. Validation is a systematic documented approach which provides a high degree of assurance that the product will consistently meet quality, safety and efficacy standards throughout the manufacturing life of the product. The studies analyzed together demonstrate the importance of conducting thorough validation processes to satisfy the strict requirements imposed by international regulatory organizations such as the FDA, EMA, ICH, and WHO.(64)

Common themes from the literature are the shift of validation from traditional fixed-batch approaches to modern science- and risk-based

lifecycle approaches. Current models stress Process Design, Process Qualification and Continuous Process Verification, as well as Quality by Design (QbD), Quality Risk Management (QRM) and modern technologies including Process Analytical Technology (PAT), Artificial Intelligence (AI) and digitalization. Critical elements for minimizing cross-contamination and assuring equipment reliability include equipment qualification (DQ, IQ, OQ, PQ), process validation and cleaning validation. Cleaning validation studies have indicated a trend towards health-based exposure limits (PDE/ADE), sophisticated analytical techniques (HPLC, RP-HPLC) and risk-based approaches such as FMEA for robust residue control in multi-product environments. The assessment of analytical methodologies has been developed extensively. Standards of ICH Q2(R1/R2) including accuracy, precision, specificity, linearity, robustness, LOD and LOQ have been studied carefully by scholars. The development of stability indicating methods forced degradation studies and Analytical Quality by Design (AQbD) approaches has enhanced the reliability of analytical methods in different dosage forms from conventional tablets to complex biopharmaceuticals and herbal formulations.(65)

Also, the role of Computer System Validation (CSV), cloud validation and Computer System Assurance (CSA) is increasing to address data integrity (ALCOA+) challenges in a fast-changing digital world. Case studies on practical application of validated specific pharmaceuticals (Paracetamol, Atorvastatin, anticancer agents) and equipment (steam sterilizers, electronic counting devices) are presented in the literature. The case studies demonstrated that the well-designed validation protocols are useful to reduce the production defects, improve the processes, decrease the operational costs and guarantee the patient safety. The body of research indicates a clear trend toward more flexible, agile and technology-based validation procedures that are more aligned with current Good Manufacturing Practices (cGMP).(66)

Challenges are limited resources, complex regulations and the need to keep pace with new technologies. The literature review in this paper provides a strong theoretical foundation for the current study and highlights the need for integrated risk-based validation approaches in pharmaceutical manufacturing. Future research needs to concentrate on better integration of AI, automation and real-time monitoring to improve the effectiveness of validation and compliance in the evolving pharmaceutical landscape.

Ethics approval and consent to participate

NA

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Data availability

The datasets of the present study are available from the corresponding author upon reasonable request.

Declaration of Competing Interest

The authors confirm, No conflicts of interest.

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ABBREVIATIONS:

- GMP- Good Manufacturing Practice
- cGMP- Current Good Manufacturing Practice
- ICH-International Council for Harmonisation
- FDA- Food and Drug Administration
- EMA- European Medicines Agency
- WHO- World Health Organisation
- DQ- Design Qualification
- IQ- Installation Qualification
- OQ- Operational Qualification
- PQ- Performance Qualification
- VMP- Validation Master Plan
- CSV- Computer System Validation
- CSA- Computer System Assurance
- GAMP 5- Good Automated Manufacturing Practice 5
- QbD- Quality by Design
- AQbD- Analytical Quality by Design
- PAT- Process Analytical Technology
- ALCOA+ - Attributable, Legible, Contemporaneous, Original, Accurate + (Complete, Consistent, Enduring, Available)
- PDE- Permitted Daily Exposure
- ADE- Acceptable Daily Exposure
- MACO- Maximum Allowable Carryover
- LOD- Limit of Detection
- LOQ- Limit of Quantification
- RP-HPLC- Reverse Phase - High Performance Liquid Chromatography
- UHPLC- Ultra High-Performance Liquid Chromatography
- HPLC- High Performance Liquid Chromatography
- HPTLC- High Performance Thin Layer Chromatography
- LC-MS/MS- Liquid Chromatography – Tandem Mass Spectrometry
- XRPD- X-Ray Powder Diffraction
- FMEA- Failure Mode and Effects Analysis
- CPP- Critical Process Parameters
- CQA- Critical Quality Attributes
- ATP- Analytical Target Profile
- MODR- Method Operable Design Region
- DoE- Design of Experiments
- GxP- Good x Practice (x = Manufacturing, Laboratory, Clinical, etc.)
- CFR- Code of Federal Regulations
- USP- United States Pharmacopoeia

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