WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL RESEARCH

Review Article

Coden USA: WJPPCL

2026
Volume: 03
Issue: 06
Page: 71-91

"CURRENT PERSPECTIVES ON EQUIPMENT QUALIFICATION (IQ, OQ, PQ) AND PROCESS VALIDATION IN PHARMACEUTICAL MANUFACTURING: A REGULATORY OVERVIEW"

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Received: 21 April 2026 **Revised: 11 May 2026** **Accepted: 31 May 2026**

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DOI: https://doi.org/10.5281/zenodo.20483684,

ABSTRACT

In the pharmaceutical industry, making high-quality medicine is not just about the final product; it is about ensuring that every machine and every process works perfectly every single time.[1] This review project focuses on the essential steps of **Equipment Qualification (EQ)** and **Process Validation (PV)**, which are the "gold standards" for safety and consistency in manufacturing.[2] The project explains the three main stages of checking equipment: **Installation Qualification (IQ)**, which ensures the machine is set up correctly; **Operational Qualification (OQ)**, which checks if the machine runs properly at different speeds or temperatures; and **Performance Qualification (PQ)**, which proves the machine consistently produces the right results during actual production. Together, these steps make sure that the hardware is reliable.[3] Beyond the machines, the project looks at **Process Validation**, which is the overall "recipe" for success. Following guidelines from regulatory bodies like the **FDA** and **EMA**, the industry is moving away from just testing a few batches and moving toward **Continuous Monitoring**. This means using modern technology to watch the production process in real-time.[4] We also discuss the **Risk-Based Approach**, where companies focus most of their energy on the parts of the process that are most likely to affect the patient's health. By looking at current trends for 2026, this project shows how these rules help factories stay compliant, reduce waste, and, most importantly, keep medicine safe for everyone.[5] **Emerging Trends,** the Digitalization, real-time monitoring, and continuous

manufacturing are transforming validation practices. With tools like Process Analytical Technology (PAT) and artificial intelligence, the focus is shifting from static batch-based checks to dynamic, lifecycle-driven approaches that enhance efficiency, transparency, and sustainability.

KEYWORDS

- **Technical terms (IQ, OQ, PQ, PV, PAT)** → Ensure your paper is indexed under pharmaceutical engineering and validation studies.
- **Regulatory bodies (FDA, EMA, WHO, ICH, PIC/S)** → Attract readers interested in compliance and international frameworks.
- **Conceptual themes (Risk-based approach, lifecycle validation, harmonization)** → Highlight modern perspectives and trends.
- **Emerging trends (Digitalization, AI, continuous manufacturing)** → Position your paper as forward-looking and relevant to 2026.

INTRODUCTION

Pharmaceutical manufacturing is one of the most highly regulated industries worldwide, owing to its direct impact on patient health and safety. Unlike other industrial sectors, even minor deviations in equipment performance or process parameters can compromise product quality, leading to serious consequences. To safeguard against such risks, global regulatory authorities have established stringent frameworks under Good Manufacturing Practices (GMP), where Equipment Qualification (EQ) and Process Validation (PV) serve as critical pillars of quality assurance.

Equipment Qualification ensures that manufacturing systems are properly designed, installed, operated, and consistently perform within defined parameters. It is typically divided into four stages: **Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ)**. Each stage provides documented evidence that equipment is reliable and suitable for its intended use.

Process Validation complements equipment qualification by confirming that manufacturing processes can consistently produce products meeting predetermined specifications. Traditional validation approaches relied on three consecutive successful batches, but modern perspectives emphasize a **lifecycle approach** that integrates validation into every stage of product development and commercial production. Regulatory bodies such as the **FDA, EMA,**

WHO, ICH, and PIC/S have progressively shifted toward risk-based, science-driven frameworks that prioritize continuous monitoring and proactive control.

Emerging trends — including **digitalization, Process Analytical Technology (PAT), artificial intelligence, and continuous manufacturing models** — are reshaping validation practices. These innovations move the industry away from static, batch-based checks toward dynamic, real-time assurance systems that enhance efficiency, transparency, and sustainability.

THE REGULATORY FRAMEWORK:

Pharmaceutical manufacturing is governed by Good Manufacturing Practices (GMP), which are codified and enforced by international and national regulatory agencies. GMP ensures that medicines are consistently produced and controlled according to quality standards. Within GMP, equipment qualification and process validation are mandatory requirements. They provide documented evidence that both equipment and processes are capable of consistently delivering products that meet safety, efficacy, and quality expectations.

1. United States – FDA

- The Food and Drug Administration (FDA) regulates pharmaceutical manufacturing under 21 CFR Parts 210 and 211.
- In 2011, FDA issued the landmark guidance *Process Validation: General Principles and Practices*, which introduced the lifecycle approach:
  - Stage 1: Process Design – scientific understanding of the process.
  - Stage 2: Process Qualification – confirming equipment and facilities can perform as intended.
  - Stage 3: Continued Process Verification – ongoing monitoring during routine production.
- FDA emphasizes risk-based validation, statistical tools, and scientific evidence rather than relying only on three consecutive successful batches.

2. European Union – EMA

- The European Medicines Agency (EMA) enforces GMP through Annex 15: Qualification and Validation.
- Annex 15 provides detailed requirements for:
  - Equipment qualification (DQ, IQ, OQ, PQ).
  - Cleaning validation.

- Process validation, including continuous verification.
- EMA emphasizes risk management and requires manufacturers to justify their validation strategies scientifically.

3. World Health Organization (WHO)

- WHO issues GMP guidelines through its Technical Report Series (TRS), such as TRS 937, TRS 981, and TRS 1019.
- These guidelines are especially important for developing countries, providing a globally recognized baseline for validation practices.
- WHO focuses on practical, implementable validation requirements for water systems, cleaning, and manufacturing processes.

4. International Council For Harmonisation (ICH)

- ICH harmonizes pharmaceutical regulations across major markets (US, EU, Japan).
- Key guidelines include:
- ICH Q8 (Pharmaceutical Development): Encourages Quality by Design.
- ICH Q9 (Quality Risk Management): Introduces structured risk assessment.
- ICH Q10 (Pharmaceutical Quality System): Establishes a holistic quality framework.
- ICH Q12 (Lifecycle Management): Provides flexibility for post-approval changes and lifecycle validation.
- ICH guidelines are widely adopted, making them central to global harmonization.

5. Pharmaceutical Inspection Co-Operation Scheme (PIC/S)

- PIC/S publishes the GMP Guide PE 009, aligned with EU GMP.
- It promotes harmonization of GMP standards across member countries, including training and inspection practices.
- PIC/S guidelines are widely respected and often adopted by regulators in Asia, Africa, and Latin America.

- ***Equipment Qualification Requirements:***

- Design Qualification (DQ): Equipment design must meet intended use and regulatory needs.
- Installation Qualification (IQ): Equipment must be installed correctly per specifications.
- Operational Qualification (OQ): Equipment must operate within defined limits.

- Performance Qualification (PQ): Equipment must consistently perform under real production conditions.
- Regulators require documented evidence, risk assessments, and periodic requalification.

- ***Process Validation Requirements***

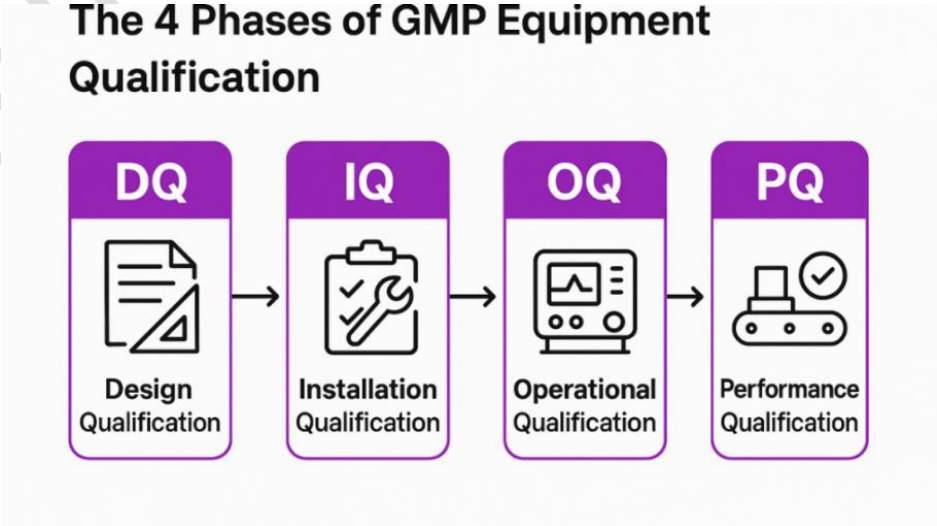
- Traditional Approach: Three consecutive successful batches to demonstrate consistency.
- Modern Lifecycle Approach: Continuous monitoring and verification throughout the product lifecycle.
- Regulators require identification of Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs), supported by statistical tools and scientific data.
- Validation must be science-based, risk-based, and lifecycle-driven.

- ***Why the Framework Matters***

- Ensures consistent batch-to-batch quality.
- Protects patient safety by minimizing risks of contamination or variability.
- Provides global harmonization, enabling multinational companies to comply across regions. Encourages innovation through risk-based and science-driven approaches.

EQUIPMENT QUALIFICATION STAGES:

(EQ) is the structured process of ensuring that manufacturing equipment is suitable for its intended purpose and consistently performs within defined parameters. It is a critical component of Good Manufacturing Practices (GMP) and forms the foundation for reliable pharmaceutical production. EQ is divided into four distinct stages, each with a specific objective.



- **Design Qualification (DQ):**

This stage verifies that the equipment design meets the intended use and regulatory requirements. It involves reviewing specifications, engineering drawings, and vendor documentation to ensure that the equipment is capable of performing the desired functions. DQ ensures that quality is built into the equipment from the very beginning.

- **Installation Qualification (IQ):**

IQ confirms that the equipment has been installed correctly according to manufacturer specifications and engineering requirements. It involves checking utilities, calibration, and environmental conditions to ensure proper setup. Documentation at this stage includes installation checklists and verification reports.

- **Operational Qualification (OQ):**

OQ tests the equipment under defined operating conditions to confirm that it functions as intended. This includes verifying alarms, control systems, and operating ranges. OQ ensures that the equipment can consistently perform within specified limits.

- **Performance Qualification (PQ):**

PQ demonstrates that the equipment performs reliably under actual production conditions. It involves running the equipment with real materials and processes to confirm consistent performance. PQ provides final assurance that the equipment is suitable for routine use.

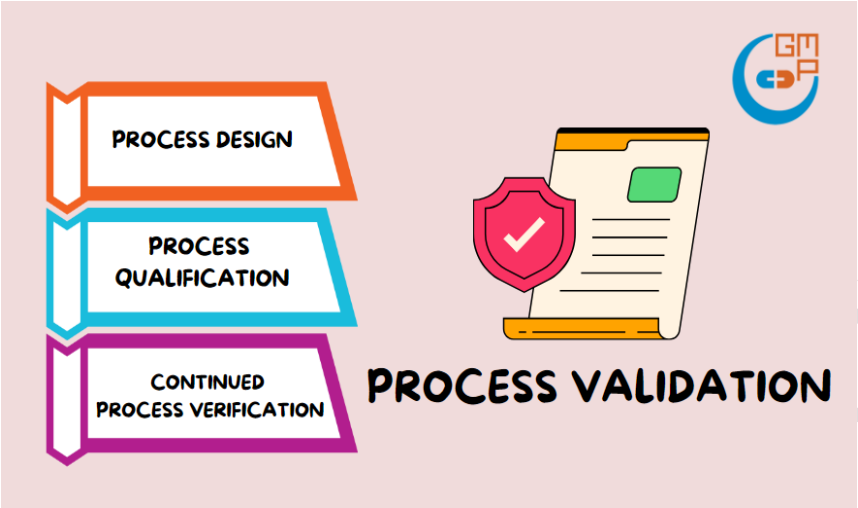
PROCESS VALIDATION (PV):

ensures that manufacturing processes consistently produce products meeting predetermined quality attributes. It is a regulatory requirement and a cornerstone of pharmaceutical quality assurance.

- **Traditional Approaches to process validation included:**

- **Prospective Validation:** Conducted before commercial production, using multiple batches to demonstrate consistency.
- **Concurrent Validation:** Performed during actual production, often used when prospective validation is not feasible.
- **Retrospective Validation:** Based on historical data from previously manufactured batches. While useful in the past, it is now considered less reliable and is rarely accepted by regulators.

Modern Lifecycle Approach introduced by the FDA and adopted globally consists of three stages:



- **Stage 1:**
  - *Process Design* – Establishing scientific understanding of the process, identifying critical process parameters (CPPs) and critical quality attributes (CQAs).
- **Stage 2:**
  - *Process Qualification* – Confirming that equipment, facilities, and processes can perform consistently under commercial manufacturing conditions.
- **Stage 3:**
  - *Continued Process Verification* – Ongoing monitoring during routine production to ensure that processes remain in control and capable of producing quality products.Tools and Technologies play a vital role in modern process validation. Statistical sampling, control charts, and trend analysis are used to monitor variability and detect deviations. Process Analytical Technology (PAT) enables real-time monitoring of critical parameters, allowing proactive adjustments and reducing reliance on end-product testing. Continuous manufacturing integrates validation directly into production, requiring new strategies to ensure ongoing compliance in a non-stop environment.

COMPARATIVE REGULATORY PERSPECTIVES:

Pharmaceutical manufacturing operates within a global regulatory environment, and while the principles of Good Manufacturing Practices (GMP) are universally recognized, different agencies emphasize distinct aspects of equipment qualification and process validation. These variations reflect regional regulatory philosophies, industrial practices, and historical

developments. A comparative analysis of the major regulatory authorities—FDA, EMA, WHO, PIC/S, and ICH—provides insight into both the diversity and convergence of global standards.

Regulatory Body	Key Focus in EQ/PV	Notable Guidelines	Highlights
FDA (USA)	Lifecycle validation, continued process verification	*Process Validation Guidance* (2011)	Introduced the **three-stage lifecycle model** (Design, Qualification, Continued Verification). Strong focus on **scientific understanding** and **ongoing monitoring**.
EMA (Europe)	Risk-based validation, structured qualification	*EU GMP Annex 15*	Provides detailed requirements for **DQ, IQ, OQ, PQ** and cleaning validation. Promotes **risk-based approaches** to target critical systems.
WHO	Flexible frameworks for global adoption	*WHO Technical Report Series*	Offers **baseline GMP standards** adaptable to resource-limited settings. Covers water systems, cleaning validation, and general PV.
ICH	Harmonization, risk management, lifecycle quality systems	*ICH Q8, Q9, Q10, Q12*	Acts as a **global harmonization platform**. Introduces **design space**, **risk tools**, and **quality systems**.
PIC/S	International cooperation, harmonized GMP inspections	*PIC/S GMP Guide (PE 009)*	Aligns GMP standards across member countries. Focuses on **inspection harmonization** and adoption of EU GMP principles globally.

Taken together, these perspectives illustrate both diversity and convergence in global regulatory expectations. The FDA emphasizes lifecycle validation and continuous monitoring, the EMA stresses risk-based approaches and detailed qualification requirements, the WHO provides flexible, globally applicable guidelines, PIC/S promotes harmonization of GMP standards and inspection practices, and ICH bridges global regulatory perspectives through harmonized guidelines. While emphasis may differ—lifecycle versus risk-based, flexibility versus harmonization—the shared goal is consistent: ensuring that pharmaceutical products are manufactured safely, effectively, and with unwavering quality.

CHALLENGES AND FUTURE DIRECTIONS

Pharmaceutical manufacturing is entering a period of profound transformation. While equipment qualification (EQ) and process validation (PV) have long been established as cornerstones of Good Manufacturing Practices (GMP), the industry is now facing new challenges driven by technological innovation, globalization, sustainability imperatives, and evolving regulatory expectations. The traditional models of qualification and validation, which once relied heavily on static documentation and batch-based verification, are being reshaped by digitalization, artificial intelligence, regulatory flexibility, and eco-friendly

practices. Understanding these challenges and future directions is essential for ensuring that validation frameworks remain robust, adaptive, and aligned with the needs of modern pharmaceutical production.

Digitalization:

Digitalization is revolutionizing pharmaceutical manufacturing by replacing paper-based systems with electronic records, automated workflows, and integrated data platforms. In the context of EQ and PV, digitalization offers several advantages. Electronic batch records (EBR) and manufacturing execution systems (MES) enhance traceability, reduce human error, and provide real-time visibility into production processes. Automated data capture from sensors and control systems ensures that deviations are detected immediately, enabling faster corrective actions.

Digital platforms also facilitate remote audits and inspections. Regulators can securely access electronic records without requiring physical site visits, a practice that became particularly important during the COVID-19 pandemic. Furthermore, digitalization supports continuous monitoring, allowing manufacturers to integrate validation into daily operations rather than treating it as a one-time event.

However, digitalization introduces challenges. **Data integrity** becomes paramount, as regulators demand assurance that electronic records are accurate, complete, and tamper-proof. **Cybersecurity risks** must be managed to protect sensitive manufacturing data from breaches. Additionally, the lack of standardized digital platforms across the industry can create interoperability issues. Future directions will likely involve harmonized digital standards, blockchain-based recordkeeping for enhanced security, and greater regulatory guidance on electronic validation systems.

Artificial Intelligence and Machine Learning:

Artificial Intelligence (AI) and Machine Learning (ML) are emerging as transformative tools for predictive analytics in process monitoring. By analyzing large datasets from equipment sensors, PAT tools, and historical production records, AI/ML models can identify subtle patterns that may indicate potential deviations or failures. Predictive maintenance is one of the most promising applications, allowing manufacturers to service equipment before breakdowns occur, thereby reducing downtime and ensuring consistent performance.

Machine learning algorithms can also optimize process parameters, improving yield and reducing variability. For example, ML can analyze thousands of process runs to determine the optimal operating ranges for critical process parameters (CPPs), thereby enhancing process robustness. AI-driven digital twins—virtual models of manufacturing processes—enable simulation and optimization without disrupting actual production.

The challenge lies in **regulatory acceptance**. Agencies must develop frameworks to evaluate and approve AI-driven validation strategies. Transparency and explainability of algorithms are critical, as regulators require clear justification for decisions made by AI systems. Future directions will involve collaborative efforts between industry and regulators to establish standards for AI/ML in validation, ensuring that predictive analytics can be harnessed without compromising compliance or patient safety.

Regulatory Flexibility:

Traditional validation models were designed for batch manufacturing and static processes. However, modern practices such as continuous manufacturing, adaptive control systems, and digital twins require new regulatory approaches. Agencies like the FDA and EMA are increasingly open to flexible, science-based validation strategies. The FDA's lifecycle model and EMA's risk-based philosophy both encourage manufacturers to justify their approaches with robust data rather than rigid checklists.

The **ICH Q12 guideline on lifecycle management** reflects this shift, providing pathways for post-approval changes without extensive revalidation. This flexibility is crucial for continuous manufacturing, where processes are dynamic and ongoing rather than discrete and batch-based. Regulatory flexibility also supports innovation, allowing manufacturers to adopt new technologies such as PAT, AI, and advanced analytics without being constrained by outdated validation models.

Sustainability:

Sustainability is becoming a priority in pharmaceutical validation. Green manufacturing practices aim to reduce energy consumption, minimize waste, and lower environmental impact. Validation strategies must adapt to eco-friendly processes, such as solvent recovery systems, energy-efficient equipment, and biodegradable cleaning agents. Equipment qualification now considers not only performance but also environmental footprint.

Additional Challenges:

Beyond these major themes, several other challenges shape the future of EQ and PV:

- *Global Harmonization:* Differences in regulatory expectations across regions create complexities for multinational companies. Harmonization efforts led by ICH and PIC/S are helping, but full alignment remains a work in progress.
- *Resource Constraints:* Implementing advanced validation strategies requires significant investment in technology, training, and infrastructure. Smaller manufacturers may struggle to keep pace.
- *Cultural Change:* Shifting from traditional validation to lifecycle and risk-based approaches requires a cultural change within organizations, emphasizing continuous improvement and proactive quality assurance.

MATERIALS AND METHODS:

The materials and methods section in pharmaceutical validation studies describes the resources, protocols, and systematic approaches used to ensure that equipment and processes consistently meet regulatory and quality standards. In the context of equipment qualification (EQ) and process validation (PV), this section outlines the physical materials, documentation systems, analytical tools, and structured methodologies employed to establish compliance with Good Manufacturing Practices (GMP). It also explains how these methods are applied in practice, from design and installation to performance verification and lifecycle monitoring.

Materials:

Manufacturing Equipment:

The primary materials include production machinery and supporting systems that require qualification. Examples are:

- *Production Equipment:* Blenders, granulators, tablet presses, capsule fillers, sterilizers, lyophilizers.
- *Utility Systems:* HVAC systems, compressed air, purified water, steam generation units.
- *Support Systems:* Cleanrooms, environmental monitoring systems, computerized control systems.

Each piece of equipment must be assessed for its impact on product quality. Critical equipment, such as sterilizers in aseptic manufacturing, requires extensive qualification, while non-critical utilities may require less rigorous documentation.

Standard Operating Procedures (SOPs):

SOPs provide written instructions for installation, operation, cleaning, calibration, and maintenance. They serve as the foundation for consistent practices and are referenced throughout qualification and validation activities.

Validation Protocols:

Protocols are pre-approved documents that define objectives, scope, responsibilities, acceptance criteria, and testing methods. They ensure that qualification and validation activities are planned, controlled, and reproducible.

Analytical Instruments and Tools:

Analytical tools are essential for monitoring critical process parameters (CPPs) and critical quality attributes (CQAs). These include:

- Calibrated sensors and gauges.
- PAT (Process Analytical Technology) instruments for real-time monitoring.
- Statistical software for data analysis, control charts, and trend monitoring.

Documentation Systems:

Documentation is central to validation. Materials include:

- Electronic Batch Records (EBR).
- Logbooks and deviation reports.
- Final qualification and validation reports.
- Audit trails and electronic data capture systems.

Methods for Equipment Qualification:

Equipment qualification is conducted in sequential stages to ensure that equipment is suitable for its intended use and consistently performs within defined parameters.

Design Qualification (DQ):

- *Objective:* Verify that equipment design meets user requirements and regulatory standards.
- *Method:* Review design specifications, engineering drawings, and vendor documentation. Assess whether design features support GMP compliance and intended functionality.
- *Documentation:* Design review reports, approval records, and risk assessments.

Installation Qualification (IQ):

- *Objective:* Confirm proper installation of equipment according to manufacturer specifications.
- *Method:* Verify utilities, calibration, and environmental conditions. Check installation against engineering drawings and specifications.
- *Documentation:* Installation checklists, calibration certificates, verification reports.

Operational Qualification (OQ):

- *Objective:* Test equipment under defined operating conditions.
- *Method:* Verify alarms, control systems, and operating ranges. Conduct stress testing to ensure equipment functions within specified limits.
- *Documentation:* Test results, deviation reports, corrective actions.

Performance Qualification (PQ):

- *Objective:* Demonstrate consistent performance under real production conditions.
- *Method:* Run equipment with actual materials to confirm reproducibility. Collect data on product quality attributes.
- *Documentation:* Final qualification reports, statistical analysis of performance data.

Documentation in EQ:

Each stage requires protocols, raw data, deviation reports, and summary reports. Regulators expect comprehensive evidence of compliance and traceability.

Current Perspectives in EQ:

- Risk-Based Approaches: Focus qualification efforts on critical equipment that impacts product quality.
- Lifecycle Management: Integrate qualification into continuous improvement and ongoing monitoring.

Methods for Process Validation:

Process validation ensures that manufacturing processes consistently produce products meeting predetermined quality attributes.

Traditional Approaches:

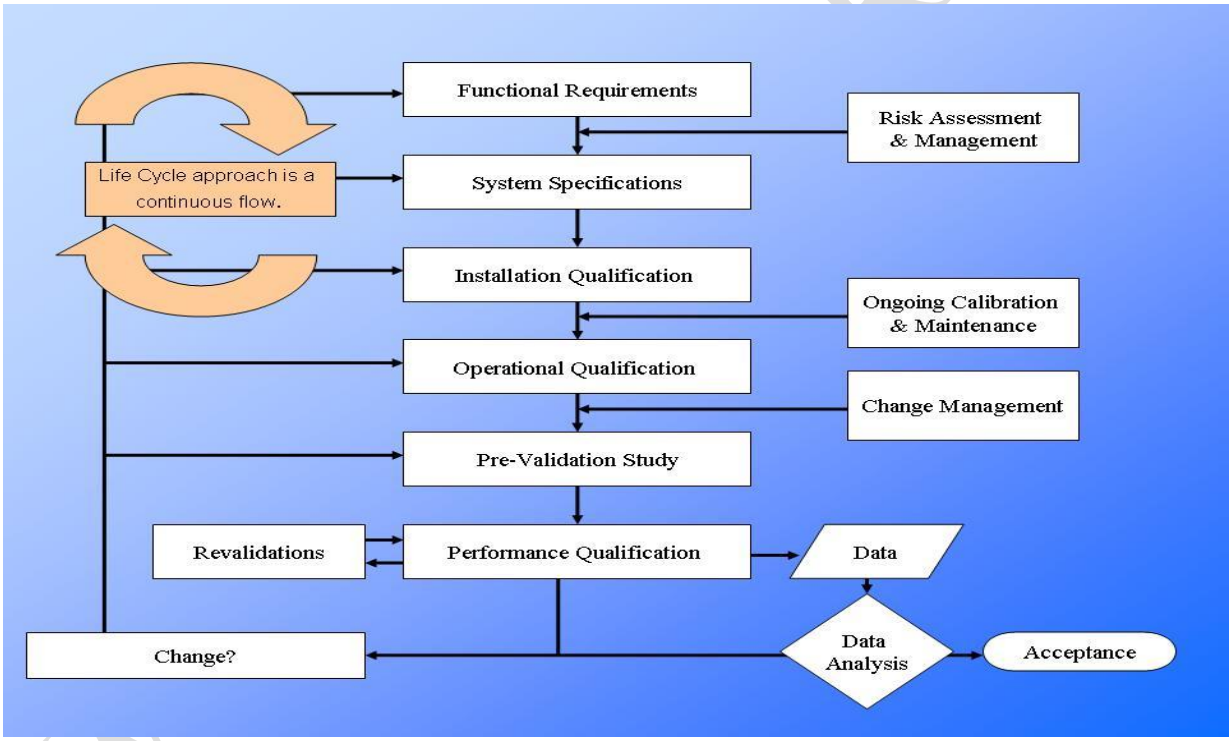
- Prospective Validation: Conducted before commercial production using multiple batches to demonstrate consistency.

- Concurrent Validation: Performed during routine production when prospective validation is not feasible.
- Retrospective Validation: Based on historical data; now rarely accepted by regulators.

Modern Lifecycle Approach:

Introduced by FDA and adopted globally, the lifecycle approach consists of three stages:

- *Stage 1:* Process Design – Establish scientific understanding of the process; identify CPPs and CQAs.
- *Stage 2:* Process Qualification – Confirm process capability under commercial manufacturing conditions.
- *Stage 3:* Continued Process Verification – Monitor processes continuously during routine production to ensure control.



Tools and Technologies in PV:

- Statistical Sampling: Evaluate variability and ensure representative data.
- Control Charts and Trend Analysis: Monitor process stability over time.
- Process Analytical Technology (PAT): Enable real-time monitoring of critical parameters.
- Continuous Manufacturing: Integrate validation directly into production, requiring adaptive monitoring strategies.

Documentation in PV:

Validation protocols, raw data, statistical analyses, deviation reports, and final validation reports are compiled to demonstrate compliance.

Integrated Materials and Methods:

The integration of EQ and PV ensures that both equipment and processes are validated in a coordinated manner. Equipment qualification establishes the foundation for reliable operation, while process validation confirms that processes consistently deliver quality products. Together, they provide documented evidence that pharmaceutical manufacturing systems are capable of producing safe, effective, and high-quality medicines.

CONCLUSION

Equipment Qualification (EQ) and Process Validation (PV) remain the **cornerstones of pharmaceutical manufacturing quality assurance**, ensuring that medicines are consistently safe, effective, and compliant with global regulatory standards. The systematic stages of qualification—Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ)—provide documented evidence that equipment is fit for purpose and capable of reliable performance. Similarly, process validation establishes confidence that manufacturing processes can reproducibly deliver products meeting predefined specifications.

The **regulatory review** highlights both convergence and divergence across global authorities. The FDA's lifecycle approach emphasizes continuous monitoring and verification, while EMA's Annex 15 promotes risk-based strategies. WHO provides adaptable frameworks for diverse manufacturing environments, and PIC/S fosters harmonization across jurisdictions. The ICH guidelines (Q8, Q9, Q10, Q12) act as a unifying backbone, integrating scientific principles, risk management, and lifecycle approaches to support global regulatory alignment.

From the **Conclusion,**several key themes emerge:

- The industry is shifting from **traditional, batch-based validation** toward **risk-based and lifecycle-driven approaches**, reflecting the need for efficiency and adaptability.
- **Digital technologies**—including AI, IoT, and blockchain—are reshaping qualification and validation practices, offering real-time monitoring, predictive analytics, and enhanced data integrity.

- Despite progress in harmonization, **regional regulatory differences** continue to challenge multinational companies, requiring flexible compliance strategies.
- **Future directions** point toward continuous manufacturing, real-time release testing, and sustainability-driven qualification frameworks.

Ultimately, this review underscores that EQ and PV are not static regulatory requirements but **dynamic, evolving disciplines**. They are increasingly integrated into holistic pharmaceutical quality systems, aligning with modern scientific and technological advancements. The convergence of regulatory perspectives, coupled with innovation in manufacturing and monitoring, is paving the way for a more **efficient, globally harmonized, and patient-centric pharmaceutical industry**.

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