

Qualification of Laboratory Equipment and Its Significance in The Pharmaceutical Quality Control System

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Abstract

This article highlights the scientific and practical aspects of qualification of laboratory equipment within the pharmaceutical quality control system. It substantiates that the proper selection, installation, and operation of laboratory instruments are crucial for ensuring the reliability, accuracy, and reproducibility of pharmaceutical analysis results.

The article provides a detailed analysis of the internationally accepted stages of laboratory equipment qualification—DQ (Design Qualification), IQ (Installation Qualification), OQ (Operational Qualification), and PQ (Performance Qualification)—their content, and their role within the pharmaceutical quality system. It also examines the classification of equipment into Groups A, B, and C in accordance with ISPE and WHO guidelines, as well as the determination of the appropriate level of qualification required for each group.

Furthermore, the importance of qualifying laboratory equipment in compliance with GMP, ISO 17025, USP <1058>, and WHO requirements is substantiated. The scientific and practical foundations for implementing this process in the pharmaceutical industry of Uzbekistan are also presented.

The research findings have practical significance for improving the quality system in pharmaceutical laboratories and ensuring reliable analytical results.

Keywords: Pharmaceutical chemistry, quality control, laboratory equipment, qualification, AIQ, DQ, IQ, OQ, PQ, GMP, ISO 17025, pharmacopoeial analysis.

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1. Introduction

In the modern pharmaceutical industry, ensuring product

quality, safety, and efficacy requires strict control throughout the entire manufacturing chain. One of the most critical elements of this chain is the quality control system,

particularly the reliability of laboratory analyses and the equipment used to perform them.

The reliability of any analytical result is directly related to the proper selection, correct installation, technical performance, and compliance of laboratory equipment with established parameters. Therefore, in international pharmaceutical practice, the concept of Analytical Instrument Qualification (AIQ) holds particular importance and is considered an integral part of GMP (Good Manufacturing Practice).

The recommendations of the World Health Organization (WHO), the United States Pharmacopeia (USP), the International Pharmaceutical Federation (FIP), and the International Society for Pharmaceutical Engineering (ISPE) require comprehensive qualification of laboratory equipment.

This process includes the stages of Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).

In pharmaceutical manufacturing enterprises, proper qualification of laboratory equipment not only ensures the accuracy of analytical results, but also serves as a fundamental factor for the stable functioning of the company's quality system.

The aim of the study is to analyze the concept of qualification of laboratory equipment used in pharmaceutical manufacturing and analytical processes, its stages, and its practical application.

In addition, the study discusses the advantages and challenges of implementing equipment qualification within pharmaceutical quality systems based on international experience.

To achieve this aim, the following main objectives were defined:

- ✓ To examine the concept of laboratory equipment qualification from theoretical and regulatory perspectives;
- ✓ To analyze the requirements and guidelines adopted in international pharmaceutical practice (WHO, ISPE, USP, FDA, ICH);
- ✓ To clarify the content of the DQ, IQ, OQ, and PQ stages and determine their role within the quality control system.

- ✓ To study the principles for determining the level of qualification of equipment based on their classification (Groups A, B, C);

- ✓ To develop practical recommendations for achieving high-quality and reliable analytical results through proper qualification of laboratory equipment;

- ✓ To scientifically substantiate the necessity of implementing national guidelines and standards in the pharmaceutical industry of Uzbekistan.

2. Object, Subject, And Methods of The Study

Object of the study: Modern laboratory equipment used in pharmaceutical and analytical laboratories, such as HPLC, GC, IR and UV/Vis spectrometers, pH meters, titrators, etc.

Subject of the study: The qualification processes of laboratory equipment and their role within the quality control system.

The following scientific and analytical methods were used in the study: Documentary analysis: Regulatory documents, GMP standards, and international pharmacopoeia requirements recommended by the World Health Organization (WHO), ISPE, USP, FDA, and ICH were reviewed and analyzed.

Comparative analysis: The qualification processes of different types of laboratory equipment (e.g., HPLC, GC, UV/Vis) were compared, and their distinctive features were analyzed.

Systematic approach: The qualification stages—DQ, IQ, OQ, and PQ—were considered as interrelated processes, and their impact on the quality system was studied in a systematic manner.

Source analysis: Theoretical conclusions were drawn based on scientific articles, ISO 9001 and 17025 standards, and practical experience from pharmaceutical enterprises.

3. Results and Discussion

In pharmaceutical quality systems, the term “qualification” refers to the process of scientifically and documentarily confirming that equipment is suitable for its intended use. The primary purpose of this process is to ensure the reliability of analytical results; that is, the equipment must not only operate, but also perform in accordance with established standards both theoretically and practically.

According to international GMP (Good Manufacturing Practice) requirements, every instrument or piece of

equipment must undergo qualification before commissioning and be requalified at specified intervals during its use. This process directly affects the quality of pharmaceutical products, as improper or inaccurate operation of equipment can compromise the reliability of analytical results.

Qualification is a part of validation and constitutes its first stage. While validation assesses the compliance of the entire technological process, qualification specifically confirms the technical and operational performance capability of the equipment.

The laboratory is considered the “heart” of the pharmaceutical quality control system. Here, the safety and efficacy of products are assessed through every analysis, test, and control operation. Therefore, each piece of equipment used in the laboratory (e.g., HPLC, GC, IR, or UV/Vis spectrometer) plays a critical role within the quality system.

Any limitation or malfunction in the operation of equipment affects the quality certificate of the product. For this reason, equipment qualification according to international standards is considered a mandatory part of laboratory accreditation and GMP audits.

The ISO 17025 standard also defines the “suitability and consistency of measurement and analytical instruments” as

a fundamental requirement for laboratory competence.

The concept of AIQ (Analytical Instrument Qualification) was scientifically introduced in the early 2000s by the International Society for Pharmaceutical Engineering (ISPE) and the Food and Drug Administration (FDA). This approach separates the technical testing of equipment from the concept of “validation” and establishes it as an independent process.

According to the AIQ concept, each analytical instrument must undergo the following four stages before commissioning:

DQ — Design Qualification

IQ — Installation Qualification

OQ — Operational Qualification

PQ — Performance Qualification

These stages are interrelated and collectively provide a scientific basis for ensuring the reliable operation of the equipment.

According to ISPE and WHO guidelines, laboratory equipment is classified into three groups based on their technical complexity and the extent of their impact on results (Table 1).

Table 1

Classification of Laboratory Equipment According to ISPE and WHO Guidelines

Group	Type of equipment	Qualification level
A	Simple equipment (mixers, timers, water baths)	Documentation and visual inspection
B	Intermediate-level equipment (balances, pH meters, thermometers, titrators)	Calibration and IQ stage are required
C	Complex equipment (HPLC, GC, IR, UV/Vis, TOC analyzers)	Full DQ–IQ–OQ–PQ processes are required

The main purpose of this classification is to determine the appropriate depth of qualification for each piece of equipment based on its impact on analytical results. For example, even a minor error in HPLC or GC instruments can significantly alter the outcome of an analysis, which is why their qualification is conducted in a very detailed manner.

In international practice, the procedures for equipment qualification are clearly defined in the following regulatory documents [1–6]. These documents serve as a unified

framework for pharmaceutical enterprises, and adapting them to the national regulatory system is also highly relevant for the pharmaceutical sector in Uzbekistan.

The process of equipment qualification is carried out step by step, with the compliance of the equipment to established requirements confirmed both scientifically and documentarily at each stage.

These stages are organized in accordance with GMP requirements as follows:

Design Qualification (DQ) – This is the scientific and technical evaluation carried out before purchasing the equipment, which demonstrates that the instrument is suitable for its intended use (Table 2).

Table 2
Activities Performed During the Design Qualification (DQ) Stage

№	Scope of activities	Description and Purpose
1	Defining the technical requirements of the equipment	Determining the equipment’s accuracy, precision, and operational range, and evaluating its suitability for the intended use
2	Reviewing the manufacturer’s quality certificates	Verifying compliance with ISO 9001, CE, FDA, or WHO requirements
3	Assessing the environment in which the equipment will be used	Analyzing the compliance of temperature, humidity, power supply, air cleanliness, and vibration levels
4	Verifying software security	Protecting data, and evaluating user access rights and password systems
5	Collecting and analyzing technical documentation	Reviewing the manufacturer’s manuals, operating instructions, and maintenance requirements
6	Documenting the rationale for selecting the equipment model	Making a scientifically and economically justified decision on why this particular model was selected
7	Preparation and approval of the DQ protocol and report	Documenting all information and preparing a report approved by management

The DQ stage is the scientific and economic evaluation phase conducted prior to purchasing the equipment. Decisions made at this stage directly affect the effectiveness of subsequent IQ and OQ processes [WHO Technical Report Series, No. 992 (2023); ISPE Baseline® Guide, Vol. 5 (2021)].

For example, when selecting an HPLC system for a pharmaceutical laboratory, the DQ stage involves evaluating the pump’s pressure range, the type of detector (UV or DAD), the operational volume of the autosampler,

the ability to maintain stable temperatures, and the data storage format.

The results of the DQ stage are documented in a “Design Qualification Report” and approved by management.

Installation Qualification (IQ) is the process of verifying that the equipment has been correctly placed, properly installed, and set up in accordance with technical documentation (Table 3).

Table 3

IQ – Installation Qualification

№	Scope of Activities	Description and Purpose
1	Checking environmental requirements for equipment placement	Evaluating compliance of temperature, humidity, airflow, and dust levels with standards

2	Inspecting equipment components and accessories	Verifying the integrity and undamaged condition of all modules, sensors, and electrical connections
3	Testing electrical and communication systems	Confirming proper connection of power sources, signal lines, and safety elements
4	Installing and loading software	Installing the instrument control software and drivers according to the manufacturer's recommendations
5	Verifying documentation and certificates	Ensuring the availability of the equipment passport, calibration certificates, and safety certifications

During the IQ stage, the physical installation of the equipment, its compatibility with the environment, and the correct placement of all technical components are verified. Errors at this stage can lead to inaccurate results in subsequent operational processes [FDA Guidance for Industry "Equipment Qualification" (2019); ISO/IEC 17025:2017].

For example, if a GC (gas chromatograph) is installed in the

laboratory, the IQ stage involves checking the gas line integrity, the sensors controlling the column temperature, and the calibration of the detector.

3. Operational Qualification (OQ) is the process of verifying that the equipment's functional capabilities meet the manufacturer's specifications. At this stage, the instrument is tested under conditions that closely simulate real operational environments (Table 4).

Table 4

Activities Performed During the Operational Qualification (OQ) Stage

Nº	Scope of Activities	Description and Purpose
1	Conducting functional tests of the equipment	Checking the operation of all buttons, sensors, and signal systems
2	Evaluating the operational range of the instrument	Verifying the accuracy of parameters such as temperature, pressure, time, and flow rate
3	Performing calibration tests	Assessing accuracy and repeatability using reference equipment
4	Testing software functions	Inspecting the processes of data collection, processing, printing, and storage
5	Conducting stress or "worst-case" scenario tests	Evaluating the instrument's stability under extreme conditions

The OQ stage demonstrates that the equipment meets the specified technical characteristics under real operational conditions. At this stage, all electronic and mechanical systems of the instrument are thoroughly tested to ensure proper functioning [ISPE Baseline® Guide, Vol. 5 (2021); WHO TRS 1010 Annex 3 (2023)].

For example, in an HPLC system, the OQ stage verifies the stability of the pump flow at 1 mL/min and 2 mL/min, the linearity of the detector signal, and the reliability of the

temperature module. The results of OQ are documented in an "Operational Qualification Report", which provides an official conclusion regarding the equipment's readiness for use.

4. Performance Qualification (PQ) – This is the final stage that confirms the equipment's ability to perform its intended functions under actual operational conditions. At this stage, the instrument is tested through practical analyses or product trials (Table 5).

Table 5

PQ – Performance Qualification

No	Scope of Activities	Description and Purpose
1	Performing test analyses under actual operating conditions	Conducting instrument validation under real laboratory conditions over a defined time period
2	Evaluating the repeatability of the results	Performing repeated analysis of identical samples and statistically evaluating the consistency of the results
3	Analyzing stability and accuracy	Determining the instrument's ability to maintain its accuracy over an extended period of time
4	Analyzing a real sample (product)	Analyzing a pharmaceutical product or chemical substance sample according to a standard method
5	Completing the PQ protocol and preparing the report	Documenting the test results and obtaining approval from the head of the user laboratory

PQ is the final stage that demonstrates the reliability of the equipment during its operational use. At this stage, the instrument's performance under "real conditions" is evaluated, and based on these results, the equipment is formally approved for use [WHO Guidelines for Pharmaceutical Laboratories (2022); FDA Process Validation Guide (2021)].

For example, during the PQ stage of an HPLC system, the instrument performs five repeated analyses of the ascorbic acid content in vitamin C tablets. If all results fall within the established standard limits, the equipment is considered "qualified for performance."

Thus, the qualification of laboratory equipment forms the scientific and practical foundation of the pharmaceutical quality system. It is not only a technical process but also an essential part of the quality philosophy, embodying the principle: "reliable results = reliable equipment."

4. Conclusion

Qualification of laboratory equipment in pharmaceutical laboratories is an integral part of the quality assurance system, ensuring the reliability, reproducibility, and accuracy of analytical results. The processes of proper equipment selection (DQ), correct installation (IQ), assessment of operational performance through functional testing (OQ), and confirmation of effectiveness under real conditions (PQ) form the scientific foundation of pharmaceutical manufacturing and laboratory quality control.

Each stage of qualification is closely interconnected, and their complete and documented execution ensures that laboratory operations comply with GMP (Good Manufacturing Practice) and ISO 17025 standards.

Today, in international practice, each laboratory instrument is evaluated as a "reliable source of information" through the AIQ (Analytical Instrument Qualification) system. This not only optimizes technical processes but also ensures the quality, safety, and compliance of pharmaceutical products with established standards.

Therefore, implementing the DQ–IQ–OQ–PQ stages based on scientific principles and in accordance with international standards is a strategically important task for pharmaceutical enterprises and analytical laboratories. Effective execution of these processes significantly enhances laboratory accreditation, internal audit outcomes, and export potential.

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