STM JOURNALS

Research & Reviews: A Journal of
Drug Formulation, Development and Production

ISSN: 2394-1944
Volume 12, Issue 3, 2025
September–December
DOI (Journal):10.37591/RRJoDFDP

https://journals.stmjournals.com/rrjodfdp

Research RRJoDFDP

# Quality Control and Assurance Practices in Modern Pharmaceutical Industry

Prachi Rajesh Patil[1,*], Shweta Vinod Raul[1], Sunila A. Patil[2]

***Abstract***

*This brief overview outlines the global techniques for figuring out the prevalence of geotaxis impurities (residual solvents and various inorganic and organic impurities) in medications. It is now necessary to reveal a pharmaceutical product's purity and impurity profiles due to both national and international regulations. These elements are discussed, together with the kinds of impurities, their origins, their control, and regulatory issues, as well as the significance of pharmaceutical quality, efficacy, and safety. The availability of high-quality important pharmaceuticals is a must for the supply of any country's healthcare system, as inferior medications have the potential to injure or even kill consumers. A medication's safety and efficacy may be impacted by the presence of unwanted chemicals, even in very small concentrations. Unlike products in other industries, pharmaceuticals are dynamic, and both during production and after final consumption, their color, consistency, weight, and even chemical identity can change. As a result, pharmaceutical quality has long been a global concern and is currently gaining significant attention from regulatory bodies. Pharmaceutical product impurities are a major concern because of the potential harm they may do to medicine stability and shelf life in addition to the intrinsic toxicity of some contaminants. In pharmaceutical and drug products, impurities are harmful chemicals (natural, inorganic, and residual solvents) that can be introduced or created during formulation, aging, or retention with the active pharmaceutical ingredients (APIs). The most prevalent impurities in all APIs are organic ones, which, even with appropriate handling, are naturally incorporated during the multi-step synthesis process.*

**Keywords:** Practical consideration in developing QA/QC system, element of QA & QC, inventory agency, QA/QC plans, QA procedure, Q. assurance, review process, methodology

## INTRODUCTION

One of the main goals of the IPCC's good practice guidelines is to guide the development of national greenhouse gas inventories that can be readily assessed for accuracy and completeness. It is recommended practice to use quality assurance and quality control (QA/QC) techniques when developing national greenhouse gas inventories to accomplish this [1]. These recommendations are consistent with the 1996 revision of the IPCC Guidelines for National Greenhouse Gas Inventories (IPCC Guidelines). The guidelines for QA/QC best practices offered here consider factors including feasibility, acceptability, cost-effectiveness, prior experience, and potential for worldwide applicability. Enhancing national inventories of emissions estimates' completeness, comparability, transparency, consistency, and confidence are among the objectives of good

***Author for Correspondence**
Prachi Rajesh Patil
E-mail: prachirpati12323@gmail.com

[1]Student, Department of Pharmaceutical Quality Assurance, P.S.G.V.P Mandal's College of Pharmacy, Untavad, Maharashtra, India
[2]Assistant Professor, Department of Pharmaceutical Quality Assurance, P.S.G.V.P Mandal's College of Pharmacy, Untavad, Maharashtra, India

Received Date: June 27, 2025
Accepted Date: June 31, 2025
Published Date: September 09, 2025

**Citation:** Prachi Rajesh Patil, Shweta Vinod Raul, Sunila A. Patil. Quality Control and Assurance Practices in Modern Pharmaceutical Industry. Research and Reviews: A Journal of Drug Formulation, Development and Production. 2025; 12(3): 7–13p.

 

practice recommendations that a QA/QC program aids in achieving. It can be necessary to revise estimates of inventory or source category uncertainty based on the outcomes of the QA/QC procedure. For example, if the data quality is found to be lower than expected and cannot be corrected within the current inventory schedule, the uncertainty estimates should be reevaluated. The phrases "quality assurance" and "quality control," which are frequently used, are defined as follows [2].

## WHAT IS QA/QC

### Quality Control (QC)

The quality of the inventory is monitored and managed during the creation process using a system of routine technical duties known as quality control (QC). The QC system is intended to.

- To guarantee data integrity, accuracy, and completeness, conduct regular and consistent reviews.
- Find and fix inaccuracies and omissions.
- Record all QC actions and keep an inventory of the materials.

General QC tasks include using authorized standardized procedures for emission calculations, measurements, estimating uncertainties, archiving information, and reporting, as well as accuracy checks on data collecting and calculations. Higher level quality control tasks include technical evaluations of methodologies, activity and emission factor data, and source categories.

### Quality Assurance (QA)

One part of quality assurance (QA) activities is a scheduled series of review procedures performed by employees who are not directly involved in the inventory compilation/development process. After the QC procedures are put into place, a finalized inventory should be reviewed, ideally by impartial third parties. Reviews confirm that the goals for data quality were fulfilled, guarantee that the inventory reflects the most accurate estimates of emissions and sinks given the state of science and data at the time and bolster the efficacy of the QC program [3].

## PRACTICAL CONSIDERATIONS IN DEVELOPING QA/QC SYSTEMS

Time, money, and experience are all necessary for QA/QC process implementation. It is anticipated that decisions will need to be made about the following when creating any QA/QC system resources allotted to quality control for the compilation procedure and several source categories.

- The amount of time assigned to validate and appraise emissions estimates.
- Information about activity data and emission parameters, including data quality, is open and easy to access.
- Protocols to guarantee inventory and source category information secrecy as necessary.
- specifications for information archiving.
- QA/QC check frequency for various inventory components.
- The QC level suitable for each type of source, whether more QC work will lead to better emissions estimates and fewer uncertainties.
- If enough experience is available to carry out the inspections and evaluations [4].

### Components of a QA/QC System Include

The primary considerations for developing a QA/QC system that will monitor inventory compilation are as follows

- An inventory agency responsible for coordinating QA/QC activities.
- A QA/QC plan.
- General QC procedures.
- Source category-specific QC procedures.
- QA review procedures.
- Reporting, documentation, and archiving procedures.

 

## INVENTORY AGENCY

The national inventory's QA/QC operations must be coordinated by the inventory agency. Other agencies or organizations may be assigned duties by the inventory agency to carry out and record these QA/QC procedures. The inventory agency is responsible for making sure that other organizations that prepare the inventory are adhering to the relevant QA/QC protocols. The inventory agency is also in charge of making sure the QA/QC plan is created and carried out. It is the best practice for the inventory agency to assign a QA/QC coordinator, who will oversee making sure the program's goals are carried out.

## QA/QC PLAN

It is best practice to create a QA/QC plan since it is a basic component of a QA/QC system. In general, the plan should include the QA/QC tasks that will be carried out and provide a timeline that corresponds to the preparation of the inventory from the beginning to the end of reporting in any given year. An overview of the procedures and a timeline for reviewing each source. Category should be included. An internal document used to plan, organize, and carry out QA/QC operations is the QA/QC plan. Once created, it can be referred to and utilized in later inventory preparation or adjusted as necessary (for example, in response to process modifications or independent reviewers' recommendations). This proposal ought to be open to outside evaluation. The International Organization for Standardization (ISO) has developed standards and recommendations, such as the ISO 9000 series, that may be helpful in creating and carrying out the QA/QC strategy. Despite not being created especially for emissions inventories, several nations have used ISO 9000 standards to assist in planning QA/QC operations [5].

## ISO AS A DATA QUALITY MANAGEMENT SYSTEM

Data documentation and auditing standards are provided by the International Organization for Standardization (ISO) series program as part of a quality management system [6]. Many of the concepts in the ISO series can be used to guarantee the creation of a high-quality inventory, even though they are not specifically intended for the collection of emissions data. These materials could be a helpful resource for inventory agencies creating QA/QC plans for greenhouse gas inventories. Certain nations, like the Netherlands and the United Kingdom, have already included some IS standards into their data management and inventory development procedures [7].

The ISO series' standards and guidelines listed below could be used in addition to source [8].

General quality criteria for putting a quality system into place (ISO 9004-1).

Guidelines for conducting continuous quality improvement inside an organization utilizing methods and technologies based on data collection and analysis are provided by ISO 9004-4 [9].

Instructions for creating quality plans for project control (ISO 10005)

- Guidelines for the auditing of a quality system, ISO 10011-1.
- Guidance on the requirements for quality systems auditors is provided by ISO 10011-2.
- Guidelines for overseeing quality system audit programs are found in ISO 10011-3.
- Guidelines for statistical controls and calibration systems to guarantee measurements are made with the desired accuracy are provided by ISO 10012.
- Guidelines for creating quality guides to satisfy certain requirements (ISO 10013) [10].

## QA METHODS

Good practice for QA procedures requires an objective assessment to determine the quality of the inventory and identify areas that require improvement. Sections of the inventory or the entire inventory can be reviewed. They apply QA techniques in addition to Tier 1 and Tier 2 QC. Incorporating reviewers capable of conducting an unbiased evaluation of the inventory is the aim of implementing quality assurance. It's recommended practice to use QA reviewers who weren't engaged in making the inventory.

 

It is essential for these reviewers to be unbiased experts from other organizations or a national or international expert or group that is not directly involved in the creation of national inventories itself. Staff members from another division of the inventory agency that is not involved in the inventory under review can also perform QA duties if third-party reviewers from outside the inventory agency are unavailable. Before submitting an inventory, inventory agencies should perform a basic expert peer review (Tier 1 QA) to find any potential issues and, if feasible, make the necessary modifications. Applying this review to every source category in the inventory is also a smart idea. However, due to time and resource restrictions, this will not always be feasible. Priority should be given to key source categories and source categories that have undergone substantial data or method modifications. Moreover, inventory authority may choose to use the available resources to conduct more comprehensive audits, peer reviews, or both as additional (Tier 2) QA procedures [11].

## QUALITY ASSURANCE REVIEW PROCESS

A thorough evaluation conducted in compliance with international standards is guaranteed by the QAR procedure. The four typical phases – planning, carrying out, reporting, and follow-up are typically involved [12].

### Planning Phase

- Planning.
- Understand the OAGN or Audit environment.
- Define QAR.
- objective & scope.
- Identify key areas for QAR.
- Select appropriate audits for QAR Decide.
- Methodology.
- Define roles and responsibilities.
- Estimate resources including time.
- Prepare QAR plan.

### Conducting Phase

The QAR plan is used by the review team to direct the evidence collection throughout the second part of the review.

- Conducting of QAR.
- Conduct entry meeting.
- Gather information.
- Record and analyse information.
- Discuss QAR findings with audit team.

### Reporting Phase

In the third phase, the review team creates a draft QAR report using the results (preliminary findings and suggestions) from the conducting phase.

- Reporting of QAR.
- Prepare draft QAR Report.
- Conduct exit meeting with.
- Finalise QAR Report.

### Follow-up

The review team uses the action plan that the audit line functions developed as inputs to assess the level of implementation of the QAR recommendations and, if any, the reasons for non-implementation in the final stage.

- Follow up QAR.

 

- Management.
- implements action Assess.
- implementation of action plan.
- Prepare follow-up QAR Report [13].

## METHODOLOGIES AND TECHNIQUES FOR CONDUCTING QA REPORT

### Techniques and Methodologies for Performing QA Reviews

The methods and strategies listed below can be applied to quality assurance.

***Review***

- The purpose of the interview is to get pertinent information from the audit team. In this situation, the quality assurance team might request information from the audit team, listen to and evaluate their answers, follow up with inquiries, and, if necessary, confirm the information. Information from the audited entity can also be obtained through the interview technique.
- Observation is watching someone else carry out a process or activity. It offers proof for that moment in time and by them, which is insufficient to make inferences about events that have transpired over time [13].
- Reading records or documents, whether electronically or visually, is known as documentation review. Correspondences, memoranda, minutes, reports, and so on are examples of records or documentation.
- Walking through or repeating operational steps is known as re-performance. For instance, the auditor may duplicate efficiency measurement methods to verify the precision of efficiency metrics. The auditor can use replication to verify that the system or a portion of it functions as stated.
- A confirmation is an answer to an inquiry, usually in writing, that serves to validate facts. It can be applied to confirm that a task was completed in the field.
- Analysis, whether done electronically or visually, shows the similarities and differences between two or more papers, physical objects, or data. Experts or individuals with understanding of the topics under analysis who can draw logical conclusions and value judgments from the facts gathered should provide analytical evidence. Data or information can be analyzed using a variety of statistical procedures.
- Focus groups are gatherings of a chosen group of people to talk on audit-related issues. Their main purpose is to gather qualitative information and statistics. Information about the execution and effects of government initiatives is gathered through focus group procedures, which are based on the perspectives of stakeholders and recipients.
- It is possible to arrange seminars and hearings to learn more about specialized fields, talk about issues and observations, and discover potential solutions. Seminar attendees may include specialists, stakeholders, and interested parties [14].

## ASSURANCE OF QUALITY IN THE PHARMACEUTICAL INDUSTRY'S REGULATORY AFFAIRS

When we hear the word "regulatory," we immediately think of "regulation and laws," as the title claims, "a regulatory affair." This section will discuss the relationship between the regulatory affairs division and quality assurance, as well as how they work together to enhance the pharmaceutical industry and boost business earnings. The regulatory side of the pharmaceutical and drug industries is specifically handled by regulatory affairs; therefore, QA documentation is also included in the regulatory aspect to secure approval on any associated regulatory difficulties.

Working closely with the authorities to guarantee that the product is registered in accordance with the regulation guidelines is the overview of the regulatory affairs job scope. An essential component of a regulatory affairs department are dossiers, which are typically used to register manufactured goods abroad. This dossier should include information on all facets of the medications; the Certificate of Analysis (COA) and quality assurance information are the two main components of a drug dossier. For

 

the drug to be registered in that nation, the prepared dossier is forwarded to the relevant authorities. A drug's registration on an export basis in another country will take over two years. Before the drug dossier is forwarded for registration, a report detailing every aspect of the analysis and assay completed in the QA department is provided [15–18].

**Two Types of Dossiers**

- Common Technical Dossier (CTD).
- Asean Common Technical Dossier (ACTD).

Drugs in nations outside of Asian are registered using the CTD, which is the standard format. Since every authority is more concerned with the quality of the medicine, QA documentation is crucial in CTD. The likelihood of a medicine being registered in a certain country is higher when it is of superior quality [16]. These directly contribute significantly to the industry's revenue. The ACTD is a standard format for drug dossiers that are used to register drugs in Asian countries. Based on this format, QA documentation is a crucial component that is needed; if the drug is of very high quality, it has a high chance of being registered in Asian countries. Furthermore, the corporation benefits and makes a substantial profit from having medications registered in multiple nations. This demonstrates unequivocally how quality assurance affects medications that are set to be registered in different nations and how it affects the specific pharmaceutical industry's earnings. If a medication is registered in a certain nation and changes need to be made to it, the national authorities should be notified, and we must get their approval. This has provided a clear explanation of how regulatory affairs and quality assurance are related [17].

## CONCLUSIONS

As a summary of the entire conversation, it is evident that quality assurance is connected to every department in the pharmaceutical sector in some way and is crucial to improving the operations of each department. As the title states, quality assurance is essential and is regarded as the foundation of the pharmaceutical sector. Quality Assurance places a strong emphasis on client happiness and follows the rules established by the government. The thalidomide episode, which occurred a long time ago, demonstrates a glaring breakdown in quality control at the clinical trial stage that resulted in such a major catastrophe that induced teratogenicity (Phocomelia). The medication was initially created to treat pregnant women's morning sickness. A negative past has resulted from improper analysis and quality control, which amply demonstrates the critical function that quality assurance plays in the manufacturing of pharmaceuticals. Quality assurance is applied or prioritized in all production industries that are connected to all senses, not just the pharmaceutical sector. Since customers are the primary source of profit and revenue for every sector, it was stated that QA operates on their satisfaction. If the product lacks attributes, the industry will suffer greatly [18]. Every aspect of an industry that is interconnected has a function for quality assurance (QA), which can create numerous departments "under their umbrella" to raise the standard of quality and its efficacy using all means necessary.

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