

RECENT TRENDS AND CHALLENGES OF QUALITY ASSURANCE IN
PHARMACEUTICALS: A REVIEW

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ABSTRACT

The overview of the Quality Assurance Department in Pharmaceutical Industry is well mooted. It explains the vital part and the objects of Quality Assurance Department. It also explains on how Quality Assurance can increase the profit of the sedulity and how it's related to the other department as an important factor. This review gives the information about the part of Advanced operation and significance of Quality Assurance in Pharmaceutical sedulity. It gives clear idea on how Quality Assurance Department works. The part of the Quality Assurance in Validation, Regulatory Affairs, and also in Business Development is explained.

KEYWORDS: Quality Assurance, Important of QA, ICH Guideline.

INTRODUCTION

For every item or article of use, whether it be a household item, household appliance, and aid merchandise, machinery bought from the market, cars for personal or professional use, food and food merchandise, or medications for use by humans and animals, quality can be a broad concept and concern. Quality assurance is the process or the tip of the method of attesting to a product's integrity to meet the quality requirements for its intended usage as no one needs to compromise on the quality of any item they use. For the end-user, perfection is the only measure of quality they can achieve; they can only enable but 100%. Quality assurance is therefore mechanically obligatory on the part of the manufacturer of any product to ensure that it meets the requirements of the user within the measures supposed for use-quality, safety, efficacy, responsibility, strength and/or sturdiness, etc.^[1]

There's a rising consummation that an enhancement in the quality of pharmaceutical products and services is a vital factor in the battle to maintain deals and remain commercially feasible in the fast- growing and changing request. It seems ineluctable that quality competition will continue to be at least as significant as price competition in numerous areas. Profitable trading will depend on strong Quality Assurance stylish practices due to the possibility of stricter product liability laws and the trouble of severe fiscal penalties for goods and services that do not meet safety, good manufacturing compliance (GMP), or functional conditions. Since material coffers are come more precious and scarcer, it makes fiscal

sense to reduce scrap product losses through bettered quality control.^[2]

DEFINITION

Quality - The term "quality" may not be as simple as it first appears. Every quality specialist may have slightly different definition of quality.

Various perspectives will be considered while shaping quality, such as the viewpoint of the client and the perspective based on specifications. Quality in the modern sense is defined by Juran's "fitness for supposed use. According to this definition, quality is defined as "meeting or exceeding customer or client expectations."^[3]

QUALITY ASSURANCE

- **Quality Assurance:** Quality assurance is a broad notion that encompasses the suppliers and final customers of the product or service as well as the full quality system. It encompasses all endeavors intended to generate goods and services of suitable caliber. As per ASQ, quality assurance (QA) encompasses.^[3]

- **Principle**

"Quality assurance" is a comprehensive term that encompasses all factors that, taken separately or in combination, affect a product's standard. It is the entirety of the plans put in place to ensure that pharmaceutical products are safe and up to the standards required for their intended usage.

Thus, quality assurance takes into account GMP, GLP, and several elements, including ones that are not

included in this guide, like product design and development.^[4]

The process of confirming and validating that manufactured goods are safe and satisfy all legal and regulatory requirements from the raw material to the packaged final product is known as quality assurance.^[5]

Since quality assurance is a means of ensuring that a product is fit for its intended use and maintains its integrity, it may be a wise practice in the production of pharmaceuticals. It is a bond that guarantees producers satisfy end-user requirements for strength, dependability, durability, safety and efficacy. For the end user, quality is the standard of excellence.^[6]

Financial strain must not affect quality assurance in any way. Financial stress in this context refers to the management's need to refrain from placing financial strain on the specific department in question because this could have a negative effect on the product's quality. A subpar product could have a significant effect on the industry's earnings. Therefore, the QA department needs to be financially stable and have enough staff members to guarantee that the product validations are completed on time. A considerable impact on the industry's revenue could result from a delay in the product's delivery to the market caused by the QA department's delay.^[5]

OBJECTIVE OF QUALITY ASSURANCE

Quality assurance has a number of objectives that include the following

- To shield the product's user from unintentional flaws in its construction, handling, storage, or usage guidelines.
- To provide reassurance that the healthcare provider is certain that each dosage will have the intended outcome.^[2]
- Ensuring strict adherence to all relevant laws, rules, legislation, and industry regulations.
- Guarding the product and producer against fines, bad press, reputational damage, monetary losses, etc.^[6]

AN OVERVIEW OF THE QUALITY ASSURANCE DEPARTMENT IN PHARMACEUTICAL INDUSTRY

The main departments or units in the pharmaceutical sector that are subject to regulations are engineering/utilities, warehousing, production, and quality control/assurance. The QA department is in charge of monitoring the operations of the warehouse, utilities, production, analytical laboratory, and environment (hygiene) to ensure that good manufacturing, good laboratory, and good storage practices are followed.^[1]

A product's quality is not something that just happens. Individuals inside an organization don't always carry out their roles effectively or adhere to regulations and directions. Quality management bears the obligation of handling situations of this nature and guaranteeing that

every member of the industrial team understands their role in maintaining quality and does their task properly. items must be built with quality in mind; to build foolproof items that are simple to make and use, creativity, discipline, and attitude must be promoted. Next, procedures for manufacturing must be developed such that the simplest way to do a task is the best one; where appropriate, worker interest must be generated; and in other cases, total control must be ingrained in the process. In order to accomplish "right first time" production, quality control must also be ingrained in the product. This means that those responsible for cutting, fitting, and assembling must be highly skilled and motivated. The general formula is straightforward, but putting it into practice is far from easy.^[2]

Nowadays, a quality executive's job in the trade is highly specialized. This is not the kind of post that is often used as a "stepping stone" in a promotional ladder. The explanation is really clear: in a quality executive function, an individual will obtain quality and immediate action by implementing value reductions, making favourable selections, etc., but the corporation will have to pay for this later.

There are good reasons for the risks associated with making snap judgments about accomplishments in this field. It's a career that's essentially focused on long-term effects, so it's not often an extremely fashionable one.^[7]

The notion that the primary responsibility of quality organizations was to "inspect out" previously completed work that was flawed was widely held in the past, especially in management circles. It's true that there have been major technological advancements in the nature of quality specialists' work, especially in the previous ten years. These have led them on a more involved journey than the straightforward and earlier strategy of evaluation. The focus of quality specialists' work today is on eliminating defects completely. "No inspection is good inspection" is the popular reading these days. In order to achieve this goal, a high level of proficiency in these novel techniques which require extensive study and real-world experience is required.^[7]

However, quality cannot be attained by the Quality Executive alone; everyone must take an active role in ensuring it. The typical executive's contribution is essentially one of coordination, working with others to verify the quality action by disseminating information to all parties involved about the various aspects of quality and managing quality observance across the entire organization. Verifying that the standards of performance within their respective areas are met should be the aim and duty of every manager. This imposes a significant duty on all senior managers.^[8]

The Responsibility of Senior Management

In order to meet the required quality standard, management organization and thought processes must be

organized to ensure that quality and reliability are appropriately considered in business decisions. Any manager must not only have a sincere understanding of the fundamentals of quality and responsibility, but also fully understand that it is his or her own job to oversee and carry out these principles. It is only with this data that they can confirm the appropriate allocation levels of resources.

As certain the customers' or the target market's requirements for quality and dependability

- a) regulate the design and manufacture of goods to fulfil these requirements.
- b) give the customers enough assurance that those goods, when received and used, will meet their specifications or requirements.^[8]

Importance of QA in Pharmaceuticals

The food industry's commitment to universal food safety standards is crucial for the pharmaceutical and biotech industries due to the strong link between artifact care and accessible health and safety. Biologic medication flaws increase the risk of chump bloom and perhaps beastly or beastly behavior as well.

In addition to improving conformity to FDA standards and improving convalescent assembly abilities and processes, effective affection affirmation helps firms build larger believability and chump confidence. It lessens the problems of renouncing publicity and putting a dampener on sales as much as possible (for example, if a well-made artifact were to be returned because of emotional faults).

Therefore, in the biologics market, love validation gives incredible benefits in exchange for rising earnings and a better reputation. Nevertheless, every component of the assembly process must be taken into account during the course of a new drug's lifespan, regardless of how it may affect artefact quality separately or in combination.

How Does a Biologic QA Administration Work?

The majority of businesses establish abstracted quality assurance divisions, where real and acquisition flaws are absorbed in the development phase (before to the final artefact being ready for market release).

Here's an overview of QA's role

- Development Date: During R&D, obstacles include obtaining raw materials, finding suppliers, developing testing strategies, validating results, controlling certificates, setting up accessories and operating procedures, applying and training cadres, recording abstracts, conducting analytical trials, conceptualizing API batches, and more.
- Manufacturing Date: During production, the QA unit plays the following roles, to name a few.
- Creating, recognizing, and evaluating important abstracts (validation master plan, affection manual, quality policy and objectives, etc.).

Recognizing an agenda for the calibration, completion, and maintenance of accessories as well as analytical utilities (such as HVAC, water, gas, and ability administration systems).

ensuring the implementation of blueprint and analytical protocols for APIs, adherence testing, in-process testing, raw materials, and packing materials, among other things.

Examining the training records to determine whether the timetable for on-the-job and dedicated training corresponds to the demographics, and whether the QC (Quality Control) analysts are validated in real life.

Ensuring that modifications or deviations, whether planned or unexpected, are recorded, counselled and evaluated; recommending investigations, testing, or validation procedures to be carried out.

Recording and handling chump complaints, approving the investigation into the problem, delivering an assessment to the client, etc.

Following distribution, the processes of initiating, recording, and looking into bazaar returns, reprocessing (for API batches) or abolition (for completed batches), and allegorical authoritative authorities on flaws begin.

MECHANISMS OF QUALITY ASSURANCE

The quality manual archives the vital or hierarchical level, which takes care of the quality approach, targets, and executives; the strategic or practical level takes care of preparation, offices, and the QA activity; and the functional level takes care of things like the Standard Working Methods (SOPs) worksheets used to carry out the program.^[20]

QA System: The Backbone of Pharma Quality

- Although more than one assembly or department may be involved in the creation, completion, and operation of an object, the main assembly often handles all assembly operations.
- An authoritative arrangement's specialist departments could also be used to manage the affection arrangement and the tasks that go along with it. In this kind of situation, the quality assurance team would take charge of designating appropriate systems for accessories and specifying them in standard operating procedures (SOPs) and college-level guidelines.
- For larger firms, it is best to assign QA tasks and control hierarchy to operating departments and cadre in order to help guarantee love on the floor. In addition, top-level administration must be intricate in its duties inside this unit, which may combine QA and QC.^[9]

Quality Assurance Functions: Ensuring Excellence and Compliance

Organizations can define their own quality requirements and set appropriate specifications and measures for their

quality assurance, which can be carried out internally or by an outside party. Quality assurance procedures in the pharmaceutical sector must guarantee that quality standards are fulfilled from the product's conception to its post-purchase maintenance.

Pharmaceutical quality assurance includes a number of vital tasks. In order to transfer technology, work stages must be reviewed, tests and procedures must be defined, training must be given, and guidelines must be established. A comprehensive record of quality measures is ensured by the supervision of record transmission and archiving, which is made possible by documentation. Programs for quality management are designed to maintain standards and look into inconsistencies. Sampling acquired goods, approving production procedures, assessing supplier deliveries, carrying out inspections, putting controls in place, and maintaining test equipment are all part of the process of ensuring product quality. Enforcing plans and confirming resource planning require validation. Together, these roles seek to uphold strict quality requirements that guarantee the dependability and security of pharmaceutical products.^[10]

Scope of quality assurance

- 1) To halt mistakes while maintaining process awareness.
- 2) To improve the development and testing processes in order to avoid mistakes.
- 3) Establish a robust quality management system and monitor its performance over time.
- 4) Preventing problems with quality through planned and deliberate efforts.^[11]

Analytical methods for maintain process and product quality



Figure 1: Quality Assurance.

Regulatory Guidelines for Quality Assurance of Pharmaceutical Industry

ICH Guidelines on Quality of Pharmaceutical Product

ICH Q1: Stability Testing

- Q1A: Stability Testing of New Drug Substances and Products
- Q1B: Stability Testing: Photostability Testing of New Drug Substances and Products
- Q1C: Stability Testing for New Dosage Forms
- Q1D: Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products
- Q1E: Evaluation of Stability Data
- Q1F: Stability Data Package for Registration Applications in Climatic Zones III and IV.

ICH Q2: Analytical Validation

- Q2A: Text on Validation of Analytical Procedures
- Q2B: Validation of Analytical Procedures: Methodology
- Q2R1: Validation of Analytical Procedures.

ICH Q3: Impurities

- Q3A: Impurities in New Drug Substances
- Q3B: Impurities in New Drug Products
- Q3C: Impurities: Guideline for Residual Solvents
- Q3D: Elemental Impurities.

ICH Q4: Pharmacopoeias

- Q4A: Pharmacopeial Harmonization
- Q4B: Evaluation and Recommendation of Pharmacopeial Texts for Use in the ICH Regions.

ICH Q5: Quality of Biotechnological Products

- Q5A: Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin
- Q5B: Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products
- Q5C: Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products
- Q5D: Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological Products
- Q5E: Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process.

ICH Q6: Specifications

- Q6A: Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances
- Q6B: Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products.

ICH Q7: Good Manufacturing Practice

- Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.

ICH Q8: Pharmaceutical Development

- Q8: Pharmaceutical Development.

ICH Q9: Quality Risk Management

- Q9: Quality Risk Management.

ICH Q10: Pharmaceutical Quality System

- Q10: Pharmaceutical Quality System.

ICH Q11: Development and Manufacture of Drug Substances

- Q11: Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities).

These guidelines provide a comprehensive framework for ensuring the quality of pharmaceutical products throughout their lifecycle, from development to manufacturing and distribution.^[12]

Quality Assurance Functions: Ensuring Excellence and Compliance

Companies define their quality criteria and set appropriate specifications and measures for quality assurance, which can be carried out internally or by a third party. Activities related to quality assurance in the pharmaceutical sector must guarantee that standards for quality are fulfilled from the product's conception to its post-purchase maintenance.

Pharmaceutical quality assurance includes a number of vital tasks. In order to transfer technology, work stages must be reviewed, tests and procedures must be defined, training must be given, and guidelines must be established. A comprehensive record of quality measures is ensured by the supervision of record transmission and archiving, which is made possible by documentation. Programs for quality management are designed to maintain standards and look into inconsistencies. Sampling acquired goods, approving production procedures, assessing supplier deliveries, carrying out inspections, putting controls in place, and maintaining test equipment are all part of the process of ensuring product quality. Enforcing plans and confirming resource planning require validation. Together, these roles seek to uphold strict quality requirements that guarantee the dependability and security of pharmaceutical products.^[13]

RECENT DEVELOPMENTS IN QUALITY ASSURANCE- STUDY OF EDUCATION SECTOR

In the late 1980s, the concept of the "Evaluative state" gained traction as public awareness of the importance of quality increased. As higher education systems evolved, they faced challenges related to increasing complexity and the requirement for greater adaptability and flexibility. When the needs of the organization changed,

the old centralized techniques of strict supervision and control were put to the test. The concept of the evaluative state emerged as a replacement for bureaucratic rule. It made an effort to replace rigid and slow guiding systems with more adaptable ones in order to aid institutions in adjusting to change more successfully and save time on administrative duties. Neave emphasized that the impetus for this shift was the need for a looser, quicker regulatory framework.^[14] Quality assurance advanced swiftly in Europe. According to research by Schwarz and Wester heijden, less than half of European nations had begun to lead quality evaluation tasks at a supra-institutional level by the middle of the 1990s.^[15]

But by 2003, all countries Greece excepted had implemented some form of supra-institutional review. The quality assurance systems in Europe share a number of essential procedural components. These consist of an external evaluation, an external master audit board visit, an external assessment, and public detailing.^[16]

It is important to keep in mind that political discourse is characterized by stark differences in terms of power dynamics, systemic control, and the application of quality evaluation, including its bearing on funding. According to recent studies, people's trust in public institutions like higher education and professions is declining.^[17] Halsey claims that as their professional status has gradually declined, academics have experienced a proletarianization. Higher education has to make a strong case for political autonomy since the academy is no longer held in the same regard as it once was.

The introduction of new concepts in public administration, such as new managerialism and reinventing government, along with the rise of markets as instruments for public regulation were the two main causes of the decline in trust.^[18] makes clear. Trollope's works make it very evident that a man who expects to be treated like a gentleman is not likely to possess these qualities. There is a growing interest in studying the effects of education on students. As to the OECD (2009), a feasibility study is being conducted for the Assessment of Higher Education Learning results (AHELO) project, which is centered around evaluating the performance of students.^[19]

CONCLUSION

The description of quality assurance is "a portion of quality operation concentrated on furnishing confidence that quality must- have will be performed." The assurance that quality assurance provides is twofold it gives operation internal confidence and external confidence to guests, authorities, controllers, certifiers, and other stakeholders." All the planned and methodical conditioning performed within the quality system that can be substantiated to furnish confidence that a commodity or service will perform must- have for quality" is another distinction that can be made.

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