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Quality Assurance & Quality Control in laboratories: A review

Md. Mazher Ahmed*

Department of Pharmaceutics, Luqman College of Pharmacy, Gulbarga, Karnataka, INDIA.

Review Article

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*For Correspondence

Department of Pharmaceutics, Luqman College of Pharmacy, Gulbarga, Karnataka, INDIA.

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E-mail:
mazher_ahmed@yahoo.com

ABSTRACT

Human services conveyance is no more a straightforward procedure of inspecting the patient and giving him a remedy. Throughout the years there has been fast development in the different branches of social insurance administrations. As a component of this development procedure and blast of investigative restorative information, research center analysis has increased huge significance in today's practice. Particularly in our nation since the start of 80's we have been seeing critical development in research center administrations. Through quality administration prepare the research center can guarantee that the outcome being issued by the research center is dependable to permit choices to be brought with certainty. Quality control furthermore, quality certification are parts of value administration. Quality control is centered around satisfying quality necessities, while quality affirmation is centered around giving certainty that quality necessities are satisfied. By using quality control rehearses, a research facility can discover and right imperfections in the logical procedures of a lab before possibly off base patient results are discharged.

INTRODUCTION

ISO 9000 Definitions

Quality Control: A piece of value administration concentrated on satisfying quality necessities.

Quality Assurance: A piece of value administration concentrated on giving certainty that quality necessities will be satisfied.

Table 1 and 2 demonstrates the contrast between quality certification and Quality control

Difference between Quality Assurance & Quality Control

Table 1. Difference between Quality Assurance & Quality Control

Quality Control	Quality Assurance
Product	Process
Reactive	Pro-active
Line Function	Staff Function
Find the defects	Prevent the defects
Walk through	Quality Audit
Testing	Defining Process
Inspection	Selection of tools
Checkpoint Review	Trainings

Table 2: Difference between Quality Assurance & Quality Control[1].

S.no	Quality Assurance	Quality Control
1	ISO 9000 Definition	ISO 9000 Definition
	A part of quality management focused on fulfilling quality	A part of quality management focused on providing confidence that

	requirements.	quality requirements will be fulfilled.
2	**Other Defination**	**Other Defination**
	is defined as “All the planned and systematic activities implemented inside the quality framework that can be exhibited to give confidence that a product or service will fulfil requirements for quality”.	Is characterized as The operational strategies and activities used to fulfill requirements for quality”.
3	Quality assurance is fundamentally focused on planning and documenting those processes to assure quality including things such as quality plans and inspection and test plans	Quality Control on the other hand is the physical verification that the product conforms to these planned arrangements by inspection, measurement etc
4	Quality Assurance is a system for evaluating performance, service, of the quality of a product against a system,standard or specified requirement for customers.	Quality Control is the process involved within the system to ensure job management, competence and performance during the manufacturing of the the product or service to ensure it meets the quality plan as designed.
5	Quality Assurance – What: Prevention of quality problems through planned and systematic activities including documentation. – How: Establish a good quality management system and the assessment of its adequacy& conformance audit of the operation system & the review of the system itself.	Quality Control – What: The activities or techniques used to achieve and maintain the product quality, process and service. – How: Finding & eliminating causes of quality problems through tools & equipment so that customer’s requirements are continually met.
6	Quality Assurance is a complete system to assure the quality of products or services. It is not only a process, but a complete system including also control. It is a way of management.	Quality Control just measures and determines the quality level of products or services. It is a process itself.

Quality is never a mishap; it is dependably the consequence of high goal, true exertion, astute heading and able execution it speaks to the shrewd decision of numerous choices." The issue of Laboratory quality has developed over 4 decades since the first proposal for quality control was distributed in 1965[2]. Now Quality Control is seen as one and only part of an aggregate research facility program. Administration of Bangladesh has as of late affirmed a draft on National Health Policy with a plan to achieve the base Health care office (MDG) by 2015[3]. The reason for the medicinal services framework in a nation is to effectively analyze the illness, distinguish the components in charge of the sickness also, take fitting preventive and corrective measures to control the infection. The pathologists and research facility individuals are extremely greatly included in the right determination, compelling treatment and follow up of the patients. For right determination quality confirmation and quality control are vital. Research center quality control is intended to identify, lessen and revise insufficiencies in research facilities logical procedure to discharge understanding results and enhance the nature of test result[4]. Quality certification (QA) is gone for guaranteeing quality test outcomes. The motivation behind quality certification is to give applicable, dependable, auspicious test results which are deciphered effectively. Quality affirmation includes exercises both inside and outside research facility, great lab rehearse and appropriate administration expertise. The

WHO meaning of quality affirmation is an aggregate procedure whereby the nature of lab reports can be guaranteed[5].

It has been outlined as the

- right result, at the
- perfect time, on the
- right example, from the
- right patient, with result/translation in light of right reference date, and at the
- perfect spot

Quality control (QC) then again covers the a portion of value certification which fundamentally concerns the control of mistakes in the execution of tests and confirmation of test outcomes. Quality control must be down to earth, achievable and reasonable. The essential point of value control is to do the test dependably. The wide point of value control is that outcomes from one lab ought to be tantamount with that from any lab on the planet given the same technique is followed.

The essentials of Quality control include:

i. All out quality administration of clinical research facility
ii. Control of pre-explanatory variable
iii. Control of explanatory variable
iv. Outer quality appraisal and capability testing programs

Numerous universal offices regulate quality certification in particular ISO, ioQA, intertek and Quality certification program keep running by various reputed laboratories aboard. Proper QA dramatically improves the effectiveness of QC program of a laboratory[6-7].

For biochemistry quality control involves ideal condition fluctuation (OCV), routine condition change known value (RCVK),composite and long term assay, and computer supported check, exactness and accuracy tests. Precision is characterized as closeness of the test result and accepted true value, while accuracy is a measure of reproducibility. Every day QC chart preparation is mandatory. Control value within ± 2SD is great sign and patient's outcomes acquired are solid and can be reported. If control value is beyond ± 2SD the result must not be accounted for and crisp control serum ought to be measured together with few patients sample. If the result is now within ± 2SD, the result can be reported. The type of material used for QC is frozen, pooled serum; commercially accessible lyophilized stop dried pool serum; monetarily available low temperature liquid serum pools[8-13].

For histo what's more, cytopathology, quality control includes intra departmental consultation, random case review, intra departmental and entomb departmental gathering, bury institutional survey,, specimen adequacy record, lost specimen record, turn around times, procedures i.e recoloring, appropriate segmenting, installing, fixation, re and dehydration of samples, clearing, mounting, labelling etc[14,15].

For microbiology, quality control involves use of ATCC strains of organisms for standardization, measuring the circle intensity, MIC, media defilement, institutionalization of staining procedures, autoclaving and sterilization of media, safe transfer of contaminated materials is too a critical methodology to keep up standard lab hone. For hematology, institutionalization of recoloring methods, planning of appropriate blood film, bone marrow smear, unique recoloring systems stream cytometry, chromosome examination are the pillar of value control[16-20]. Wrong test outcomes are created by flaws on the part of the clinicians like sending test without recognizable proof number and name of the test, accumulation date, proper holder, sending examples isolated in a few sections to various labs; without clinical history, temporary analysis, other applicable test outcomes, radiology/imaging reports/and so forth. Wrong results are additionally brought on by the issues of research center and the pathologists which can be partitioned into pre-investigative stage deficiencies, expository stage blames and post explanatory stage flaws. In the pre-systematic stage the issues are misidentification of patients because of deficient ID, inaccurately marked example compartment, mostly eradicated or obscured name and difference between demand structure and example. Issues may likewise be with the example[21-22].

A flawed example is one which is deficient, gathered at off base time in filthy and sullied holder, in a compartment without legitimate anticoagulant and put away erroneously or in hemolysed status[23-24]. These are known as pre systematic deficiencies. In the expository stage the deficiencies bringing about wrong discoveries if the rule and method of the test is not entirely took after; reagents, guidelines, QC materials are most certainly not readied, blended, handled legitimately and execution guidelines are not took after entirely. In the post systematic stage the flaws may happen if reporting, checking and confirmations are not done appropriately, translation of test outcomes are definitely not considered genuinely, and unusual/unforeseen result is not considered important and not inspected and on the other hand performed once more.

Quality control is a piece of aggregate research center control program which can be accomplished through legitimate recorded and approved intercessions at pre-diagnostic, expository and post-explanatory stages. Actualizing quality does not ensure a blunder free research center yet it distinguishes mistakes that may happen and keeps them from repeating[25-49].

To screen QA and QC, minimize blunders foundation of a Central Reference Laboratory also, Institute of Pathology is an unquestionable requirement and need of the hour. The sooner the Government, individuals' agents, Medical experts, Social laborers, Journalists, Patients and their relative comprehend this, the better is the result. Bangladesh Society of Pathologists ought to come up with solid recommendations for this and converse with the Government and other proper organizations for its initial execution. The uplifting news is that Government has acknowledged on a fundamental level the idea of a Central reference research center, assigned spending plan for this anticipate and preparatory gauge work has been done. Now the general public of Pathologists ought to work shoulder to bear with Ministry of Health for brisk execution of the task. It is imperative to keep up Quality Assurance and Quality Control for solid, fast and tried and true results in most limited conceivable time. This will push the clinicians to gone to a right finding and treat the patient early. This will prompt early recuperation and recovery working time, cash for the patient and the country.

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