

Available online on 15.04.2019 at <http://jddtonline.info>

Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

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Review Article

Quality Assurance and Quality Management in Pharmaceutical Science and Pharmaceutical Industry

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ABSTRACT

Affection affirmation (QA) is aimed at ensuring affection analysis results. The purpose of affection affirmation is to accord relevant, reliable, appropriate analysis after-effects which are interpreted correctly. Affection affirmation involves activities both central and alfresco laboratory, acceptable class convenance and able administration skill. The WHO analogue of affection affirmation is a absolute action area by the affection of lab letters can be guaranteed. I capital to animadversion on the beat entitled, "An in-flight absorption on affirmation and quality."The acreage of Affection Administration has abounding methods to abate and anticipate defects in any industry. Some of the best accepted methods today are Six Sigma, Lean Enterprise, and Benchmarking. There is a abundance of accurate affirmation to appearance how these methods accept helped the bloom affliction industry even out defects, waste, basis causes, and optimal solutions, application anarsenal of administration tools.

Keywords: Affection assurance, quality management, pharmaceutical industry.

Article Info: Received 13 Feb 2019; Review Completed 22 March 2019; Accepted 23 March 2019; Available online 15 April 2019



Cite this article as:

Kushare S, Darekar A, Saudagar R, Quality Assurance and Quality Management in Pharmaceutical Science and Pharmaceutical Industry, Journal of Drug Delivery and Therapeutics. 2019; 9(2-s):537-542
<http://dx.doi.org/10.22270/jddt.v9i2-s.2462>

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INTRODUCTION

The World Health Organization defines Affection Ascendancy (QC) as "the accession of all procedures undertaken to ensure the character and abstention of a accurate pharmaceutical."The purpose of QC is to ensure the assurance and ability of a accomplished biologic artefact afore it is appear to the public. Supporting affection systems charge to ascertain whether items such as raw materials, components, containers, labeling and packaging abort to accommodated above-mentioned specifications. The QC Department is amenable for administering this assignment as able-bodied as testing the accomplished artefact to ensure it meets authoritative requirements. For pharmaceuticals, Affection Ascendancy may absorb analytic procedures alignment from simple actuality screenings to circuitous pharmacopoeia monographs. biologic manufacturers of the accepted of articles actuality fabricated and sold, but QC abandoned cannot agreement that a aerial affection artefact will be consistently produced. Substantial accomplishment decay (time and abstracts as a aftereffect of action deviations) and post-market recalls are affirmation of this. A bigger access is bare as the FDA accede in their 2006 Guidance for Industry, Affection Systems Access to Biologic Current Good Accomplishment Practice Regulations stated,

"Quality should be congenital into the product, and testing abandoned cannot be relied on to ensure artefact quality." Affection Assurance (QA) involves demography a proactive access to ensure biologic articles are fabricated in accordance with accomplishment standards and met their pre-defined artefact specifications. The aim is for affection and acquiescence to be accomplished "right the aboriginal time" rather than depend on audition problems. The aim is to always advance accomplishment standards, eliminating errors forth the way. Affection ascendancy role to play, but with able QA and reliable operational achievement during the process, it becomes a basic of the biologic affection system.^{1,2}

Quality Assurance

The responsibilities of affection affirmation include:

- Products advised for accessible are safe, effective, and adapted as to dosage.
- Predetermined affection standards are upheld back allotment and accepting articles from suppliers.
- Recall action is affiliated and able for defects inpost-market products.

- Post-market communications are accessible for public concerns and questions.
- Objectives of Biologic QA
- Offering the affirmation that a healthcare able prescribing or administrate the biologic is assured of anniversary unit's efficacy.
- Attention the accessible adjoin abeyant hazards acquired by adventitious accomplishment and architecture defects, or instructions for artefact usage/storage space.
- Making abiding of complete acquiescence with applicative industry regulations, statutes, laws and guidelines.
- Attention the artefact and architect adjoin penalties, abrogating publicity, accident of credibility, budgetary losses, etc.

Importance of QA in Pharmaceuticals

The aliment industry, adherence to all-embracing affection standards is important for the pharma and biotech sectors because of the absolute affiliation amid artefact affection and accessible health/safety. Defects in biologic drugs accession the accident of compromising chump bloom and potentially beastly or beastly activity as well.

Effective affection affirmation helps organizations body bigger believability and chump confidence, in accession to advancement adherence to FDA regulations and convalescent assembly ability and processes. It reduces the affairs of abrogating publicity and appulse on sales as able-bodied (e.g. if a accomplished artefact were to be recalled due to affection defects).

Hence, affection affirmation in the biologic industry offers amazing allowances in agreement of ascent profits and a stronger reputation. However, through the lifecycle of a new drug, every aspect of the assembly action needs to be taken into consideration, whether it alone or collectively impacts artefact quality.

How Does a Biologic QA Administration Work?

Most companies set up abstracted QA departments, with the absorbed to acquisition and actual defects in the development date (before the final artefact is accessible to hit the market).

- Here's an overview of QA's role:
- Development Date – During R&D, blockage the accomplishment of raw material, vendors, testing methods, validation, certificate control, accessories arrangement and operating procedures, cadre application and training, abstracts recording, analytic trials, conception of API batches and more.
- Manufacturing Date – These are a few examples of the QA unit's role during production:
- Preparing, acknowledging and ecology the accomplishing of key abstracts (Quality Policy and Objectives, Affection Manual, Validation Master Plan, etc.).

Acknowledging an accessories calibration, accomplishment and aliment schedule, as able-bodied as analytical utilities accomplishment agenda (HVAC, water, gas and ability administration systems, etc.).

Ensuring that blueprint and analysis procedures for raw materials, packing materials, in-process testing, APIs, adherence testing, etc. are all in place.

Reviewing training annal to analysis if on-the-job and consecration training is demography abode according to the schedule, and whether QC (Quality Control) analysts are actuality validated.

Ensuring that planned/unplanned changes or deviations are documented, advised and analyzed, and advising studies, tests or validation activities to be performed.

Logging and responding to chump complaints, authoritative the analysis into the account of the issue, accouterment an assay address to the customer, etc.

Initiating, documenting and investigating bazaar returns, reprocessing (for API batches) or abolition (for accomplished batches), and allegorical authoritative authorities about defects begin afterwards distribution.

Training and arch the centralized analysis aggregation for anniversary department collaborate with auditors during external, centralized and chump inspections, and intimating administration of the observations.

Reviewing and acknowledging accomplishment annal and QC testing abstracts afore any intermediate, API or accomplished accumulation is released, as able-bodied as alternate trending of this data.

Initiating an OOS (out of specification) analysis and reviewing the QC analysis if any raw material, packaging, average or adherence sample does not accommodated accustomed and accustomed blueprint during the latter.

Qualifying and auditing arrangement account providers for tests and calibrations not performed in-house, reviewing and advancing Affection and Technical agreements for added accomplishment sites.

QA System: The Backbone of Pharma Quality

- While the development, accomplishment and business of articles may absorb added than one assemblage or department, the affection assemblage is usually absolute of assembly processes.
- You could additionally use specialized departments congenital in an authoritative arrangement to handle the affection arrangement and its accompanying duties. In such a scenario, the QA assemblage would booty on the assignment of accessories acceptable systems as able-bodied as defining them in SOPs (standard operating procedures) and college akin instructions.
- Delegating QA functions and controlling ascendancy to operation departments and cadre is ideal for beyond organizations, to advice ensure affection on the floor. Top-level administration additionally needs to be complex in the responsibilities of this unit, which may be a aggregate of QA and QC.

Good convenance for QA procedures requires an cold analysis to appraise the affection of the inventory, and additionally to analyze areas area improvements could be made. The account may be advised as a accomplished or in parts. QA procedures are utilized in accession to the Tier 1 and Tier 2 QC. The cold in QA accomplishing is to absorb reviewers that can conduct an aloof analysis of the inventory. It is acceptable convenance to use QA reviewers that accept not been complex in advancing the inventory. Preferably these reviewers would be absolute experts from added agencies or a civic or all-embracing able or accumulation not carefully affiliated with civic account compilation. Area third affair reviewers al fresco the account bureau are not available, agents from addition allotment of the account bureau not complex in the allocation of the account actuality

advised can additionally fulfil QA roles. It is acceptable convenience for account agencies to conduct a basal able associate analysis (Tier 1 QA) above-mentioned to account acquiescence in adjustment to analyze abeyant problems and accomplish corrections area possible. It is additionally acceptable convenience to administer this analysis to all antecedent categories in the inventory. However, this will not consistently be applied due to timing and ability constraints. Key antecedent categories should be accustomed antecedence as able-bodied as antecedent categories area cogent changes in methods or abstracts accept been made. Account agencies may additionally accept to accomplish added all-encompassing associate reviews or audits or both as added (Tier 2) QA procedures aural the accessible resources³

Quality management

The abstraction of accepted biologic affection administration arrangement is based on a internationally harmonized advice ICH Q10, which is developed by the Expert Working Group (Quality) of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and USFDA and in final phases for acceptance by the authoritative bodies of the European Union, Japan, and the United States is which describes a archetypal for a biologic affection arrangement that encourages the use of science- and risk-based approaches and can be implemented throughout the altered stages of a artefact lifecycle.

Pharmaceutical affection administration system

It is applicative to biologic products, including biotechnology and biological products, throughout the artefact lifecycle the systems acknowledging the development and manufacture of biologic biologic substances. It includes

1. Biologic Development

- A. Accomplishment and development of APIs.
- B. Manufacture of medical kits and accessories for investigation.
- C. Development of medical commitment systems.
- D. Pilot bulb scale-up activities.
- E. Accomplishment activity of formulation.
- F. Development of medical devises for authentic dosing.

2. Analytical adjustment development.

- A. During accomplishment process.
 - Acquisition and ascendancy of materials.
 - Provision of facilities, utilities, and equipment.
 - Production (including packaging and labeling)
 - Affection ascendancy and assurance.
 - Release.
 - Storage.

B. During artefact technology transfer.

C. During artefact discontinuation

- Retention of sample and accompanying documentation
- Continued artefact appraisal and reporting

Objectives:

Three capital objectives are as follows:

1. Achieve Artefact Realization
2. Able ascendancy over variables
3. Continuous Advance⁴⁻⁷

Elements of Biologic Affection System:

Fundamental elements for able biologic affection systems are as follows:

- Managerial analysis of activity achievement and artefact quality
- Activity achievement and artefact affection ecology system
- Corrective activity and antitoxin activity (CAPA) system
- Change ascendancy administration system.⁸

Quality Administration of biologic contempo approaches and advancement.

Affection administration is administration of assorted sectors to ensure acceptable affection of the product. Affection administration abide of four capital apparatus i.e. Affection planning, Affection control, Affection assurance, Affection advance⁹. The outline of affection administration arrangement is accustomed in Outline of Affection administration arrangement Fig. 1 Practices afore TQM Practices afore TQM Afore actuality of TQM, acceptable affection administration tools, alone included final artefact affection ascendancy (FPQC) and on base of these affection ascendancy tests, it was assured that whether artefact acquired is of adapted affection or not. If all ambit of final artefact were begin to be aural limit, again it was advised as affection artefact but if after-effects were begin to be out of blueprint again artefact was said to be of poor affection and rejected. Capital drawbacks of acceptable methods were that they do not accommodate any activity or accomplish for affection administration of artefact during the process. Alone affection ascendancy administration was amenable for affection of the product, added departments were accepting no affair with the quality, which usually aftereffect in batch-to-batch variability.^{10,11}

Quality accident management' is authentic as a adjustment for the assessment, control, advice and assay of risks to the affection of the biologic (medicinal) artefact through the artefact lifecycle area decisions can action at any point in the process. It is a broadly acclimated administration apparatus acclimated in biologic industry, which involves analytical action for identification, assay and ascendancy of accident complex in any advancing action in the industry. Various genitalia included in affection accident administration.



Figure 1: Quality Management

Quality accident administration includes

- Identification of risks: It involves identification of risks of risks afore they become austere to be solved.
- Assay of data: It involves assay of accident abstracts Assay of abstracts that and classifying the risks based on their appulse and priority.
- Planning: Based on assay of accident abstracts planning or acknowledgment of risks complex and authoritative decisions how to abate risks.
- Track: Monitor the affairs for accident acknowledgment and al Track so ecology accident indicators.
- Control: It involves austere ascendancy over accident Ascendancy acknowledgment plan to abstain aberration from these plans.
- Communication: It involves advice of Advice acknowledgment about affection accident administration plans, their account in acknowledgment of risks and about award the arising risks. ^{12,13}

Current cachet

TQM is best broadly acclimated affection administration access worldwide. But it is not acclimated broadly in Indian biologic industry. India is one of the better producers of pharmaceuticals in the apple with about 20% of absolute assembly of pharmaceuticals artefact in the world. The capital acumen for belted appliance of TQM in India is that, cardinal of baby calibration companies is added than the cardinal of bunch companies. Further added the cardinal of WHO-GMP or US-FDA certified industries is actual beneath in India. These baby calibration industries adopt to consign to poor countries such as African countries because of abridgement of affection products. The capital acumen for poor affection is abridged appliance of affection administration approaches such as TQM.¹⁴

TQM: The Concept and Approaches

TQM is a accumulated accomplishment advised by alignment to advance affection at every level. TQM is about affair affection expectations as authentic by the customer; this is alleged customer-defined quality.



Figure 2: Total Quality Management

Approaches for TQM

Various approaches as accomplished by industries in TQM of biologic action are:

These are set of accoutrement or techniques acclimated for action advance or affection administration of process. Six Sigma address can advance the affection of action outputs by anecdotic and removing the causes of errors and aspersing air headedness in accomplishment and business processes 15-17

Management responsibility:

Leadership is capital to authorize and advance a Company advanced charge to affection and for the achievement of the pharmaceutical quality system. Administration has the albatross to accomplish affection accompanying goals as per the affection policy. There charge be a bright compassionate and actual set of authority and albatross at all levels including alone and aggregate role. Strict charge against the affection objectives should be demonstrated. Management should participate in the design, implementation, monitoring, and aliment of an effective biologic affection system. Affection audits should be performed periodically for adapted advance in action performance. Training needs of staff should be finer articular and chase up arrangement should be accustomed to ensure able training. Adequate ability management, able communication between all levels of administration and journal assay of the affection arrangement helps to achieve adapted biologic affection arrangement governance.

Continuous advance in action achievement and artefact quality:

artefact affection depends on adapted architecture of affection attributes during artefact development phase. Abstruse ability or specification, ascendancy action and validation approaches should be finer transferred aural or amid accomplishment sites for bartering manufacturing. Artefact cessation aspects accommodate assimilation of accordant documents, samples and assay of artefact assessment, complaint administration and adherence accompanying problems as per authoritative provisions: 18-20

Objectives of affection administration arrangement may be accomplished by afterward means:

A. Ability Management

B. Affection Accident Management

The abstruse aspects of the process, abnormality of the artefact architecture and problems during artefact activity cycles helps to actualize a ability database and should be systematically documented. ICH Q9 provides attempt and examples of accoutrement for quality accident administration and access to identifying, scientifically evaluating and controlling abeyant risks to quality. Innovation, around-the-clock advances the outputs of process achievement and artefact affection ecology and CAPA drive changes. It facilitates around-the-clock advance of action achievement and artefact quality throughout the artefact lifecycle. Developing a new biologic affection arrangement or modifying an absolute one requires accurate appraisal of admeasurement and complexities of the

company's activity; Identification of administration responsibilities; systems, responsibility and blueprint for arrangement accomplishment activities; Change control measures; identification and enactment of achievement indicators. Affection riskmanagement action should analyze attributes for altitude and assay of state of ascendancy with assorted approaches including statistical indicators. ²¹

CONCLUSION

The term quality cannot be confined to one definition. It is tensile in nature and people define it in their own ways but one thing is common in all and that is satisfaction. Manufacturer is satisfied if the product meets its specification and consumer is happy when the particular product fulfills his need. But in any ways Quality is unavoidable thing today and one cannot ignore it. When it comes in context of Pharma then Quality is a legal issue and must be maintained in pharmaceutical products. The present paper focuses on some aspects and need of maintaining Quality in Pharma through Quality Management System.

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