Review Article

Quality Assurance: Importance of Systems and Standard Operating Procedures

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Received: 13-08-2022; **Revised:** 20-10-2022; **Accepted:** 26-10-2022; **Published on:** 15-11-2022.

ABSTRACT

It is necessary for sponsors of clinical trials and contract analysis organizations alike to ascertain, manage and monitor their internal control and quality assurance systems and their integral normal operative procedures and alternative quality documents to produce high-quality merchandise and services to completely satisfy client wants and expectations. Internal control and quality assurance systems along represent the key quality systems. Internal control and quality assurance square measure elements of quality management. Internal control is concentrated on fulfilling quality necessities, whereas quality assurance is concentrated on providing confidence that quality necessity square measure consummated. The standard systems should be commensurate with the corporate business objectives and business model. Prime management commitment and its active involvement square measure crucial so as to make sure in the slightest degree times the adequacy, suitableness, effectiveness and potency of the standard systems. Effective and economical quality systems will promote timely registration of medicine by eliminating waste and therefore they would like for makeover with overall monetary and social advantages to the corporate.

Keywords: Quality assurance, elements of quality management, economical quality systems, quality standards.

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DOI: 10.47583/ijpsrr.2022.v77i01.009

DOI link: http://dx.doi.org/10.47583/ijpsrr.2022.v77i01.009

INTRODUCTION

High levels of quality area unit essential to realize Company business objectives. Quality, a supply of competitive advantage, ought to stay an indicator of Company product and services. Prime quality isn't another value; it's an important basic demand. Quality doesn't solely relate exclusively to the tip product and services a corporation provides however additionally relates to the manner the corporate worker does their job and therefore the work processes they follow to supply product or services. The work processes ought to be as economical as potential and frequently rising. Company workers represent the foremost necessary resource for rising quality. Every worker altogether structure units is chargeable for making certain that their work processes area unit economical and frequently rising. high management ought to offer the coaching Associate in Nursing an appropriate motivating surroundings to foster cooperation each among and across structure units for workers to enhance processes. Ultimately, everybody in a very Company is chargeable for the standard of its product and services. a corporation within the role of a sponsor of clinical trials will best deliver the goods its business objectives by establishing and managing strong quality systems with their integral quality documents together with customary operative procedures (SOPs).

Quality Systems

A quality system is outlined because the structure, responsibilities, processes, procedures and resources for implementing quality management. Quality management includes those aspects of the management operate that confirm and implement the corporate quality policy and quality objectives. Each internal control and quality assurance square measure elements of quality management. The thirteenth principle within the International Conference on Harmonization smart Clinical apply (ICH GCP) guideline clearly states that systems and procedures that assure the standard of each side of the (clinical) trial ought to be enforced. The sponsor is accountable for implementing and maintaining quality assurance and internal control systems with written SOPs to make sure that trials square measure conducted and information square measure generated, documented (recorded) and reported in compliance with the protocol, smart Clinical apply (GCP) and also the applicable regulative necessities. Although a sponsor may transfer any or all of its trial-related duties and functions to a contract research organization (CRO), the ultimate responsibility for the quality and integrity of the trial knowledge perpetually resides with the sponsor.[1] But, the scope is additionally needed in its title to perpetually implement quality assurance and internal control. Each internal

control and quality assurance systems should be proportionate with the corporate business objectives and business model. The two along represent the key quality systems.

Top management commitment and active involvement within the institution, management and observation of quality systems is important and is achieved by: [2]

- Defining and documenting a high quality policy and quality objectives and making certain that each the policy and objectives are understood and enforced by all staff the least bit levels;
- Making certain that applicable processes square measure enforced to totally satisfy client wants and expectations and Company objectives;
- Shaping and documenting the responsibility, authority and relation of key personnel managing the standard systems;
- Providing adequate resources for implementing and maintaining the standard systems;
- Conducting regular management reviews of the standard systems to assess their continuing suitableness, Adequacy, effectiveness and efficiency; and
- Electing actions for continual quality improvement.

Internal control is concentrated on fulfilling quality needs, and as associated with clinical trials, it encompasses the operational techniques and activities undertaken among the standard assurance system to verify that the necessities for quality of the trial-related activities are consummated. [1]

Quality assurance, on the opposite hand, is concentrated on providing confidence that quality necessities area unit consummated. As associated with clinical trials, it includes all those planned and general actions that are established to confirm that the trial is performed and therefore the knowledge are generated, documented (recorded), and reported in compliance with GCP and therefore the applicable regulative needs.[1]

Quality control is mostly the responsibility of the operational units and quality is infused into the outputs and verified as they're being generated. Therefore, quality control is Associate in nursing integral a part of the daily activities occurring within every operational unit.

Quality assurance is that the responsibility of the standard assurance department. The mission of a high quality assurance department is to produce economical a good and efficient quality assurance system and counsel for the operational units. The standard assurance department should be manned by Associate in Nursing adequate number of dedicated and adequately qualified and trained personnel with well-developed social skills. The well-developed social skills can offer the standard assurance personnel with persuasive, diplomatic, tactful and resilient qualities typically needed of them. the standard assurance department should operate severally from the operational units and it should often perform quality review activities (self-inspection audits/internal audits) to ensure compliance among operational units with Company quality standards, smart operating practices [GxPs: current Good producing follow (cGMP), smart Laboratory Practice (GLP), GCP, etc.], and local, national, regional and international legal, moral and regulative needs.

The quality assurance department below the leadership of a Quality Assurance Manager can make sure the following:

- Acceptable world and affiliate-specific quality documents (Level 1: Company policies together with quality policy and quality management plan; Level 2: SOPs; Level 3: operating instructions; Level 4: conventions, guidelines, forms, templates, logs, tabs, and labels) are determined, developed and enforced.
- Personnel concerned in clinical analysis and development are, and remain, properly qualified and trained for job roles that they're created accountable. The training can embody new workers induction, ongoing quality awareness coaching together with coaching in applicable SOPs and different quality documents, training for dynamical roles among and between purposeful units, Associate in nursing coaching ensuing from an analysis of needs together with the results of audits and regulative inspections, prime management reviews and worker appraisals. Additional education and extra coaching needs ought to be perpetually assessed by the corporate.
- All clinical analysis and development activities are conducted in step with Company quality standards, current GxPs, and every one applicable native, national, regional and international legal, moral and regulative requirement as outlined within the quality documents, to meet with Company quality objectives and client requirements.
- A system is place in situ to trace all international and affiliate specific quality documents associated to keep up an up-to date overall inventory of all historical and effective quality documents.
- Personnel can have written verbal descriptions which can clearly outline their roles and responsibilities, and the processes and SOPs that they need to follow.
- A system is place in situ to initiate and maintain a personal file on every worker, containing his/her current resume, job description, education and coaching records and private and skilled development arrange.
- Associate auditing perform, freelance of the operational units and therefore the internal control system, is formed to arrange, conduct, and report internal and external audits and to support and monitor their close-out via applicable corrective actions and preventive actions (CAPA) plan.[3,4] The

effectiveness of the corrective and therefore the preventive actions should be assessed.

- A system is place in situ to administer client audits, regulatory inspections and Company certifications/ accreditations as applicable.
- A system is place in situ to

  a) Share audit and regulative inspection findings and learning with the relevant functional units and high management,

  b) Promote auditing-in-tandem, and cross-pollination of auditors,

  c) Track all internal and external audits, client audits and regulative inspections, and

  d) Track standing of findings (open, closed or pending) created throughout audits and regulative inspections.
- Liaison is maintained with practical units, affiliates, and human resources for continuing personal and professional development (basic and advanced knowledge-based and skill-based coaching and retraining) of workers worldwide.
- Liaison is maintained with and between practical units and affiliates to market standardization, improve communication, and to boost potency of quality systems through cooperation.
- All practical units and affiliates are unbroken up-to-date with numerous established and rising native, national, regional and international legal, moral and regulative standards.
- Continual quality improvement initiatives (adoption of industry best practices: determination, development, implementation and observation of key performance indicators; and internal and external benchmarking) are known, enforced and monitored via the Plan–Do–Check–Act (P–D–C–A) cycle.[5,6]
- Persons liable for the standard assurance system are available in associate degree informative role to staff worldwide on matters associated with the standard systems, rules in force together with GxPs and regulative compliance.

Standard Operating Procedures

Standardization is outlined as associate activity that provides rise to solutions for repetitive application to issues in numerous disciplines together with science and it's aimed toward achieving the optimum degree of order in a very given context. Generally, the activity consists of the method of creating (determining, formulating, and issuing) and implementing standards. Therefore, standards area unit the final word results of a standardization activity and inside the context of quality systems incorporates quality documents or documents connected to the standard systems. The quality documents incorporates Company policies, quality management set up, SOPs, operating directions, conventions, guidelines, forms, templates, logs, tags and labels. They are established by accord and approved by a nominative body and that they offer for common and perennial use, rules, guidelines or characteristics for activities or their results with a read to market transparency, consistency, dependability, interchangeability and to facilitate communication. The hierarchy and kinds of quality documents relevant to quality systems can rely upon Company business objectives and business model. SOPs square measure Level a pair of quality documents and, along with different relevant quality documents, ensure the effectiveness and potency of quality systems.

The ICH GCP guideline defines SOPs as “detailed, written instructions to realize uniformity of the performance of a particular function”. [1]

Simply put, SOPs specify in writing, United Nations agency will what and once, or the thanks to perform an activity or a method. SOPs establish a scientific means of doing work and make sure that work is finished systematically by all persons United Nations agency square measure needed to try to identical task. SOPs must be written so as to supply a good control of GCP and forestall errors from occurring, thereby minimizing waste and process. Poorly written SOPs square measure a supply of info. To be user friendly, they should be clear, unambiguous and should be written in plain language. SOPs square measure controlled documents and square measure best written by persons concerned within the activity, process or perform that's needed to be given or lined in the SOP.

SOPs should be reviewed before their approval for unharness, for adequacy, completeness and compliance with Company standards and every one applicable legal, ethical and restrictive needs. They have to be reviewed and updated PRN over their life cycle and any changes made to the SOPs should be re-approved. They must bear a revision standing on them and their distribution should be documented and controlled. Once obsolete SOPs are required to be preserved for any purpose, they must be suitably known to stop unwitting use. Solely relevant SOPs in their current version should be obtainable at points of use and should stay clear. SOPs are obligatory for the implementation of GCP and different GxPs, namely, cGMP and GLP, among the scope of quality systems; so, it is well aforementioned that while not SOPs there are not any GxPs: no SOPs, no quality systems, and no GxPs. For AN activity to become the subject of AN SOP it must be either subject to rules or it should address a task important among quality systems or between quality systems and different practical units.

Quality systems connected SOPs should typically cowl the subsequent topics so as to capture the core internal control and quality assurance activities and processes:

- Definition, format, content, compilation, indexing, review, approval, update, distribution and archiving of quality documents;
- Definition, format, content, review, approval, update, distribution and archiving of quality management plan;
- Definition of and activities associated with internal control of clinical trials and compilation of trial-specific quality control plan;
- Initiation and maintenance of personnel files including format and content of resume, job description, coaching records and private and professional development plan;
- high management reviews of quality systems and issuance of management review reports;
- choice and management of contract auditors;
- Format, content, compilation, review, approval, update, distribution and archiving of audit program;
- Format, content, compilation, review, approval, update, distribution and archiving of audit plan;
- Planning, conduct, coverage and close-out of risk based internal and external audits;
- Planning, conduct, coverage and close-out of specific audits of web sites, processes, systems and documents: sponsor web site, third party (CRO, central clinical laboratory) web site, investigator web site, quality management system together with SOP management, education and training and auditing, document management system including archives, information management system together with information technology support, serious adverse events management system, pharmacovigilance system, medical lexicon management system, and regulative submission documents (clinical trial reports, and Clinical sections of latest drug applications, marketing authorization applications and customary technical documents);
- Planning, conduct, reporting and close-out of for cause/directed audits;
- Hosting of client audits;
- Preparation of websites for restrictive inspections;
- Coordination and management of restrictive inspections;
- Format, content, compilation, review, approval, update, distribution and archiving of CAPA arrange, and assessment of its effectiveness;
- Amendment management to confirm that changes and therefore the current status of quality systems connected elements as well as documents area unit identified; and
- Roles and responsibilities of quality assurance in handling of scientific misconduct/ fraud.

Benefits of Quality Systems

The importance of properly established and managed quality control and quality assurance systems with their integral literary SOPs and alternative quality documents for the accomplishment of Company business objectives cannot be ignored. They function a passport to success by aiding the Company to attain high-quality processes, procedures, systems, and people, with ultimate high-quality product and services and improvement of the following:

- client satisfaction, and thus, client loyalty and repeat business and referral;
- Timely registration of medication by eliminating waste and the need for rework;
- Operational results like revenue, profitableness, market share and export opportunities;
- Alignment of processes with accomplishment of higher results;
- Understanding and motivation of staff toward the Company quality policy and business objectives, as well as participation in continual quality improvement initiatives; and
- Confidence of interested parties within the effectiveness and potency of the corporate as incontestable by the financial and social gains from Company performance and name.

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Source of Support: The author(s) received no financial support for the research, authorship, and/or publication of this article.

Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.