

Quality Systems in Clinical Trials – The Tools for Optimal Results

Looking from a wider perspective, quality stands for a set of characteristics that some sort of service or a product is expected to have in order to be responsive to different requirements, laws, legislations and other formal documents. The concept of quality in the Pharmaceutical sector and clinical trials specifically, is a complex one. It can be defined in various manners depending on the used context and subject matter. **Generally speaking, when it comes to clinical studies quality is explained as this state of scientific data which signifies credibility.** What is more, quality can also be examined in close relation to processes which are compliant with diverse ethical standards and Good Clinical Practice (GCP) norms. Finally, when talking about pharmaceuticals, quality refers to their condition of being usable and effective. To make sure that there are sufficient and reliable levels of quality, an increasing number of researchers focus on using quality systems during many stages of the on-going clinical research.

In the history of clinical trials there is not even a single one that has run perfectly and smoothly. Complications are always present and deviations as well as discrepancies can occur at any moment. Due to this vulnerable and open-to-changes nature of studies complete accuracy of records and datasets, for instance, could sometimes be hard to achieve. Nevertheless, even in cases when accuracy is reported to have been accomplished, 100% quality is not guaranteed. This is so because quality is not co-dependent or interrelated to accuracy. To affirm that quality has been reached means to affirm that participants' safety is kept; bias-free observations as well as opinions are at place; clear end-points are maintained and, lastly, that there is a relevant study design.



Using quality systems and quality system approaches can help get all of this done. **Even though it is no longer a pioneering technique in the industry, it still serves to ensure useful and efficient research processes as well as end-products.** On top of this, it is widely considered to be the most effectively-working method. It is capable of not only generating positive, time-effective and resource-saving results but also of matching the changing demands of the Pharma field. Still, the current tendency of using systems to monitor quality of trials does the opposite – quality detecting procedures are carried out after some type of crisis has already occurred. Which is wrong and ineffective. Therefore, to guarantee successful and quality completeness of a trial, experts have suggested the use of quality systems since the beginning of the trial. **There are several requirements which must be followed when utilizing quality systems. They include:**

1. Hiring suitable personnel

Among the key stipulations when using quality systems in clinical trials requires the presence of qualified personnel. Clinical trial managers, researchers, sub-investigators, assistants and others must showcase sufficient expertise in the field. Moreover they should fully understand and commit to their responsibilities in order to comply with external and internal policies as well as international guidelines.

2. Training of personnel

Using quality systems in clinical studies asks for experienced members of staff but also such that is well-prepared and trained. In this regard, the sponsor should hire proper personnel but also provide people with relevant training and certification. This will stiffens and strengthens personnel's understanding about policies, good clinical practices, subjects' protection and data integrity. What is more, trainings also give guidance on how to adequately handle Standard Operating Procedures (SOPs) and other protocols.

3. Quality risks' preventative and corrective actions

Before mitigating quality risks, variances and inconsistencies they should be anticipated. But when an unexpected issue has already been found, corrective actions should be carried out next. Well-built quality system will limit errors and problems. But to have such system, automation and reevaluation of it should be performed on regular basis.

In summary, the use of a reliable quality systems in clinical studies have become a necessity in the last couple of years. It has turned into **a tactic for more efficient monitoring of trials** which works best when it comes to guaranteeing protection of trial participants, quality of data and producing valid study results.

Article originally posted here: <https://crotraining.co.uk/quality-systems-in-clinical-trials-the-tools-for-optimal-results/>