Risk-based Quality Assurance – The Benefits

In any industry which deals with product–development processes, quality assurance becomes an integral part of all of their procedures. **When it comes to clinical trials** and the Pharmaceutical, Medical and Clinical sector, **making sure that high quality is achieved supports Good Clinical Practice (GCP) principles**. What is more, it adds up to other quality practices, standards and requirements, thus having a direct impact on the overall relative industry performance. Ever since these particular branches have started to shape and contribute to the economic growth of one country, there has been an increasing emphasis by regulators on utilizing quality systems throughout each and every phase when carrying out clinical researches. The implementation of such systems serves a lot of purposes. Above all it guarantees lower levels of inefficacy of pharmaceuticals as well as other medicinal products and also minimizes unplanned costs and additional time-dedication.

Across different time periods, the research community has been noted to adopt quality-assurance processes after the appearance of a problem, difficulty or discrepancy of any kind. This is pointed out to be either partially or completely ineffective. On the other hand, **if the quality-assurance is integrated into an established quality-management system, it will allow the qualified personnel to conduct quality-assurance actions well ahead the occurrence of such crises**. Which, of course, will save a lot of unnecessary efforts, time and resources. Currently, the methodological approaches used to assure quality are somewhat old-fashioned. The logistics of their functionalities are expressed in the following concatenation: practitioners produce and retain specific products in the form of documentation, find the ineffective ones among them and, then, throw them out. However, this type of discarding of clinical trial data after an already presented defect is, to a great extent, wasteful and burdensome on many levels.

In light of these and many other similar issues when talking about clinical trials, **the use of risk-based quality assurance has been suggested as more efficient than the methods used for the time being**. Risk-based approaches to quality assurance are constructed around the division of regulatory resources in accordance to the possible risks. The risks themselves are estimated and forecasted by the regulator who takes into close consideration their likelihood of occurrence plus the potential effects on the clinical trial's course and its outcomes. In addition to this, **when there is risk-based quality assurance merged in a context this involves monitoring quality concerns**. This sort of assurance demonstrates vivid appeal and can improve the nature of work when performing a study in a number of ways. For instance, risk-based quality assurance includes reflecting and reviewing curricula. It can also enhance the whole process of researching by simply initiating more intensive horizontal communication, exchange of information between parties and strengthening clinical trials transparency.

The proper execution of risk-based quality assurance, however, depends on several key elements:

- Performing internal and external audits by independent auditors
- Verifying the validity of computerized systems
- Appropriate management of data and quality control
- Observing trial sites and used technical facilities
- Training of personnel

Nevertheless, there are various challenges that influence the risk-based quality assurance. Such challenges include:

- Unavailability of data and inability to predict human behavior
- The size of a risk not being proportionate to the resource needed for its mitigation

To sum up, **the basic principle of risk-based quality assurance resides in the idea of identifying the risks for each and every activity** which is likely to be risk-bearing. This can be done by designing, performing and evaluating clinical studies and basing them on already available

specifics regarding the investigational pharmaceuticals and systems. And while the mostly and traditionally used quality assurance methods lack ultimate efficacy, the adaption of the more conventional risk-based model promises improved and more informed decision making while using the present resources as practically as possible.

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